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UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Program studiów

Wydział:	Wydział Farmaceutyczny
Kierunek:	Drug Discovery and Development
Poziom kształcenia:	drugiego stopnia
Forma kształcenia:	stacjonarne
Rok akademicki:	2019/20

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Charakterystyka kierunku

Informacje podstawowe

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Nazwa kierunku:	Drug Discovery and Development
Poziom:	drugiego stopnia
Profil:	ogólnoakademicki
Forma:	stacjonarne
Język studiów:	polski

Przyporządkowanie kierunku do dziedzin oraz dyscyplin, do których odnoszą się efekty uczenia się

Nauki farmaceutyczne	**100,0%**

Charakterystyka kierunku, koncepcja i cele kształcenia

Charakterystyka kierunku

Studia Drug Discovery and Development oferują unikalny nie tylko na poziomie Uniwersytetu Jagiellońskiego, ale w skali kraju program edukacyjny na poziomie kształcenia magisterskiego II stopnia.
Realizowane na Wydziale Farmaceutycznym UJ CM studia na kierunku Farmacja to jednolite studia magisterskie, zakończone uzyskaniem prawa wykonywania zawodu farmaceuty. Są one nastawione głównie na przygotowanie do pracy z lekiem już zarejestrowanym w kontekście klinicznym. Kształcenie ukierunkowane jest na pracę bezpośrednio z pacjentem i pomoc w konkretnym przypadku.
Niniejsze studia przygotowują specjalistów do prac badawczo-rozwojowych nad nowymi lekami. Prezentują w sposób całościowy proces wdrażania nowych produktów, stanowią praktyczne rozwinięcie i uzupełnienie podstawowej wiedzy studentów będących absolwentami studiów I lub II stopnia.

Koncepcja kształcenia

"...Misją Wydziału Farmaceutycznego jako części Uniwersytetu Jagiellońskiego jest prowadzenie działalności naukowej i upowszechnianie wiedzy oraz kształcenie studentów w zakresie nauk farmaceutycznych wg standardów, które przygotowują ich do działalności zawodowej lub naukowej opartej na głębokiej wiedzy i najwyższych wartościach etycznych, jakimi szczyci się historia krakowskiej farmacji i Uniwersytetu...".
Mając powyższe na uwadze, planowane w ramach uruchamianego kierunku kształcenie wysokiej klasy specjalistów o unikalnych kompetencjach integrujących nauki farmaceutyczne z aplikacyjnymi aspektami prac nad nowym lekiem, zasilających kadry szeroko pojętego sektora farmaceutycznego, innowacyjnego i generycznego, jednostek naukowo-badawczych zajmujących się tematyką prac nad lekiem oraz instytucji regulujących rynek farmaceutyczny, należy uznać za w pełni zbieżne zarówno z misją Wydziału jak i Uczelni.
Według informacji portalu Business Insider z 01.01.2018, analiza przeprowadzona przez specjalizującą się w doradztwie personalnym firmę Hays, umieściła stanowisko “specjalista ds. rozwoju w branży farmaceutycznej” w gronie 10 najbardziej pożądanych zawodów w 2018 roku. Zatem, uruchomienie kierunku studiów o zakładanym profilu jest również w pełni zbieżne z celem 2.1 strategii rozwoju Uniwersytetu Jagiellońskiego “Wzrost atrakcyjności oferty dydaktycznej na UJ” oraz

wpisującym się w niego celem 2.1. strategii rozwoju Wydziału Farmaceutycznego. Warto także nadmienić, że w jego punkcie 3 celu 2.1 przewidziano uruchomienie na Wydziale studiów w języku angielskim, co jest również zbieżne z jednym z najbardziej priorytetowych w ostatnim czasie kierunków rozwoju Uniwersytetu, jakim jest internacjonalizacja.
Podkreślenia wymaga fakt, że w proocesie dydaktycznym stosowane są nowoczesne metody dydkaktyczne obejmujące nauczanie problemowe, oparte o rozwiązywanie problemów, bazujące bezpośrednio na działalności naukowej wykładowców. Studenci już od 2 semestru włączani są w prace naukowe odpowiadające tematycznie programowi studiów.

Cele kształcenia

1. Podstawowym celem kształcenia jest przekazanie absolwentom unikalnych kompetencji integrujących nauki farmaceutyczne z aplikacyjnymi aspektami prac nad nowym lekiem.
2. Absolwenci mają posiadać również podstawowe kompetencje menedżerskie oraz umiejętności pracy w zespole badawczo-rozwojowym.
3. Aplikacyjnie ukierunkowane wykształcenie akademickie ma służyć przygotowaniu wysokiej klasy specjalistów, zasilających kadry szeroko pojętego sektora farmaceutycznego, innowacyjnego i generycznego, jednostek naukowo-badawczych zajmujących się tematyką prac nad lekiem oraz instytucji regulujących rynek farmaceutyczny.
4. Wielokierunkowy charakter wykształcenia ma w szczególności predysponować do przyszłego zarządzania procesem odkrywania i rozwoju leków.

Potrzeby społeczno-gospodarcze

Wskazanie potrzeb społeczno-gospodarczych utworzenia kierunku

Absolwenci niniejszego kierunku będą posiadali wykształcenie predysponujące ich do podjęcia pracy w ramach szeroko pojętego sektora farmaceutycznego, jednostek naukowo-badawczych zajmujących się tematyką prac nad lekiem oraz instytucji regulujących rynek farmaceutyczny. Jak wspomniano powyżej, według informacji portalu Business Insider z 01.01.2018, analiza przeprowadzona przez specjalizującą się w doradztwie personalnym firmę Hays, umieściła stanowisko "specjalista ds. rozwoju w branży farmaceutycznej” w gronie 10 najbardziej pożądanych zawodów w 2018 roku. Świadczy to bezpośrednio o wysokim zapotrzebowaniu na tego typu specjalistów, a co za tym idzie, możliwości znalezienia zatrudnienia.

Wskazanie zgodności efektów uczenia się z potrzebami społeczno-gospodarczymi

Szeroki wachlarz wiedzy i kompetencji, z uwzględnieniem przedmiotów fakultatywnych, będzie obejmował cały proces odkrywania i rozwoju leków, zarówno innowacyjnych, jaki i generycznych. Z uwagi na brak analogicznych programów edukacyjnych w Polsce i Europie Środkowo-Wschodniej, posiadanie takiego wykształcenia będzie stanowiło istotną przewagę konkurencyjną nad absolwentami kierunków studiów, które nie oferują uzyskania tego typu kwalifikacji. Odpowiada to w pełni wskazanej wyżej potrzebie społeczno-gospodarczej.

Nauka, badania, infrastruktura

Główne kierunki badań naukowych w jednostce

Wydział Farmaceutyczny UJCM prowadzi szerokie badania naukowe związane z poszukiwaniem nowych substancji biologicznie aktywnych jako kandydatów na nowe leki, obejmujące zarówno otrzymywanie innowacyjnych związków chemicznych i ich szeroką charakterystykę farmakologiczną, a także szereg aspektów związanych z losami leku w ustroju, toksycznością i bezpieczeństwem stosowania oraz technologią postaci leku.
Wiodące obszary badawcze na Wydziale Farmaceutycznym UJCM, to:
1. Badania chemiczno-farmakologiczne w poszukiwaniu nowych leków układu nerwowego i układu krążenia
2. Biotechnologia i mikrobiologia farmaceutyczna oraz bromatologia
3. Farmakokinetyka, toksykologia i farmakologia bezpieczeństwa
4. Technologia postaci leku i biofarmacja
5. Modelowanie matematyczne w naukach farmaceutycznych
Aktualnie na Wydziale realizowane jest kilkanaście grantów finansowanych przez NCN, poświęconych tematyce badań nad nowymi substancjami o potencjale terapeutycznym, a w prace te zaangażowanych jest ponad 20 samodzielnych pracowników naukowych Wydziału.
Wydział stanowi wiodącą jednostkę badawczą w obszarze nauk farmaceutycznych w Polsce, o czym świadczą wyniki zarówno ostatniej parametryzacji jednostek naukowych (kategoria A+, jedno z czołowych miejsc pod względem osiągnięć naukowych), jak i niezależnych rankingów ogólnopolskich (sześciokrotne uzyskane I miejsce w rankingu opiniotwórczego czasopisma branżowego „Perspektywy”), a także bezprecedensowo wysokie miejsce w Rankingu Sznanghajskim uniwersytetów w dyscyplinach - miejsce 51-75 w dyscyplinie nauk farmaceutycznych.
Co warto podkreślić, Wydział jest też niekwestionowanym liderem pośród wydziałów farmaceutycznych w Polsce, w zakresie realizacji współpracy naukowo-badawczych z przemysłem farmaceutycznym, poświęconych poszukiwaniu nowych leków (aktualnie aktywne współprace badawcze z takimi firmami jak Adamed, Celon Pharma, Spherium Biomed, Neurolixis, Certara/Simcyp i in.).

Związek badań naukowych z dydaktyką

Jako, że tematyka kształcenia dotyczy opracowywania nowych kandydatów na leki, należy stwierdzić, iż działalność naukowa Wydziału jest w zdecydowanej większości zbieżna, lub wręcz tożsama z przedmiotem kształcenia na niniejszym kierunku. Projekty badawcze realizowane w ramach prac magisterskich będą ściśle związane z badaniami naukowymi realizowanymi na Wydziale. Magistranci będą włączani w realizację szerszego nurtu prac badawczych.

Wykaz modułów zajęć powiązanych z prowadzonymi badaniami naukowymi w dziedzinie nauki lub sztuki związanej z danym kierunkiem studiów, służących zdobywaniu przez studenta pogłębionej wiedzy oraz umiejętności prowadzenia badań naukowych (F – moduł fakultatywny):

Moduł ECTS
Principles of Medicinal Chemistry 6
Diseases States and Pharmacotherapy Strategies 8
Principles of Pharmaceutical Technology 3
Molecular ADME and In vivo Pharmacokinetics 3
Introduction to Drugs Safety and Toxicology 2
Molecular Screening Systems 2
Introduction to Animal Models of Disease States 2
Chemistry in Pharmaceutical Sciences 8
Biology in Pharmaceutical Sciences 6
Biological drugs (F) 4
Pharmaceutical Biotechnology (F)

Medicinal Chemistry (F) 36
Experimental Pharmacology (F)
Model Informed Drug Development (F)
Master Project 18
Suma ECTS 98

Punktacja ECTS przypisana powyższym modułom stanowi 82% liczby punktów ECTS koniecznej do uzyskania kwalifikacji odpowiadających poziomowi kształcenia.

Opis infrastruktury niezbędnej do prowadzenia kształcenia

BAZA DYDAKTYCZNA
Część zajęć dydaktycznych realizowana jest w kompleksie budynków przy ul. Medycznej 9 o łącznej kubaturze 90 633 m3 i powierzchni 5684 m2.
Zaplecze dydaktyczne stanowią 2 sale wykładowe, 8 sal seminaryjnych na stałe wyposażonych wg tabeli w odpowiedni sprzęt audiowizualny, 10 sal ćwiczeń laboratoryjnych oraz studencka pracownia komputerowa.
W katedrach, zakładach i klinikach na Wydziale Lekarskim oraz na Wydziale Nauk o Zdrowiu zajęcia dydaktyczne odbywają się w 12 salach wykładowych, 30 salach ćwiczeniowych oraz 15 salach seminaryjnych również wyposażonych w rzutniki multimedialne, rzutniki pisma oraz rzutniki przeźroczy.

WARUNKI LOKALOWE ul. Medyczna 9
- Sale wykładowe
L.p. Adres Liczba miejsc Wyposażenie
1 Aula A im. Prof. Jana Szastera 112 + 40 rzutnik multimedialny
rzutnik pisma
rzutnik przeźroczy
magnetowid
wizualizer
nagłośnienie
tłumaczenie symultaniczne
tablice
ekran
2 Aula B im. Prof. Józefa i Floriana
Sawiczewskich 112 rzutnik multimedialny
rzutnik pisma
rzutnik przeźroczy
magnetowid
wizualizer
nagłośnienie
tablice
ekran

- Sale seminaryjne
L.p. Adres Liczba miejsc Wyposażenie
1 Nr 1-106 30 rzutnik pisma
tablica
ekran
2 Nr 1-107 30 rzutnik pisma
tablice
ekran
3 Nr 1-108 30 rzutnik pisma

monitor
tablica
ekran
4 Nr 1-109 30 rzutnik pisma
monitor
tablica
ekran
5 Nr 1/1 48 rzutnik multimedialny
rzutnik pisma
rzutnik przeźroczy
telewizor
magnetowid
tablica
ekran
6 Nr 1/2 48 rzutnik multimedialny
rzutnik pisma
rzutnik przeźroczy
telewizor
magnetowid
tablica
ekran
7 Nr 2
20 rzutnik pisma
telewizor
magnetowid
tablica
8 Nr 3
20 rzutnik pisma
tablica
ekran

Dodatkowo do dyspozycji na zajęcia dydaktyczne:
1. rzutniki multimedialne – 5 szt.
2. komputer (laptop) - 3 szt.
3. nagłośnienie - 1 szt.

Ćwiczenia praktyczne realizowane są w laboratoriach przedmiotowych:

Wydział Farmaceutyczny
1. Katedra Chemii Nieorganicznej i Analitycznej
2. Katedra Technologii Chemicznej i Biotechnologii Środków Leczniczych
3. Katedra Chemii Organicznej
4. Katedra Farmakobiologii
5. Katedra Farmakodynamiki
6. Katedra Toksykologii
7. Katedra Technologii Postaci Leku i Biofarmacji
8. Zakład Farmacji Społecznej
9. Zakład Farmakokinetyki i Farmacji Fizycznej
10. Zakład Biochemii Farmaceutycznej
11. Zakład Analityki Biochemicznej
12. Zakład Mikrobiologii Farmaceutycznej

Wydział Lekarski
1. Katedra Patofizjologii

Wydział Nauk o Zdrowiu
1. Zakład Filozofii i Bioetyki

Centrum Językowe Uniwersytetu Jagiellońskiego - Collegium Medicum

Laboratoria wyposażone są w odpowiedni sprzęt i aparaturę potrzebną do nabycia przez studenta określonych umiejętności praktycznych z danego przedmiotu.

BAZA NAUKOWA
Z uwagi na bardzo szeroką bazę sprzętową Wydziału Farmaceutycznego, lista sprzętu została ograniczona do jednostek bezpośrednio zaangażowanych w prowadzenie zajęć na kierunku Drug Discovery and Development.

Katedra Chemii Farmaceutycznej Tandemowy spektrometr masowy sprzężony z chromatografią cieczową - zestaw LC/MS, Zestaw do UPLC/MS Waters ACQUITY TQD, Analizator CHNS Elementar Vario EL III 2, Zestawy do syntezy równoległej Radleys, chłodnice powietrzne Findenser, wyparki rotacyjne Heidolph i Buchi, mieszadła mechaniczne z funkcją grzania Heidolph i Buchi, Aparat do oznaczania temperatury topnienia Buchi, Reaktor mikrofalowy z automatycznym podajnikiem próbek (Biotage Initiator), Syntezator mikrofalowy - Discovery LabMate; Aparat do elektroforezy kapilarnej - EC Beckman Coulte; Systemy do „Flash"chromatografii - Isolera SpectraOne Biotage i Teledyne Isco; System do chromatografii błyskawicznej (flash) z detektorem ELS/UV/UV-VIS, Liofilizator kaskadowy Labconco Freezone 2,5 l, Generator wodoru PG-H250, Spektrofluorymetryczny czytnik wielofunkcyjny EnSpire firmy Perkin Elmer, mający opcje odczytu poprzez pomiar absorbancji, fluorescencji i luminescencji, 2 wieloprocesorowe klastry obliczeniowe.

Katedra Technologii i Biotechnologii Środków Leczniczych Laboratoria syntezy chemicznej:
Syntezator mikrofalowy – Discovery LabMate, system do „Flash” chromatografii – TELEDYNE ISCO USA; generator wodoru - PerkinElmer; spektrofotometr UV-Vis - Jasco V-530; spektrofotometr IR - ThermoFisher Scientific Nicolet 155; spektrofluorymetr - Jasco DIP-1000; polarymetr, HPLC - DIONEX.
Pracownia hodowli eukariotycznych:
Inkubator Heracell 240 (Heraeus), loża laminarna II klasy bezpieczeństwa MN 120 (Nüve), aparat do zliczania komórek Countness II (Life Technologies), mikroskop z przystawką do obrazowania fluorescencyjnego CKX 41 (Olympus), system do transfekcji komórek Neon (Life Technologies), wirówka z wychylnym rotorem LMC-300
Pracownia hodowli mikrobiologicznych II klasy bezpieczeństwa:
Loża laminarna II klasy bezpieczeństwa Class II A2 (Biobase), wytrząsarka z termoregulacją ES-20 (Biosan), spektrofotometr do pomiaru wzrostu bakterii BioPhotometr (Eppendorf), wirówka z chłodzeniem Mikro 22R (Hettich)
Pracownia biologii molekularnej:
Aparat do real-time PCR StepOnePlus (Applied Biosystems), termocykler do reakcji PCR Mastercycler (Eppendorf), aparatura do elektroforezy DNA, białek oraz Western-blot (Bio-Rad), system liofilizacyjny FreeZone (Labconco), czytnik płytek do pomiaru absorbancji LT-4000 (Labtech), wielofunkcyjny czytnik płytek do pomiaru absorbancji, fluorescencji i bioluminescencji EnSpire (Perkin Elmer)
Inne:
Fermentor laboratoryjny 5l (Labfors), homogenizator ultradźwiękowy (Sonoplus), zamrażarka -80°C (Sanyo), wirówka z wychylnym rotorem i chłodzeniem 3-30KS (Sigma), system oczyszczania wody do celów laboratoryjnych (Hydrolab)
Cytometr przepływowy LSRII (Becton Dickinson)

Katedra Chemii Organicznej Spektrometr NMR - Varian Mercury -VX 300 MH, Semipreparatywny chromatograf do wysokosprawnej chromatografii cieczowej HPLC La Chrom ELITE, Spektrofotometr UV-VIS - CECIL BioAquarius 7250, England, Zestaw do syntezy równoległej Radleys, chłodnice powietrzne Findenser, wyparka rotacyjna Heidolph, mieszadła mechaniczne Heidolph, mieszadło elektromagnetyczne Heidolph, Radleystech, kriometr elektroniczny Buchi M-560, Spektrofotometr UV-VIS, Czytnik ELISA, Licznik kolonii, HPLC z detektorem Corona CAD

Katedra Farmakobiologii Mikroskop optyczny i fluorescencyjny, kriostat, mikrotom parafinowy, komputerowy zestaw do analizy obrazu mikroskopowego, chromatograf gazowy, inkubator, komora laminarna, aparatura do elektroforezy białek i kwasów nukleinowych, aparatura do Western blot, aparatura do RT-qPCR, zestaw urządzeń do badań radioreceptorowych

Katedra Farmakodynamiki Zestaw do narządów izolowanych sprzężony z komputerem, zestaw do izolowanego serca, kompletna aparatura ELISA, aparat do pomiaru ciśnienia tętniczego u małych zwierząt - DATAMAX, firmy Columbus sprzężony z komputerem, aparat EKG dla małych zwierząt laboratoryjnych z komputerową możliwością analizy elektrokardiogramu, aparat EKG przystosowany do zapisu elektrokardiogramu izolowanego serca szczura, aparaty EKG: E-30, Multicard E - 30, AsCARD B5, EK 1 T - 03M2, generator elektrowstrząsów GE - 01, mikropompy dozujące, aparat do badania aktywności p/bólowej związków metodą „hot plate", analgezymetr typu Ugo-Basile do badania aktywności p/bólowej związków, zestaw aparatury do techniki PCR i RLT, aparat ROTAROD, aparat do oznaczania aktywności przeciwbólowej i przeciwzapalnej u szczura metodą termiczną „ Plantar test", zestaw do pomiaru obrzęku łapy szczura i myszy wraz z programem komputerowym i zestawem statywów, automatyczny system do pomiaru ciśnienia tętniczego u szczurów i myszy metodą bezkrwawą, zestaw "Von Frey" wraz z oprogramowaniem., klatki z czujnikami do badania aktywności lokomotorycznej zwierząt (Ugo Basile), aparat do pomiaru ciśnienia metodą bezkrwawą, pletyzmometr, klatka dla myszy MICE PASIVE z oprogramowaniem, labirynt wodny Morrisa, labirynt uniesiony dla myszy, moduł SMART do oprogramowania, kamera.

Katedra Toksykologii ● zestawy do wysokosprawnej chromatografii cieczowej z detekcją: UV/VIS, DAD, spektrofluorometryczną, masową, zestawy do chromatografii gazowej z detekcją FID, masową, spektrofotometry (pomiary statyczne, analizy kinetyczne),
● aparat do elektroforezy żelowej, Trans-Blot Turbo Transfer System, kamera do obrazowania Western Blot, komora laminarna do badań in vitro

Katedra Technologii Postaci Leku i Biofarmacji Wyposażenie laboratoryjne i aparaturowe Katedry stwarzają możliwość realizacji badań w szerokim zakresie, obejmującym prace technologiczne oraz analityczne służące ocenie jakości postaci leku. Spośród najważniejszych elementów wyposażenia Katedry należy wymienić aparaturę wytwórczą, która służy do sporządzania na skalę laboratoryjną różnorodnych form leku.
Z punktu widzenia realizacji projektów badawczych istotnymi urządzeniami znajdującymi się na wyposażeniu jednostki są tabletkarki uderzeniowe i rotacyjne: Korsch EK0, Korsch PH 103, Erweka TRB 10, pozwalające na produkcję tabletek ODT oraz tabletek z peletkami, zestaw do ekstruzji i sferonizacji: ekstruder Aleksanderwerk GA 60, sferonizator Caleva 120, granulator szybkoobrotowy FS-GS Fukae Powtec, aparaty fluidalne do granulacji, suszenia i powlekania: Bosch-Solidlab i 4M8-F Pro-C-epT, suszarka rozpyłowa Buchi B-191, aparat do wytwarzania filmów polimerowych o ściśle zdefiniowanej grubości Elcometer 4340, młyny planetarne Fritsch Pulverisette 7 Classic Line i Premium Line, drukarka 3D Z-Morph 2.0S.
Katedra dysponuje także szerokim spektrum urządzeń badawczych służącym do oceny postaci leku m.in.: zestawy do badania uwalniania substancji leczniczej (aparat 1 i 2 wg FP): łaźnia wodna Hanson SR8 oraz kolektor frakcji Dissoette II oraz Hanson Research Elite 8 Vision G2, zestaw do badania uwalniania substancji leczniczej metodą przepływową (aparat 4 wg FP) Erweka DFZ 60 z pompą HKP 60, friabilator PharmaTest PTF-E, twardościomierz VanKel VK 200, aparat do badania czasu rozpadu Electrolab ED-2 SAPO, spektrofotometry: UV-VIS JASCO V-530 oraz Schimadzu UV-1800 UV-VIS, zestaw do wysokosprawnej chromatografii cieczowej HPLC Agilent 1260 Infinity, urządzenie do pomiaru wielkości cząstek metodą dyfrakcji laserowej Malvern Mastersizer 3000, analizator tekstury Schimadzu EZ-SX, reometr Haake VT 550, mikroskopy optyczne: Hund Wetzlar H600 oraz MST-ZOOM PZO.

Zakład Farmacji Społecznej Zespół ośmiu serwerów z automatycznym systemem rozpraszania obliczeń, Automatyczny aparat PatchClamp (CytoPatch2)

Zakład Farmakokinetyki i Farmacji Fizycznej HPLC z detekcją DAD, elektrochemiczną i spektrofluorymetryczną (Merck Hitachi), LC-MS/MS, amplifikator DNA z detekcją w czasie rzeczywistym, aparat do elektroforezy kapilarnej (PACE/MDQ), aparat do badania uwalniania leków metodą przepływową (USP4 SOTAX AG), system do perfuzji izolowanych narządów małych zwierząt (myszy, szczury), zestaw do mikrodializy (CMA Microdialysis), API 2000 LC/MS/MS (Applied Biosystems/MDS Sciex)

Zakład Biochemii Farmaceutycznej Aparat do elektroforezy MINIPOL 2, wirówka centrifuge 5415 R, eppendorf thermomixer compact 5350, mieszadło Vortex Gilson DVLab, mieszadło magnetyczne Labstir Gilson, komora laminarna BioActiva, dygestorium POLLAB DSL – 15.00, destylarka do wody DE5, waga analityczna, mieszadło magnetyczne Color Squid ikamag, pH-metr BT-676, cyfrowa łaźnia wodna, spektrofotometr, uniwersalna wirówka z rotorem, suszarka laboratoryjna, autoklaw, urządzenie do elektroforezy MIDI, transiluminator, komora laminarna DNA/RNA, inkubator CO2, czytnik płytek spectramax ID3, inkubator z wytrząsaniem, myjka ultradźwiękowa, zbiornik LS-750, aparat do wyznaczania SPF + stacja robocza, mikroskop odwrócony LEICA DM IL, Eppendorf BioSpectrometer basic, ThermoMixer EPPENDORF F1.5, uniwersalny pH-metr HANNA EDGE pH HI 2002, aparat do badań starzeniowych Suntest CPS+, komora świetlna

Zakład Analityki Biochemicznej Spektrofotometr; Sprzęt do elektroforezy kwasów nukleinowych i białek; termocykler; Komora z CO2 + mikroskop odwrócony

Zakład Mikrobiologii Farmaceutycznej Amplifikator DNA z detekcją w czasie rzeczywistym - Rotor-Gene RG-3000 (Corbett Research), Termocykler T-Personal (Biometra) mikroskop świetlny wyposażony w cyfrowy aparat fotograficzny (NIKON Eclipse 200), inkubator CO2 (New Brundswick Scientific), zamrażarka niskotemperaturowa (-80oC) (New Brundswick Scientific), Spektrofotometr Sunrise (Tekan).

Program

Podstawowe informacje

Klasyfikacja ISCED:	0916
Liczba semestrów:	4
Tytuł zawodowy nadawany absolwentom:	magister

Opis realizacji programu:

Drug Discovery and Development (DDD) to studia koncentrujące się na wszystkich aspektach identyfikacji i opracowywania nowych leków. Celem studiów jest przygotowanie wysokiej klasy specjalistów, posiadających unikalne połączenie zaawansowanej wiedzy teoretycznej z zakresu pracy nad lekiem z umiejętnościami praktycznymi. Student otrzymuje solidną podstawę w zakresie nauk farmaceutycznych, ale także możliwość specjalizacji w konkretnym obszarze odkrywania i rozwoju leków. Pierwszy semestr ma na celu zapewnienie podstawowego zrozumienia procesu odkrywania i opracowywania leków oraz kluczowych aspektów chemicznych, biologicznych i patofizjologicznych istotnych z punktu widzenia prac nad lekiem. Drugi semestr to szerokie i zrównoważone tematycznie szkolenie w dziedzinie nauk farmaceutycznych, które służy za podstawę dalszego, ukierunkowanego rozwoju kwalifikacji zawodowych. Semestry trzeci i czwarty koncentrują się na jednej z trzech dziedzin wiodących, takich jak: Chemia Leków, Farmakologia Eksperymentalna oraz Rozwój Leku Wspierany Modelowaniem Matematycznym.
Absolwenci studiów DDD szczegółowo zapoznają się z procesem poszukiwania nowych leków ich identyfikacji, badania, produkowania i testowania. Kształcenie obejmuje także najważniejsze aspekty prawno-regulacyjne, niezbędne do ich oficjalnej akceptacji jako produktów leczniczych. Ponadto, zdobędą umiejętności zarządzania i kompetencje językowe, wspierające ich przyszłe zatrudnienie w branży pharma-biotech, agencjach rejestracyjnych oraz centrach badań nad lekiem na całym świecie.

Liczba punktów ECTS

konieczna do ukończenia studiów	120
w ramach zajęć prowadzonych z bezpośrednim udziałem nauczycieli akademickich lub innych osób prowadzących zajęcia	64
którą student musi uzyskać w ramach zajęć z zakresu nauki języków obcych	4
którą student musi uzyskać w ramach modułów realizowanych w formie fakultatywnej	40
którą student musi uzyskać w ramach praktyk zawodowych	-
którą student musi uzyskać w ramach zajęć z dziedziny nauk humanistycznych lub nauk społecznych	5

Liczba godzin zajęć

Łączna liczba godzin zajęć: 1926

Praktyki zawodowe

Wymiar, zasady i forma odbywania praktyk zawodowych

nie dotyczy

Ukończenie studiów

Wymogi związane z ukończeniem studiów (praca dyplomowa/egzamin dyplomowy/inne)

Ukończenie studiów wymaga uzyskania zaliczenia ze wszystkich przedmiotów obowiązkowych i fakultatywnych określonych w programie i realizowanych w ramach programu studiów.
Przygotowanie i obrona pracy magisterskiej umożliwia uzyskanie tytułu magistra po spełnieniu obowiązujących prawem wymagań.

Efekty uczenia się

Wiedza

Kod	Treść	PRK
DDD_KDR_W01	The graduate knows and understands phenomena and interpretations of parameters describing the properties of a drug and its fate in the body	P7S_WG
DDD_KDR_W02	The graduate knows and understands mechanisms of action, application and side effects of drugs most important from the point of view of society and the economy	P7S_WG
DDD_KDR_W03	The graduate knows and understands the process of searching, obtaining and properties of medicinal substances (biologically active)	P7S_WG
DDD_KDR_W04	The graduate knows and understands the specificity of the studies on the pharmacokinetic, pharmacodynamic and toxicological properties of drugs and drug candidates in vitro and in vivo	P7S_WG
DDD_KDR_W05	The graduate knows and understands guidelines for the development, production and evaluation of the properties of the dosage form	P7S_WG
DDD_KDR_W06	The graduate knows and understands application of analytical methods used in drug research	P7S_WG
DDD_KDR_W07	The graduate knows and understands statistical methods, mathematical models and in silico research used in pharmaceutical sciences	P7S_WG
DDD_KDR_W08	The graduate knows and understands principles of functioning of the pharmaceutical sector and main trends and prospects for its development	P7S_WG, P7S_WK
DDD_KDR_W09	The graduate knows and understands requirements and legal and ethical aspects regarding the development and implementation of the drug	P7S_WK
DDD_KDR_W10	The graduate knows and understands issues necessary for independent planning and implementation of research tasks in the area of its specialty	P7S_WG
DDD_KDR_W11	The graduate knows and understands rules of functioning of the equipment and apparatus used at various stages of drug research and development	P7S_WK
DDD_KDR_W12	The graduate knows and understands functioning of equipment and apparatus used at various stages of drug research and development	P7S_WK
DDD_KDR_W13	The graduate knows and understands principles of protection of intellectual and industrial property	P7S_WK
DDD_KDR_W14	The graduate knows and understands principles and methodology of scientific research, development and processing of research results as well as preparation and evaluation of scientific publications	P7S_WK

Umiejętności

Kod	Treść	PRK
DDD_KDR_U01	The graduate can critically analyze information and research results in the field of pharmaceutical sciences and draw correct conclusions based on them	P7S_UW
DDD_KDR_U02	The graduate can plan and carry out specialized research in the field of drug discovery and development by selecting the appropriate methodology and using professional equipmnt and software	P7S_UW, P7S_UK
DDD_KDR_U03	The graduate can interpret the results of specialist research and draw conclusions, formulate opinions and solve problems related to the search and development of a drug	P7S_UW

Kod	Treść	PRK
DDD_KDR_U04	The graduate can support research with appropriate statistical methods and mathematical models, and with the use of databases and specialized software	P7S_UW
DDD_KDR_U05	The graduate can cooperate and communicate effectively with people with various expertise, experience, and knowledge levels and specialists in various fields of science in order to implement research plans and solve complex problems in the field of drug discovery and development	P7S_UK
DDD_KDR_U06	The graduate can obtain reliable scientific information, use appropriate databases, professional literature and expert opinions	P7S_UW
DDD_KDR_U07	The graduate can present and disseminate knowledge and research results in a professional, understandable and accessible way for various groups of recipients	P7S_UK
DDD_KDR_U08	The graduate can communicate in English at the B2 + level using specialized vocabulary in the field of pharmaceutical sciences	P7S_UK
DDD_KDR_U09	The graduate can effectively work in a group, assuming an advisory, expert or managerial role depending on the needs	P7S_UK, P7S_UO
DDD_KDR_U10	The graduate can identify errors and neglects in the process of drug research and development as well as own work and research	P7S_UW
DDD_KDR_U11	The graduate can take care of the continuous development of knowledge and skills as well as dissemination of professional knowledge in the society	P7S_UU

Kompetencje społeczne

Kod	Treść	PRK
DDD_KDR_K01	The graduate is ready to gain reliable knowledge and critically assess the received content in solving cognitive and practical problems	P7S_KK
DDD_KDR_K02	The graduate is ready to reliably and responsibly fulfill professional duties and comply with the rules of professional ethics	P7S_KR
DDD_KDR_K03	The graduate is ready to take responsibility for their work and for critical self-evaluation	P7S_KR
DDD_KDR_K04	The graduate is ready to assign priorities for the implementation of a chosen goal or other tasks, and if necessary, consult experts	P7S_KK
DDD_KDR_K05	The graduate is ready to act in an entrepreneurial way and for the benefit of society	P7S_KO
DDD_KDR_K06	The graduate is ready to evaluate ethical issues related to human research	P7S_KK
DDD_KDR_K07	The graduate is ready to concern for personal safety, the environment and colleagues	P7U_K

Plany studiów

Student zobowiązany jest wybierać 1 przedmiot fakultatywny w roku

Semestr 1

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Legal and Scientific Basics of Drug Discovery and Development	lecture: 45 seminar: 45	6,0	written examination	O	Or
Chemistry in Pharmaceutical Sciences	seminar: 75 classes: 75	8,0	written examination	O	Or
Biology in Pharmaceutical Sciences	lecture: 22 seminar: 14 classes: 64	6,0	written examination	O	Or
Humanities - Bioethics in pharmaceutical sciences	lecture: 15 seminar: 15	3,0	graded credit	O	Os
Humanities – Scientific writing	seminar: 30	2,0	graded credit	O	Os
Foreign Language in Pharmaceutical Sciences	seminar: 20	1,0	-	O	Os
Diseases States and Pharmacotherapeutic Strategies	lecture: 15 seminar: 60	-	-	O	Or
Health and Safety	Health and Safety training: 6	-	credit	O	Os

Semestr 2

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Diseases States and Pharmacotherapeutic Strategies	lecture: 15 seminar: 60	8,0	written examination	O	Or
Principles of Medicinal Chemistry	lecture: 30 seminar: 60	6,0	written examination	O	Or
Molecular Screening Systems	lecture: 5 seminar: 25	2,0	graded credit	O	Os
Molecular ADME and In Vivo Pharmacokinetics	seminar: 20 workshop: 10 classes: 30	3,0	written examination	O	Or
Introduction to Animal Models of Disease States	lecture: 5 seminar: 10 classes: 15	2,0	graded credit	O	Os
Introduction to Drugs Safety and Toxicology	seminar: 10 classes: 4 workshop: 16	2,0	graded credit	O	Or
Principles of Pharmaceutical Technology	lecture: 20 seminar: 20 classes: 20	3,0	written examination	O	Os

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Principles of Clinical Trials	lecture: 15 seminar: 15	2,0	graded credit	O	Os
Pharmaceutical Project Management	seminar: 15	1,0	graded credit	O	Os
Foreign Language in Pharmaceutical Sciences	seminar: 25	1,0	credit	O	Os
Biological drugs	lecture: 15 seminar: 10 classes: 25	4,0	graded credit	F	Os
Pharmaceutical Biotechnology	lecture: 15 seminar: 10 classes: 25	4,0	graded credit	F	Os

Semestr 3

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Foreign Language in Pharmaceutical Sciences	e-learning: 15 seminar: 30	2,0	examination	O	Os
Team-work Case Studies	seminar: 30	-	-	O	Os
Medicinal Chemistry	e-learning: 135 seminar: 170 classes: 145	36,0	written examination	F	Os
Experimental Pharmacology	e-learning: 20 seminar: 30 classes: 400	36,0	written examination	F	Os
Model Informed Drug Development	e-learning: 45 seminar: 120 classes: 120 workshop: 165	36,0	written examination	F	Os

Semestr 4

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Team-work Case Studies	seminar: 30	4,0	graded credit	O	Os
Master Project	tutorial: 375	18,0	credit	O	Os

O - obowiązkowy
F - fakultatywny
Or - obowiązkowy do zaliczenia roku
Os - obowiązkowy do zaliczenia w toku studiów

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Legal and Scientific Basics of Drug Discovery and Development

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	

Period Semester 1	**Examination** written examination **Activities and hours** lecture: 45, seminar: 45	**Number of ECTS points** 6.0

Goals

C1	Introducing the student to the subject of drug discovery and development and equipping him with a basic conceptual apparatus, necessary to acquire further, more advanced content. Presentation of basic processes carried out today as part of the discovery and development of medicines, against the background of historical development of this field. To acquaint students with the basic legal and market conditions for the functioning of the pharmaceutical industry, important from the point of view of researching a new drug. Acquainting with the methodology of scientific works, sources of knowledge, principles of statistical inference, structure and scope of regulations regulating the pharmaceutical industry and scientific and laboratory work, including the principles of intellectual property.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			

W1	basic terminology in the field of drug discovery and development	DDD_KDR_W01, DDD_KDR_W07	written examination
W2	cycle of drug discovery and development	DDD_KDR_W08, DDD_KDR_W09	written examination
W3	methodological and regulatory milestones in the history of drug discovery and development	DDD_KDR_W08, DDD_KDR_W09	written examination
W4	organizational conditions and trends in the pharmaceutical industry	DDD_KDR_W08	written examination
W5	basic legal acts shaping the activities of the pharmaceutical industry in the three most economically important areas of the world	DDD_KDR_W09	written examination
W6	competences of registration agencies and procedures used in them	DDD_KDR_W09	written examination
W7	issues related to the protection of intellectual property	DDD_KDR_W13	written examination
W8	legal issues related to the organization and conduct of scientific research	DDD_KDR_W09	written examination
W9	sources and methods of obtaining scientific information	DDD_KDR_W14	written examination
W10	principles of planning scientific research	DDD_KDR_W14	written examination
W11	methods of collecting and analyzing scientific data.	DDD_KDR_W14	written examination
Skills – Student can:			
U1	describe the most important legal acts shaping the functioning of the pharmaceutical industry in the world	DDD_KDR_U06	written examination
U2	list the most important legal acts regarding the organization and conduct of scientific research	DDD_KDR_U05	written examination
U3	discuss the process of work on the drug with specialists and non-specialists in this field	DDD_KDR_U05	written examination
U4	identify and use sources of scientific information	DDD_KDR_U06	written examination
U5	plan a simple experiment and indicate the necessary legal requirements that must be met in order to carry it out	DDD_KDR_U02	written examination
U6	analyze and synthesize scientific data	DDD_KDR_U01	written examination
U7	characterize the types of scientific publications	DDD_KDR_U07	written examination
U8	prepare a short speech, poster, e-poster	DDD_KDR_U07	written examination
U9	identify and use sources of patent information	DDD_KDR_U06	written examination
Social competences – Student is ready to:			
K1	recognize the importance of using reliable sources of information	DDD_KDR_K01	written examination
K2	take the responsibility for comprehensive data evaluation	DDD_KDR_K03	written examination

Calculation of ECTS points

Activity form	Activity hours*
lecture	45
seminar	45
preparation for classes	30
preparation for examination	30
Student workload	**Hours** 150
Workload involving teacher	**Hours** 90

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	The most important concepts related to the discovery and development of the drug. The history of the process of drug discovery and development. Contemporary methods used in drug research.	W1, W2, U3	lecture, seminar
2.	Organizational structure of pharmaceutical companies. Structure of the pharmaceutical market. The role of large and small pharmaceutical companies, research contract companies and academic laboratories in the discovery and development of the drug. The evolutionary cycle of the project team. Aspects of financing work on a new drug.	W4	lecture, seminar
3.	Important stages of legal regulations. Sources, scope and structure of legal regulations concerning the pharmaceutical industry.	W3, W5, W6, U1, U2	lecture, seminar
4.	The rules of intellectual property protection. Forms of protection of intellectual property. Patent as a form of intellectual property protection, patent design, patent proceedings schedule. Industrial property law. Discussion of various forms of intellectual property protection. Getting acquainted with various forms of patents, patent database Esp @ cenet (PL / EU), other patent databases. Patent search by: numbers, key words, authors, date of publication.	W7, U9, K1, K2	lecture, seminar

5.	Basics of scientific methodology and statistical inference in scientific papers. Basic principles of laboratory work. Work with scientific literature databases, search for thematic publications (PubMed, pages of major scientific publications providing Life science literature). Case study: analysis of selected scientific publications.	W10, W11, W8, W9, U4, U5, U6, U7, U8, K1, K2	lecture, seminar

Course advanced

Teaching methods:

seminar, lecture

Activities	Examination methods	Credit conditions
lecture	written examination	
seminar	written examination	

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Chemistry in Pharmaceutical Sciences

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	

Period	**Examination**	**Number of ECTS points**
Semester 1	written examination **Activities and hours** seminar: 75, classes: 75	8.0

Goals

C1	Expanding and systematizing knowledge useful in pharmaceutical sciences in the field of general chemistry, organic chemistry, analytical chemistry and physical chemistry
C2	Introduction to chemical and analytical laboratory techniques used in the process of drug discovery and development
C3	Developing the ability to plan and execute tasks based on cooperation in the group

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			

W1	the most important issues for pharmaceutical sciences in the field of: ◦ general chemistry, chemistry of solutions and physical chemistry, ◦ chemical properties and methods of synthesis of the main classes of organic compounds, ◦ analytical methods used in qualitative and quantitative analysis.	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W12	multiple choice test
W2	principles of good laboratory practice and workplace safety and health in a chemical laboratory	DDD_KDR_W11	project
Skills – Student can:			
U1	correctly interpret chemical formulas, chemical names, stereoisomerism, draw and name compounds according to current IUPAC nomenclature	DDD_KDR_U01, DDD_KDR_U03	multiple choice test
U2	predict simple relationships between the structure of a chemical compound and its physicochemical properties	DDD_KDR_U01, DDD_KDR_U03	project, multiple choice test
U3	recognize the most important for pharmaceutical sciences types of chemical reactions: is able to name them, write the equations and predict their course	DDD_KDR_U01	multiple choice test
U4	perform calculations relevant for the process of drug discovery and development in the field of general chemistry and chemistry of solutions and interpret their results	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	project, multiple choice test
U5	plan and perform simple laboratory operations in the field of organic synthesis, qualitative and quantitative analysis and analysis of physicochemical properties, useful in drug discovery and development process	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	project
U6	interpret results of simple chromatographic and spectrometric analyzes	DDD_KDR_U01, DDD_KDR_U03	project, multiple choice test
U7	use software and Internet tools to obtain information on chemical compounds, useful for drug discovery and development process	DDD_KDR_U01, DDD_KDR_U04, DDD_KDR_U06	project, multiple choice test
Social competences – Student is ready to:			
K1	cooperate in a group in order to solve complex problems and carry out tasks	DDD_KDR_K04	project
K2	take the responsibility for his/her work and is capable of critical self-appraisal	DDD_KDR_K02, DDD_KDR_K03	project

Calculation of ECTS points

Activity form	**Activity hours***
seminar	75
classes	75
preparation for classes	30
preparation for examination	20
preparation of a project	10

Student workload	**Hours** 210
Workload involving teacher	**Hours** 150
Practical workload	**Hours** 75

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	General chemistry (chemical bonds, electronegativity, partial and full charges, intermolecular interactions, kinetics of processes, catalysis, reaction equilibrium)	W1, U1, U2, U4	classes, seminar
2.	Chemistry of solution (acidity, alkalinity, pH, pKa, electrolyte power, buffers, Henderson-Hasselbalch equation)	W1, U1, U2, U4	classes, seminar
3.	Basics of physical chemistry (solubility, precipitation, dispersion systems, lipophilicity, surface tension)	W1, U2, U3, U4	classes, seminar
4.	Qualitative and quantitative analysis (chromatography, spectroscopy, other instrumental methods)	W1, U4, U5, U6, U7	classes, seminar
5.	Main classes of organic compounds – reactivity and properties (saturated, unsaturated and aromatic hydrocarbons, heterocycles, halogeno-derivatives, alcohols, phenols, aldehydes, ketones, amines, acids and their derivatives)	W1, U1, U2, U3	classes, seminar
6.	Reactions in organic chemistry and their mechanisms (halogenation, alkylation, acylation, hydrolysis, condensation, oxidation, reduction, mechanisms of substitution, addition and rearrangement reactions)	W1, U1, U3	seminar
7.	Nomenclature of organic compounds by IUPAC, stereochemistry	W1, U1	seminar
8.	Basic laboratory operations and unit processes in organic synthesis	W2, U5, U6, U7, K1, K2	classes
9.	Qualitative and quantitative pharmaceutical analysis	W1, W2, U4, U5, U6, U7, K1, K2	classes, seminar

Course advanced

Teaching methods:

classes / practicals, computer classes, laboratories (labs), demonstration, discussion, e-learning, project method, presentation, computer room, lecture, lecture with multimedia presentation, practical classes

Activities	Examination methods	Credit conditions
seminar	multiple choice test	1. Completion of written tests – scoring each test at least 60% 2. Attendance at seminars - at least 75%

Activities	Examination methods	Credit conditions
classes	project	1. Completion of the project (preparation and presentation) 2. Completion of all laboratory tasks 3. Attendance at laboratory classes - at least 80%

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Biology in Pharmaceutical Sciences

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	

Period Semester 1	**Examination** written examination **Activities and hours** lecture: 22, seminar: 14, classes: 64	**Number of ECTS points** 6.0

Goals

C1	The learning objective within the module is to broaden knowledge, skills and social competences in the field of molecular biology, genetics, biochemistry and microbiology, in the aspects related to drug discovery and development.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the current development direction for molecular biology, genetics, biochemistry and microbiology, in the level necessary to assimilate basics of drug design and development	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, oral examination, test

W2	the theories of cell, the fundamentals of genetics, their relevance to pharmacogenetics, and the methods of their evaluation in the level necessary to assimilate principles of drug design and development	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
W3	the structure and properties of nucleic acids, proteins, saccharides and lipids in the context of drug action,	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
W4	theories in biochemistry, including: theory of metabolic processes, enzymatic reactions, concepts of inhibition and induction in the level necessary to assimilate principles of drug design and development	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
W5	the theories of microbiology in the context of anti-infective drugs and selective toxicity	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
W6	genetic information and gene expression in microorganisms and eukaryotic cells	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
W7	ethical and legal conditions related to scientific, didactic and implementation activities in the aspect of molecular biology, genetics, biochemistry and microbiology, in the level necessary to assimilate principles of drug design and development	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04	written examination, test
Skills – Student can:			
U1	use advanced technical methods and equipment useful in molecular biology, genetics, biochemistry and microbiology, in the level necessary to assimilate principles of drug design and development	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U09	written examination, test
U2	use principles of asepsis, antiseptics and microbiological purity necessary for studies with microorganisms in laboratory practice	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U09	written examination, test
U3	use specialized IT tools for search and collection of data in the field of molecular biology and genetics as well as to analyze and critically evaluate these data	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U08, DDD_KDR_U10	written examination, test
U4	work in planning and carrying out research tasks in the field of molecular biology, genetics, biochemistry and microbiology in the level necessary to assimilate principles of drug design and development	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U09	written examination, oral examination, test
Social competences – Student is ready to:			

K1	consult with experts in the field of molecular biology, genetics, biochemistry and microbiology, in case of difficulty in solving problem independently	DDD_KDR_K01, DDD_KDR_K04	written examination, oral examination
K2	show respect for the prestige associated with the profession and properly understood professional solidarity	DDD_KDR_K02, DDD_KDR_K07	written examination, oral examination
K3	care about safety of her/his own, her/his colleagues and the environment	DDD_KDR_K05, DDD_KDR_K07	written examination, oral examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	22
seminar	14
classes	64
preparation for classes	20
preparation for examination	20
preparation of multimedia presentation	10
Student workload	**Hours** 150
Workload involving teacher	**Hours** 100
Practical workload	**Hours** 64

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	Principles of molecular biology and genetics, including: 1. Introduction - organisms classification and taxonomy 2. Structure of cells and cell components, in the context of the emergence and therapy of diseases 3. Protein structure - in the context of biological targets - receptors, enzymes (amino acids, peptides, primary-quaternary protein structure), 4. General information on the structure of nucleic acids, saccharides and lipids in the context of drug action, 5. Central Dogma and cell cycle in the context of drug targets 6. Principles of genetics and their relationship to pharmacogenetics,	W1, W2, W3, W6, W7, U1, U3, U4, K1, K2, K3	lecture, classes, seminar

2.	Principles of biochemistry, including: ◦ Main metabolic processes, enzyme characteristics, ◦ Main concepts and relationships in biochemistry: Michaelis-Menten equation, inhibition (reversible, irreversible), and induction.	W1, W4, W7, U1, U4, K1, K2, K3	lecture, classes
3.	Principles of microbiology in the context of anti-infectious drugs to understand the selective toxicity, principles of asepsis, antiseptics and microbiological purity studies: ◦ Classification of microorganisms, ◦ General characteristics of bacteria, fungi and viruses, ◦ Growth requirements and breeding of microorganisms, ◦ Antibiotics, antibiotic therapy and bacterial sensitivity to drugs, sterilization and disinfection, ◦ Hospital infections including infections from medicines (definitions), presence of microorganisms in medicines, pharmaceutical raw materials and water.	W1, W5, W6, W7, U1, U2, U4, K1, K2, K3	classes
4.	Pharmacognosy and pharmaceutical botany – general overview in the context of natural drug discovery & development	W1, K1	seminar

Course advanced

Teaching methods:

brainstorm, classes / practicals, computer classes, laboratories (labs), demonstration, discussion, educational film, presentation, group work, seminar, lecture, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
lecture	written examination	Final examination: written exam
seminar	oral examination, test	Full seminars attendance, partial written tests – scoring each test at least 60%.
classes	written examination	Full classes attendance, final examination: written exam

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Humanities - Bioethics in pharmaceutical sciences

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period	**Examination**	**Number of ECTS points**
Semester 1	graded credit **Activities and hours** lecture: 15, seminar: 15	3.0

Goals

C1	Understanding of the essential elements of bioethical issues in pharmaceutical sciences.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	DDD_KDR_W09 The graduate knows Declaration of Helsinki, CIOMS International Ethical Guidelines for Health-related Research Involving Humans and other national and international standards and regulations	DDD_KDR_W09	written examination, classroom observation
Skills – Student can:			

U1	DDD_KDR_U10 The graduate can identify irregularities, failures and malpractices in the process of drug research and development and own work and research	DDD_KDR_U10	written examination, classroom observation
Social competences – Student is ready to:			
K1	DDD_KDR_K02 The graduate is ready to act according ethics standards	DDD_KDR_K06	written examination, classroom observation

Calculation of ECTS points

Activity form	**Activity hours***
lecture	15
seminar	15
preparation for classes	30
preparation for colloquium	30
Student workload	**Hours** 90
Workload involving teacher	**Hours** 30

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	1. Case study: research or treatment, benefits and risk in research	W1, K1	seminar
2.	2. Case study: fair recruitment rules	W1, U1	seminar
3.	3. Case study: informed consent form, relevant information	U1, K1	seminar
4.	4. Case analysis: therapeutic obligation, clinical equipoise	W1, U1, K1	seminar
5.	5. Case study: research involving vulnerable groups	W1, U1	seminar
6.	1. Biomedical research with human subjects – introduction	U1, K1	lecture
7.	2. Risks and benefits in biomedical research	W1, U1, K1	lecture
8.	3. Therapeutic obligation, the principle of clinical equipoise, use of placebo in research	W1, U1	lecture
9.	4. Vulnerable populations in research	W1, U1	lecture
10.	5. Informed consent, assent and dissent in research	U1, K1	lecture

11.	6. Justice in biomedical research: recruitment, post-approval drug access, international research	W1, U1, K1	lecture

Course advanced

Teaching methods:

case study, textual analysis, brainstorm, discussion, case study method, presentation, group work, seminar, lecture, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
lecture	written examination	
seminar	written examination, classroom observation	

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Humanities – Scientific writing

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period	**Examination**	**Number of ECTS points**
Semester 1	graded credit **Activities and hours** seminar: 30	2.0

Goals

C1	Introduction to scientific writing and scientific reading
C2	The format of an original manuscript
C3	Principles of effective writing (organization, crafting better sentences and paragraphs)
C4	Issues in scientific writing: plagiarism, ghostwriting, authorship
C5	Review process

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			

W1	principles and methodology of scientific research, development and processing of research results as well as preparation and evaluation of scientific publications	DDD_KDR_W14	practical examination, group assessment
Skills – Student can:			
U1	critically analyze information and research results in the field of pharmaceutical and medical (life) sciences and draw correct conclusions based on them	DDD_KDR_U01	practical examination, group assessment
U2	communicate with representatives of different areas of life representing different levels of knowledge and specialists in various fields of science in order to implement research plans and solve complex problems in the field of drug discovery and development	DDD_KDR_U05	practical examination, group assessment
U3	obtain reliable scientific information, use appropriate databases, professional literature and expert opinions	DDD_KDR_U06	practical examination, group assessment
U4	present and disseminate knowledge and research results in a professional, understandable and accessible way for various groups of recipients	DDD_KDR_U07	practical examination, group assessment
Social competences – Student is ready to:			
K1	ready to take responsibility for their work and for critical self-evaluation	DDD_KDR_K03	practical examination, group assessment

Calculation of ECTS points

Activity form	**Activity hours***
seminar	30
practice	15
conducting literature research	15
Student workload	**Hours** 60
Workload involving teacher	**Hours** 30
Practical workload	**Hours** 15

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	Introduction: effective scientific writing and reading	W1, U1, U2, U3, U4, K1	seminar
2.	Organization of writing process	W1, U1, U2, U3, U4, K1	seminar
3.	The format of an original manuscript	W1, U1, U2, U3, U4, K1	seminar

4.	Plagiarism, ghostwriting, authorship,	W1, U1, U2, U3, U4, K1	seminar
5.	Scientific writing: tips and tricks for writing better and faster	W1, U1, U2, U3, U4, K1	seminar
6.	Review process	U1, U3	seminar

Course advanced

Teaching methods:

textual analysis, computer classes, discussion, educational film, foreign language course, presentation, group work, seminar, workshop, practical classes

Activities	Examination methods	Credit conditions
seminar	practical examination, group assessment	

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Foreign Language in Pharmaceutical Sciences

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20, 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Linguistics	**Examination** examination
ISCED classification 0231 Language acquisition	

Period	Examination	Number of ECTS points
Semester 1	- **Activities and hours** seminar: 20	1.0

Period	Examination	Number of ECTS points
Semester 2	credit **Activities and hours** seminar: 25	1.0

Period	Examination	Number of ECTS points
Semester 3	examination **Activities and hours** seminar: 30, e-learning: 15	2.0

Goals

C1	The aim of the course is to prepare the student to use English fluently in speaking and writing for professional, academic and social purposes as well as to understand specialist literature and express opinions on topics related to it at the level of proficiency B2+ of the Common European Framework of Reference for Languages

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	English terminology related to the process of searching, obtaining and properties of medicinal substances	DDD_KDR_W03	written examination, oral examination, oral answer, test
Skills – Student can:			
U1	take part in a discussion - introduce a point, ask for and express opinions, express pros and cons, express doubts, express disagreement and support, give reasons, draw conclusions, sum up a discussion, talk about his/her field and projects, make a presentation using specialized vocabulary, follow a discussion in a team meeting, argue for and against an idea appropriately, support ideas with evidence, interrupt a meeting appropriately (Speaking)	DDD_KDR_U08	oral examination, oral answer
U2	summarize a research proposal, fill in an application form, recognize different styles of writing, ask for help using an online forum, describe data for statistical analysis, write a caption for a figure or graph, describe a figure or graph in a paper, take notes at a meeting, write an abstract (Writing)	DDD_KDR_U08	written examination, test
U3	read and understand specialist literature, find necessary information and evaluate its importance, understand arguments in scientific articles (Reading)	DDD_KDR_U08	written examination, test
U4	understand discussions, presentations, papers, telephone conversations (Listening)	DDD_KDR_U08	written examination, test
Social competences – Student is ready to:			
K1	objectively reflect on and critically evaluate his/her own progress and skill development, study on his/her own and constantly expand his/her knowledge and skills	DDD_KDR_K03	written examination, oral examination, oral answer, test

Calculation of ECTS points

Semester 1

Activity form	Activity hours*
seminar	20
preparation for classes	5

Student workload	**Hours** 25
Workload involving teacher	**Hours** 20

* hour means 45 minutes

Semester 2

Activity form	**Activity hours***
seminar	25
preparation for classes	10
Student workload	**Hours** 35
Workload involving teacher	**Hours** 25

* hour means 45 minutes

Semester 3

Activity form	**Activity hours***
seminar	30
preparation for examination	15
e-learning	15
Student workload	**Hours** 60
Workload involving teacher	**Hours** 45

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**

1.	Professional English: 1. The pharmaceutical company: job profiles, professions and departments. 2. New drug developments and launches. 3. Cultural differences in marketing drugs and medicine. 4. Substance discovery and product development: a new chemical entity, drug dosage forms, categories of drugs. 5. Good pharmaceutical industry practice. 6. Quality assurance audits. 7. Laboratory safety systems. 8. Standard operating procedures. 9. Preclinical and clinical testing, dealing with authorities, experimental drugs on trial. 10. Drug safety and regulatory affairs: pharmacovigilance, regulatory documentation, patient information, counterfeit medicines. 11. Production and packaging of drugs: safety requirements, production processes, packaging challenges.	W1, U1, U2, U3, U4, K1	seminar, e-learning
2.	Academic English: 1. Planning a career in science. 2. Applying for research funding. 3. Applications and application forms. 4. Communicating with scientific communities. 5. Taking part in a meeting. 6. Giving a paper and presenting a poster at a conference. 7. Reading and presenting facts, evidence, data, numbers, statistics, graphs and diagrams. 8. Writing an abstract and a paper to a scientific journal	W1, U1, U2, U3, U4, K1	seminar, e-learning
3.	General English: 1. Introducing oneself, one’s job, projects, interests and hobbies. 2. Taking part in a discussion - discussion phrases. 3. Socializing at a conference. 4. Writing a formal email. 5. Writing a memo.	W1, U1, U4, K1	seminar, e-learning
4.	Grammar: 1. Revision of past, present and future tenses. 2. Conditional sentences (type 0, 1, 2, 3 and mixed) 3. Subjunctive (wish, if only, would rather, as if/though, suppose, it’s high time) 4. Passive Voice 5. Modal Verbs, Modal Verbs + Perfect Infinitives 6. Direct and Indirect Questions 7. Reported Speech 8. Articles	W1, U1, U2, U3, U4, K1	seminar, e-learning

Course advanced

Semester 1

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
seminar	oral answer, test	1. attendance at classes (one absence is allowed per semester) 2. active participation in classes 3. obtaining pass marks for written tests and oral presentations

Semester 2

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
seminar	oral answer, test	1. attendance at classes (one absence is allowed per semester) 2. active participation in classes 3. obtaining pass marks for written tests and oral presentations

Semester 3

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
seminar	written examination, oral examination, oral answer, test	In order to take the examination, it is necessary to obtain a credit in all semesters. If the first date of the final examination is lost due to a failed pass, the date is not reinstated. A prerequisite for passing the course is attendance at all classes (one absence per semester allowed) and obtaining positive marks from mid-term tests and oral answers by the end of the retake examination period in a given semester.
e-learning		

Entry requirements

Knowledge of English at the level of proficiency B2 of the Common European Framework of Reference for Languages

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Diseases States and Pharmacotherapeutic Strategies

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	Examination	Number of ECTS points
Semester 1	- **Activities and hours** lecture: 15, seminar: 60	0.0

Period	Examination	Number of ECTS points
Semester 2	written examination **Activities and hours** lecture: 15, seminar: 60	8.0

Goals

C1	Expanding and systematizing knowledge, in the field of human anatomy and physiology and general pharmacology, necessary to understand the mechanisms of disease formation and their pharmacotherapy.
C2	Understanding the basics of pathophysiology and pharmacotherapy of the most important diseases
C3	Developing the ability to independently expand knowledge basing on reliable sources

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	basics of the structure and functioning of the body, as a basis for understanding the effects of drugs	DDD_KDR_W02	written examination, oral answer, test
W2	pathophysiological changes occurring in the human body, necessary to understand the mechanisms of action of drugs	DDD_KDR_W02	written examination, oral answer, test
W3	routes of drugs administration and their fate in the body	DDD_KDR_W01, DDD_KDR_W02	written examination, oral answer, test
W4	mechanisms of action of drugs and therapeutic strategies	DDD_KDR_W02	written examination, oral answer, test
W5	therapeutic effects and the most important side effects of drugs, as well as the basis for obtaining the selectivity of therapy	DDD_KDR_W02	written examination, oral answer, test
W6	basic indications for the most important drug groups and the most important drug interactions	DDD_KDR_W02	written examination, oral answer, test
Skills – Student can:			
U1	decide which drug groups are suitable for the treatment of specific diseases	DDD_KDR_U01	written examination, oral answer, test
U2	assess what side effects may occur after selected drugs	DDD_KDR_U01	written examination, oral answer, test
U3	estimate the risk of interactions between drug groups	DDD_KDR_U01	written examination, oral answer, test
U4	independently acquire knowledge based on reliable sources and critically evaluate it	DDD_KDR_U01, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U11	written examination, oral answer, test
Social competences – Student is ready to:			
K1	consult with experts in the field of experimental pharmacology in case of facing difficulties in solving certain tasks independently	DDD_KDR_K01	written examination, oral answer, test
K2	show respect for the prestige associated with her/his profession and properly understood professional solidarity	DDD_KDR_K02, DDD_KDR_K07	written examination, oral answer, test
K3	care about safety of her/his own, her/his colleagues and the environment	DDD_KDR_K07	written examination, oral answer, test

Calculation of ECTS points

Semester 1

Activity form	Activity hours*
lecture	15
seminar	60

preparation for classes	35
Student workload	**Hours** 110
Workload involving teacher	**Hours** 75

* hour means 45 minutes

Semester 2

Activity form	**Activity hours***
lecture	15
seminar	60
preparation for classes	35
preparation for examination	20
Student workload	**Hours** 130
Workload involving teacher	**Hours** 75

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	Basics of the structure and functioning of the human body and pathophysiological processes in the context of drug action mechanisms	W1, W2, U4, K1	lecture, seminar
2.	Basic concepts and definitions in the field of pharmacology - ED50, LD50, therapeutic index, agonism, antagonism	W4, U4, K1	lecture, seminar
3.	Routes of drug administration and the fate of drugs in the body	W3, U4, K1	lecture, seminar
4.	Biological targets (enzymes, receptors, ion channels, membrane transporters)	W4, U4, K1	lecture, seminar
5.	Cellular and molecular mechanisms of drug action (interaction with receptors, ion channels, enzymes, transporters	W4, U4, K1	lecture, seminar
6.	Pharmacological properties of drugs acting in the central and peripheral nervous system, cardiovascular system, respiratory system, digestive system, endocrine system, immune system, as well as antimicrobial and anticancer drugs	W4, W5, W6, U1, U4, K1, K2, K3	lecture, seminar
7.	Basic indications for selected groups of drugs	W5, U1, U4, K1, K2, K3	lecture, seminar

8.	The most important group/drug specific side effects	W5, U2, U4, K1, K2, K3	lecture, seminar
9.	The most important drug interactions	W6, U3, U4, K1, K2, K3	lecture, seminar

Course advanced

Semester 1

Teaching methods:

computer classes, e-learning, educational film, educational game, project method, case study method, situation method, presentation, seminar, lecture, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
lecture		efsegsgsgsr
seminar		sgsrgsrgsrgsrgr

Semester 2

Teaching methods:

computer classes, e-learning, educational film, educational game, project method, case study method, situation method, presentation, seminar, lecture, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
lecture	written examination	The grade of the course according to the result of the final test
seminar	written examination, oral answer, test	Partial tests passed (> 60%). The grade of the course according to the result of the final test

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Health and Safety

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines	**Examination** credit
ISCED classification No ISCED cat. found	

Period Semester 1	**Examination** credit **Activities and hours** Health and Safety training: 6	**Number of ECTS points** 0.0

Goals

C1	1. Acquainting students and doctoral students starting education in doctoral schools with the provisions and principles of safety and hygiene of education on the basis of selected legal provisions
C2	2. Getting to know the threats to life and health that occur during classes, how to protect against these threats and how to deal with these threats
C3	3. Informing students and doctoral students starting education in doctoral schools about the principles of fire protection and in particular about how to prevent fires, fire detection systems, fire-fighting equipment and conducting evacuation in the event of fire and other local threats
C4	4. Introduction to the general principles of first aid

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			

W1	Principles of safety and hygiene of education based on selected legal provisions	DDD_KDR_W11	credit
W2	Threats to life and health occurring during classes, ways of protection against these threats and management during these threats	DDD_KDR_W12	credit
W3	Principles of fire protection, in particular methods of fire prevention, fire detection systems, fire-fighting equipment and rules for conducting evacuation in the event of fire and other local threats	DDD_KDR_W12	credit
W4	General rules for first aid	DDD_KDR_W11	credit
Skills – Student can:			
U1	List the principles of safety and hygiene of education using selected legal acts	DDD_KDR_U01	credit
U2	List and analyze threats to life and health that occur during classes, list and choose ways to protect against these threats and is able to behave properly when these threats occur	DDD_KDR_U09	credit
U3	Apply fire protection rules, list the causes of fires and ways of fire prevention, use fire-fighting equipment properly, act properly during evacuation	DDD_KDR_U05	credit
U4	Apply the acquired knowledge of first aid in practice (accident or other threat to life)	DDD_KDR_U06	credit
Social competences – Student is ready to:			
K1	Taking appropriate action during an emergency	DDD_KDR_K01, DDD_KDR_K07	credit

Calculation of ECTS points

Activity form	**Activity hours***
Health and Safety training	6
analysis of the research material	2
Student workload	**Hours** 8
Workload involving teacher	**Hours** 6

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**

1.	Module I - Selected legal regulations - legal grounds for safety and hygiene of education - rights and obligations of a student and Rector in the field of safety and hygiene of education - basic safety principles applicable to students during classes organized by the University	W1, U1, K1	Health and Safety training
2.	Module I - Conditions of safety and hygiene of education in the University's premises - roads and passages - the University's premises - lighting - heating and ventilation - first aid kit - stand equipped with a screen monitor	W2, U2, K1	Health and Safety training
3.	Module I - Educational environment factors and their threats and prevention - dangerous factors - harmful factors - arduous factors	W2, U2, K1	Health and Safety training
4.	Module I - Accidents to which students may suffer during classes organized by the University - rules of conduct in the event of accidents and in the event of danger and failure	W2, U2, K1	Health and Safety training
5.	Rules of using student houses	W3, W4, U3, U4, K1	Health and Safety training
6.	Module i - Rules for first aid - medical rescue system in Poland - first aid in legal acts - survival chain - lifeguard safety - injured party assessment (ABC) and call for help - safe position - cardiopulmonary resuscitation (CPR) - automatic cardiopulmonary resuscitation AED external defibrillator - emergency procedures	W1, W4, U4, K1	Health and Safety training
7.	Module I - Fire protection - legal bases for fire protection - duties of the University, students and doctoral students in the field of fire protection - definition of fire - fire groups - causes of fires - ways of fire fighting - fire fighting equipment - rules of use and operation - rules of behavior during a fire - rules of behavior during evacuation	W1, W3, U1, U3, K1	Health and Safety training
8.	Module II - 1. Threats of biological agents in the learning environment. 2. Personal protective equipment against biological threats. 3. Problems of environmental protection	W2, U2, K1	Health and Safety training
9.	Module III - 1. Threats of chemical agents in the learning environment. 2. Personal protective equipment against chemical threats. 3. Problems of environmental protection	W2, U2, K1	Health and Safety training

Course advanced

Teaching methods:

e-learning, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
Health and Safety training	credit	watching and listening to the presentation is the basis for recognizing participation in compulsory training

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Principles of Medicinal Chemistry

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 2	written examination **Activities and hours** lecture: 30, seminar: 60	6.0

Goals

C1	Introduction to basic issues in the field of medicinal chemistry

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the basic concepts of medicinal chemistry	DDD_KDR_W03	written examination, oral answer, project
W2	molecular basis of the mechanisms of drug action	DDD_KDR_W02	written examination, oral answer, project

W3	basic physicochemical properties characterizing the molecules and their importance for pharmacological activity	DDD_KDR_W01	written examination, oral answer, project
W4	the principles of quantitative structure-activity relationship (QSAR) determination	DDD_KDR_W06, DDD_KDR_W07	written examination, oral answer, project
W5	principles and the stages of the drug discovery process	DDD_KDR_W03	written examination, oral answer, project
W6	molecular modeling methods and their application in drug design	DDD_KDR_W07	written examination, oral answer, project
Skills – Student can:			
U1	use standard software to calculate structural and physicochemical parameters	DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	test
U2	assess the drug-like properties of the compound based on structural and physicochemical parameters	DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	written examination, oral answer, project, test
U3	find and explain a relationship between activity and structural and physicochemical parameters	DDD_KDR_U01, DDD_KDR_U03	written examination, oral answer, project, test
U4	use standard software to visualize 3D molecules and to support molecular modeling calculations	DDD_KDR_U02, DDD_KDR_U04, DDD_KDR_U06	test
U5	professionally and comprehensively present knowledge and research results	DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U11	project
Social competences – Student is ready to:			
K1	work in a group in order to implement the project	DDD_KDR_K04	project

Calculation of ECTS points

Activity form	**Activity hours***
lecture	30
seminar	60
preparation for classes	30
preparation for examination	25
case analysis	5
Student workload	**Hours** 150
Workload involving teacher	**Hours** 90
Practical workload	**Hours** 5

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Basic drug targets (enzymes, receptors, ion channels, transport proteins)	W1, W2, U5	lecture, seminar
2.	biochemical basis of drug action	W1, W2, U5	lecture, seminar
3.	drug-target interactions (van der Waals, hydrogen bonds, electrostatic/ionic bonds)	W1, W2, U3, U5, K1	lecture, seminar
4.	pharmacological activity of drugs (agonists, antagonists, enzyme inhibitors)	W1, W2, U3, U5, K1	lecture, seminar
5.	concept of drug-likeness and methods of its expression; ligand efficiency	W1, W3, U1, U2, U5, K1	lecture, seminar
6.	physicochemical and structural properties important for ADMET	W1, W3, U1, U2, U5, K1	lecture, seminar
7.	rules for defining relationships between structure and structural, physicochemical and pharmacokinetic properties	W1, W3, U2, U5, K1	lecture, seminar
8.	drug design	W1, W3, W5, U1, U2, U3, U4, U5, K1	lecture, seminar
9.	structure-activity relationship (SAR)	W1, W4, W5, U3, K1	lecture, seminar
10.	bioisosteres in drug discovery	W1	lecture, seminar
11.	pharmacophore and privileged structures	W1	lecture, seminar
12.	drug discovery process	W1, W5	lecture, seminar
13.	prodrugs	W1	lecture, seminar
14.	lead structure and methods of its optimization	W1, W6, U4	lecture, seminar
15.	principles of combinatorial and parallel synthesis	W1	lecture, seminar
16.	quantitative structure-activity relationship (QSAR)	W1, W4, U1	lecture, seminar
17.	basic computational methods as a tool for the discovery of bioactive compounds	W6, U4	lecture, seminar
18.	conformational analysis and energy minimization	W1, W6, U4	lecture, seminar
19.	principles of structure- and ligand-based drug design	W1, W6, U4	lecture, seminar
20.	de novo design	W1, W6, U4	lecture, seminar
21.	virtual screening	W1, W6, U4	lecture, seminar

Course advanced

Teaching methods:

case study, textual analysis, brainstorm, computer classes, discussion, project method, case study method, presentation, group work, seminar, lecture

Activities	Examination methods	Credit conditions
lecture	written examination, project	full classes attendance accepted presentation scoring at least 60% at the final exam

Activities	Examination methods	Credit conditions
seminar	written examination, oral answer, project, test	full classes attendance completion of seminars based on the results of partial tests (at least 60% from each) accepted presentation scoring at least 60% at the final exam

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Molecular Screening Systems

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period	**Examination**	**Number of ECTS points**
Semester 2	graded credit **Activities and hours** lecture: 5, seminar: 25	2.0

Goals

C1	The aim of the module's education is to acquire knowledge, skills and social competences in the field of molecular screening systems in the scope that is necessary to acquire the basics of drug design and development.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	The current development direction for molecular screening systems, in the level necessary to assimilate basics of drug design and development Pharmacology in the context of the biological target - expected activity	DDD_KDR_W01, DDD_KDR_W03	written examination

W2	Basic terms of screening in vitro and fundamentals of assay systems and methods of detection in the level necessary to assimilate basics of drug design and development	DDD_KDR_W01	written examination
W3	Pharmacology in the context of the biological target - expected activity	DDD_KDR_W04	written examination
Skills – Student can:			
U1	Is able to calculate the values of the most important descriptors of phamacological activity in vitro based on terms and equations of molecular screening systems in the level necessary to assimilate basics of drug design and development	DDD_KDR_U03	written examination
U2	Is able to assess and compare pharmacological activity of screened compounds on the basis of values of descriptors coming from principal pharmacological assays in vitro	DDD_KDR_U02	written examination
Social competences – Student is ready to:			
K1	Consult with experts in the field of molecular screening systems in case of difficulty in solving problem independently	DDD_KDR_K01	written examination
K2	Show respect for the prestige associated with the profession and properly understood professional solidarity	DDD_KDR_K03	written examination
K3	Care about safety of her/his own, her/his colleagues and the environment	DDD_KDR_K03, DDD_KDR_K07	written examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	5
seminar	25
preparation for classes	20
Student workload	**Hours** 50
Workload involving teacher	**Hours** 30

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**

1.	1. Basic terms of screening in vitro - concentration response curves and IC50 - dissociation constants (Kd) and inhibition constants (Ki) - efficacy versus binding: EC50 - agonists and partial agonists - antagonists - basal activity and inverse agonists - allosteric modulation - receptor reserve 2. Basic differences between biochemical and cellular assays 3. Fundamentals of assay systems and methods of detection 4. Fundamentals of radioligand assay systems 5. Basics of enzyme-linked immunosorbent assay (elisa) 6. Fundamentals of fluorescence-based assay systems - fluorescence polarization (FP) - fluorescence resonance energy transfer (FRET) - time-resolved fluorescence resonance energy transfer (TRFRET) - amplified luminescent proximity homogeneous assay (AlphaScreen™) - fluorescent detection of calcium flux 7. Theoretical basics of : -reporter gene assays - kinetic fluorescent measurement systems - label-free assay systems	W1, W2, W3, U2, K2	lecture, seminar
2.	1. Basic terms of screening in vitro - concentration response curves and IC50 - dissociation constants (Kd) and inhibition constants (Ki) - efficacy versus binding: EC50 - agonists and partial agonists - antagonists - basal activity and inverse agonists - allosteric modulation - receptor reserve 2. Basic differences between biochemical and cellular assays 3. Fundamentals of assay systems and methods of detection 4. Fundamentals of radioligand assay systems 5. Basics of enzyme-linked immunosorbent assay (elisa) 6. Fundamentals of fluorescence-based assay systems - fluorescence polarization (FP) - fluorescence resonance energy transfer (FRET) - time-resolved fluorescence resonance energy transfer (TRFRET) - amplified luminescent proximity homogeneous assay (AlphaScreen™) - fluorescent detection of calcium flux 7. Theoretical basics of : -reporter gene assays - kinetic fluorescent measurement systems - label-free assay systems	U1, K1, K3	lecture, seminar

Course advanced

Teaching methods:

computer classes, laboratories (labs), demonstration, discussion, seminar, workshop, lecture, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
lecture	written examination	Attendance mandatory Partial tests (> 60%)
seminar	written examination	Attendance mandatory Partial tests (> 60%)

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Molecular ADME and In Vivo Pharmacokinetics

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	

Period Semester 2	**Examination** written examination **Activities and hours** seminar: 20, workshop: 10, classes: 30	**Number of ECTS points** 3.0

Goals

C1	Structure - physicochemical - biological properties relationships.
C2	ADME parameters necessary for the drug development.
C3	Non-compartmental and compartmental pharmacokinetic analysis.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	The basic physicochemical properties of the chemical compounds and the structure – physicochemical properties relationship.	DDD_KDR_W01, DDD_KDR_W04	written credit

W2	The relationship between compound structure and its properties including pharmacokinetic properties: solubility, stability, permeability through biological membranes, distribution, metabolism, excretion, and toxicity.	DDD_KDR_W01, DDD_KDR_W04	written credit
W3	In vitro methods used for drug permeability and metabolism assessment.	DDD_KDR_W01, DDD_KDR_W04	written credit
W4	The biological basis for drug transporters.	DDD_KDR_W01, DDD_KDR_W04	written credit
W5	The biological basis of enzymatic induction and inhibition.	DDD_KDR_W01, DDD_KDR_W04	written credit
W6	Drug pharmacokinetic parameters and the methods of their determination in the compartmental and non-compartmental analysis.	DDD_KDR_W01, DDD_KDR_W04	written credit
Skills – Student can:			
U1	To assess the approximate physicochemical properties of the compound on the basis of its structure and to use in practice the biopharmaceutics classification systems.	DDD_KDR_U03, DDD_KDR_U04	assignment report
U2	To identify the applicability of the particular in vitro experiments used in the absorption, distribution, metabolism, and excretion processes screening.	DDD_KDR_U03, DDD_KDR_U04	assignment report
U3	To interpret the results of drug permeability assays, to predict drug's metabolic clearance with the use of in vitro experiment results.	DDD_KDR_U03, DDD_KDR_U04	assignment report
U4	To calculate and interpret the pharmacokinetic parameters in the compartmental and non-compartmental analysis.	DDD_KDR_U03, DDD_KDR_U04	assignment report

Calculation of ECTS points

Activity form	**Activity hours***
seminar	20
workshop	10
classes	30
preparation for classes	15
preparation for examination	10
participation in examination	1
Student workload	**Hours** 86
Workload involving teacher	**Hours** 60

Practical workload	Hours 40

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Chemical compound’s structure, its physicochemical properties, and the processes it undergoes in the body.	W1, W2, U1	seminar
2.	In vitro ADME screening methods.	W3, W4, W5, U2, U3	classes, seminar
3.	In vivo pharmacokinetics.	W6, U4	seminar, workshop
4.	Clinical trials and safety pharmacology.	W4	seminar

Course advanced

Teaching methods:

case study method, seminar, workshop, lecture

Activities	Examination methods	Credit conditions
seminar	written credit	To pass the final exams it is required to score at least 50% points.
workshop	assignment report	Report assignment.
classes	written credit	To pass the final exams it is required to score at least 50% points.

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Introduction to Animal Models of Disease States

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 2	graded credit **Activities and hours** lecture: 5, seminar: 10, classes: 15	2.0

Goals

C1	Acquire basic knowledge, skills and social competences in the field of experiments of animals.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the basic ethical and legal aspects of performing experiments on animals	DDD_KDR_W09	written examination
W2	the main sources from which animals can be obtained for experiments	DDD_KDR_W09, DDD_KDR_W10	written examination

W3	various routes of drug administration	DDD_KDR_W10	written examination
W4	the rules for the selection of the appropriate route of administration, dose, group size and species of animals for pharmacological research	DDD_KDR_W10	written examination
W5	selected animal models of diseases used in search for new drugs	DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W12, DDD_KDR_W14	written examination, assignment report
Skills – Student can:			
U1	choose the appropriate route of administration, dose, size of the group as well as the species of animals for pharmacological experiments	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U10	written examination
U2	determine the sources from which animals can be obtained for experiments	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U07, DDD_KDR_U10	written examination
U3	characterize selected animal models of diseases used in research on new drugs with central, circulatory, antimicrobial and antineoplastic activity	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04, DDD_KDR_U06, DDD_KDR_U08, DDD_KDR_U10, DDD_KDR_U11	written examination, assignment report
Social competences – Student is ready to:			
K1	consult with experts in the field of experimental pharmacology in case of facing difficulties in solving certain tasks independently	DDD_KDR_K01, DDD_KDR_K03	written examination, assignment report
K2	show respect for the prestige associated with her/his profession and properly understood professional solidarity	DDD_KDR_K02	written examination
K3	care about safety of her/his own, her/his colleagues and the environment	DDD_KDR_K07	written examination
K4	independently acquire knowledge based on reliable sources and critically evaluate it	DDD_KDR_K01, DDD_KDR_K03	written examination, assignment report

Calculation of ECTS points

Activity form	**Activity hours***
lecture	5
seminar	10
classes	15
preparation for examination	30
Student workload	**Hours** 60

Workload involving teacher	**Hours** 30
Practical workload	**Hours** 15

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Ethical and legal aspects regarding experiments on animals (current regulations on the protection of experimental animals, guidelines on how to write an application for Ethics Committee)	W1, K4	lecture, seminar
2.	Rules for the selection of the appropriate species for testing and the size of the group	W4, U1, K1, K2, K3, K4	lecture, seminar
3.	Various routes of administering compounds	W3, U1, K1, K4	lecture, seminar
4.	Sources from which animals can be obtained for testing	W2, U2, K4	lecture, seminar
5.	Selected animal models of disease states (models of diseases of the central nervous system, cardiovascular system, infectious diseases, models in oncological research)	W5, U3, K1, K2, K3, K4	lecture, seminar
6.	Analysis of exemplary pharmacological experiments (forced swim test, elevated plus maze test, novel object recognition test, ECG analysis)	W5, U3, K1, K2, K3, K4	classes

Course advanced

Teaching methods:

computer classes, seminar, lecture, lecture with multimedia presentation, practical classes

Activities	Examination methods	Credit conditions
lecture	written examination	The grade of the course according to the result of the final written examination.
seminar	written examination	Partial tests passed (> 60%). The grade of the course according to the result of the final written examination.
classes	assignment report	Computer classes and report passed. The grade of the course according to the result of the final written examination.

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Introduction to Drugs Safety and Toxicology

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing a year
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period Semester 2	**Examination** graded credit **Activities and hours** seminar: 10, classes: 4, workshop: 16	**Number of ECTS points** 2.0

Goals

C1	To deliver knowledge and understanding in the field of drugs safety and toxicity testing. This includes data analysis and in vitro/in vivo study planning.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	The in vitro animal studies used for the drugs' safety and toxicity assessment.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	written credit

W2	The correlations between physicochemical properties of the chemical compounds and their potential toxicity.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	written credit
W3	The in vivo animal studies used for the drugs' safety and toxicity assessment.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	written credit
W4	Most important clinical studies utilized for the drugs' safety assessment.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	written credit
W5	Basic in silico models utilized for the drugs' safety and toxicity screening.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	written credit
W6	Guidelines for the drugs' safety and toxicity assessment (ICH, FDA, EMA).	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W07	assignment report
Skills – Student can:			
U1	To identify the applicability of the particular in vitro experiments used for the drugs' safety and toxicity testing.	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	written credit
U2	To identify the applicability of the particular in vivo animal models and experiments used for the drugs' safety and toxicity testing.	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	written credit
U3	To interpret results of the chosen in vitro and in vivo animal experiments towards drugs safety and toxicity assessment.	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	written credit
U4	To calculate and interpret the toxicokinetic parameters in the compartmental analysis.	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	written credit

Calculation of ECTS points

Activity form	**Activity hours***
seminar	10
classes	4
workshop	16
preparation for examination	5
preparation for classes	20

Student workload	**Hours** 55
Workload involving teacher	**Hours** 30
Practical workload	**Hours** 20

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Correlation between the chemicals structure and their toxicity.	W1, W6	classes, seminar
2.	In vitro methods for the drugs toxicity and safety assessment.	W2, U1, U3	classes, seminar
3.	In vivo animal models utilized for the drugs toxicity and safety assessment.	W3, U2, U3	seminar, workshop
4.	Clinical trials and safety pharmacology.	W4	seminar
5.	In silico methods for the drugs toxicity and safety assessment.	W5, U4	classes, seminar

Course advanced

Teaching methods:

case study method, seminar, lecture

Activities	Examination methods	Credit conditions
seminar	written credit	To pass the final exams it is required to score at least 50% points.
classes	written credit	To pass the final exams it is required to score at least 50% points.
workshop	assignment report	

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Principles of Pharmaceutical Technology

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 2	written examination **Activities and hours** lecture: 20, seminar: 20, classes: 20	3.0

Goals

C1	To familiarize the student with selected types of dosage forms, methods of their production and quality control.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	Naming, composition, structure and properties of various dosage forms	DDD_KDR_W05	written examination

W2	Methods for preparing liquid, semi-solid and solid dosage forms on a laboratory and industrial scale; knows and understands the principles of operation of devices for their production,	DDD_KDR_W05, DDD_KDR_W12	written examination
W3	Methods of testing the quality assessment of the selected drug forms	DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W12	written examination
W4	Selected properties of excipients and their choice depending on the type of the drug	DDD_KDR_W05	written examination
W5	Influence of technological process parameters on the properties of selected drug forms	DDD_KDR_W05	written examination
W6	Requirements for various forms of medicinal products, including pharmacopoeial requirements.	DDD_KDR_W05, DDD_KDR_W09	written examination
Skills – Student can:			
U1	Assess the properties of a medicinal product and present the method of its production in general	DDD_KDR_U01, DDD_KDR_U03	written examination
U2	Plan general production cycle of selected drug forms, taking into account the manufacturing conditions and type of apparatus	DDD_KDR_U02	written examination
U3	Design pharmaceutical availability tests for different drug forms and interpret the results of these tests	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03	written examination
Social competences – Student is ready to:			
K1	Recognize the importance of reliable knowledge and critical assessment of received content in solving cognitive and practical problems	DDD_KDR_K01	written examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	20
seminar	20
classes	20
analysis of the research material	10
preparation for classes	10
preparation for examination	10
Student workload	**Hours** 90
Workload involving teacher	**Hours** 60
Practical workload	**Hours** 30

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	1. Solid dosage forms, 2. Semi-solid dosage forms, 3. Liquid forms dosage forms 4. Methods for the production and quality control of selected dosage forms, 5. Requirements for various dosage forms, including pharmacopoeial requirements and quality assessment of medicinal products.	W1, W2, W3, W4, W5, W6, K1	lecture
2.	1. Analysis of pharmacopoeial monographs for selected medicinal products (PhEur., USP), 2. Selection of excipients for various dosage forms.	W4, U2, K1	seminar
3.	1. Preparation of solid dosage forms, 2. Assessment of solid dosage forms, including dissolution testing studies, 3. Preparation of liquid and parenteral dosage forms, 4. Quality control of selected dosage forms	U1, U2, U3	classes

Course advanced

Teaching methods:

laboratories (labs), seminar, lecture

Activities	Examination methods	Credit conditions
lecture	written examination	Score at least 50% of the exam points
seminar	written examination	Score at least 50% of the exam points
classes	written examination	Score at least 50% of the exam points

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Principles of Clinical Trials

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	Examination	Number of ECTS points
Semester 2	graded credit **Activities and hours** lecture: 15, seminar: 15	2.0

Goals

C1	To familiarize students with the chosen types of clinical trials and their application in various phases of the process of discovering and developing new drugs and development of generic drugs

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	Goals and applications of clinical trials in the process of drug discovery and development	DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W09	written examination

W2	Various types of clinical trials and methods of their design and analysis of their results	DDD_KDR_W04, DDD_KDR_W07	written examination
W3	Where to find detailed information on the applicable regulations regarding clinical trials	DDD_KDR_W14	written examination
Skills – Student can:			
U1	Interpret parameters analyzed in selected types of clinical trials	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	written examination
Social competences – Student is ready to:			
K1	Recognize the importance of reliable knowledge and critical assessment of content received in solving cognitive and practical problems	DDD_KDR_K01	written examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	15
seminar	15
preparation for classes	15
preparation for examination	15
Student workload	**Hours** 60
Workload involving teacher	**Hours** 30

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	1. Place of clinical trials in the process of drug discovery and development 2. Phases and types of clinical trials 3. Sources of knowledge about the principles of design and reporting of clinical trials (industrial guidelines, EMA, FDA, ICH) 4. Clinical trials design (place, composition and size of the sample, analyzed variables, randomization and blinding) 5. Analysis and inferences in clinical trials 6. Ethical issues in clinical trials	W1, W2, W3, K1	lecture
2.	1. Statistical basis of clinical trials 2. Clinical trials protocols (crossed, parallel) 3. Case study: mostly used protocol of clinical trials for demonstration of bioequivalence (2x2x2)	U1, K1	seminar

Course advanced

Teaching methods:

computer classes, seminar, lecture

Activities	Examination methods	Credit conditions
lecture	written examination	Minimum score 50%
seminar	written examination	Minimum score 50%

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Pharmaceutical Project Management

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period	**Examination**	**Number of ECTS points**
Semester 2	graded credit **Activities and hours** seminar: 15	1.0

Goals

C1	The aim of education within this subject is to provide the basics of knowledge and skills in the field of project management, especially in relation to pharmaceutical projects. Acquiring these competences aims to enable effective planning and implementation of project tasks, as a part of working in a research group as well as building the basis for further development in the field of pharmaceutical project management.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the life cycle of the project, knows how to plan and implement it	DDD_KDR_W08, DDD_KDR_W09	written credit
W2	what are the tools used to plan and manage a project	DDD_KDR_W07, DDD_KDR_W11	written credit

W3	what are the basic documents of the project throughout the entire life cycle	DDD_KDR_W09	written credit
W4	what are the roles of individual project stakeholders and the role of Project Manager	DDD_KDR_W08	written credit
W5	basic methodologies and their dfferences	DDD_KDR_W08, DDD_KDR_W14	written credit
W6	the importance and principles of communication in the project	DDD_KDR_W08	written credit
W7	the specifics of pharmaceutical projects	DDD_KDR_W08	written credit
Skills – Student can:			
U1	to schedule the project, define the milestones and monitor its implementation	DDD_KDR_U02	written credit
U2	to analyse the influence of the project stakeholders	DDD_KDR_U06	written credit
U3	to estimate the risk of the project and react to its occurrence	DDD_KDR_U01, DDD_KDR_U06	written credit
Social competences – Student is ready to:			
K1	cooperation in a group in order to solve complex problems and carry out tasks	DDD_KDR_K05, DDD_KDR_K07	written credit

Calculation of ECTS points

Activity form	**Activity hours***
seminar	15
preparation for classes	7
preparation for examination	8
Student workload	**Hours** 30
Workload involving teacher	**Hours** 15

* hour means 45 minutes

Study content

No.	**Course content**	**Subject's learning outcomes**	**Activities**
1.	Introduction to Project Management a. What is a project and what its life cycle looks like b. Triple limitation c. Key stakeholders of the project, stakeholders mapping d. Factors affecting the project e. The role of the Project Manager and his duties f. Project team g. Selection of the project and its cost-effectiveness	W1, W3, W4, U1, U2	seminar

2.	Project Planning a. Work breakdown structure b. Defining the scope of the Project c. Project schedule e. Resource planning and balancing g. Estimating the risk in the Project	W2, U1, U3	seminar
3.	The specifics of pharmaceutical projects a. Types of pharmaceutical projects b. Good practices and the most common management errors c. Examples of pharmaceutical projects	W6, W7, K1	seminar
4.	Implementation of the Project a. Monitoring and evaluation of the Project implementation b. Current project management tools c. Reporting the implementation of the Project d. Communication in the project e. Negotiations in the Project f. Change management	W2, W4, U1, K1	seminar
5.	Project Management Methodologies a. Classical methodologies b. Agile methodologies	W5, W7, K1	seminar

Course advanced

Teaching methods:

educational game, case study method, seminar, lecture with multimedia presentation

Activities	Examination methods	Credit conditions
seminar	written credit	At least 50% of the points from the final test

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Biological drugs

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** elective
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period Semester 2	**Examination** graded credit **Activities and hours** lecture: 15, seminar: 10, classes: 25	**Number of ECTS points** 4.0

Goals

C1	The learning objective within the module is to broaden knowledge, skills and social competences in the field of pharma biotechnology in the aspects related to biological drugs

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			

W1	basic knowledge in pharmaceutical biotechnology	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W08, DDD_KDR_W09, DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W12, DDD_KDR_W13, DDD_KDR_W14	written examination
W2	classification and application of biopharmaceuticals and its mode of action and therapeutic use.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03	written examination
W3	the general principles of biosimilar and innovative biological drugs drugs discovery and development	DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W08, DDD_KDR_W09	written examination
W4	molecular biology and recombinant DNA techniques related to the production of biological medicine.	DDD_KDR_W03, DDD_KDR_W06, DDD_KDR_W12	written examination
W5	bioprocess design in the bioreactors, types of bioreactor, basic concepts of bioreactor design and selection	DDD_KDR_W03, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W11, DDD_KDR_W12	written examination
W6	the system validation and optimisation, economics of bioprocesses, scale-up of up-stream and down-stream process.	DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W11, DDD_KDR_W12	written examination
W7	the industrial requirements for bioprocessing and biomanufacturing such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Clinical Practise (GCP) and International Organization of Standarization (ISO).	DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W11, DDD_KDR_W12	written examination
Skills – Student can:			
U1	differentiate and select appropriate microbial strains or eukaryotic cell lines depending on the produced biological drugs	DDD_KDR_U02, DDD_KDR_U06, DDD_KDR_U07	written examination
U2	perform basic laboratory activities in the field of breeding, banking and storing microbiological and eukaryotic organisms	DDD_KDR_U02, DDD_KDR_U06, DDD_KDR_U07	written examination
U3	to present and discuss the issues concerning the development of the biological or biosimilar drugs.	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U08, DDD_KDR_U09	written examination

U4	to use bioinformatic methods in the design of the biological processes, during which recombinant proteins are being obtained	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination
U5	to identify the latest trends in research on innovative biological drugs and the prospects for the introduction of biosimilars into the pharmaceutical market.	DDD_KDR_U01, DDD_KDR_U05, DDD_KDR_U06	written examination
U6	to perform basic steps in obtaining recombinant protein and its initial analysis.	DDD_KDR_U02	written examination
U7	to handle and operate basic laboratory biofermentor and can keep adequate bioprocessing documentation.	DDD_KDR_U02	written examination
U8	to communicate with specialists in the field of: bioinformatics, molecular biology, bioprocess engineering on the special topics related to the preparation of recombinant protein	DDD_KDR_U05, DDD_KDR_U08, DDD_KDR_U09	written examination
U9	to design, plan and organize a collaborative research project, focused on obtaining a recombinant biological drug.	DDD_KDR_U02	written examination
Social competences – Student is ready to:			
K1	to consult experts from different areas of biology, biotechnology, pharmacy and ethics if he has difficulty solving the problem	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03, DDD_KDR_K04, DDD_KDR_K05, DDD_KDR_K06	written examination
K2	takes care for the safety of biological medicine production in accordance with all safety standards, GLP, GMP, etc	DDD_KDR_K07	written examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	15
seminar	10
classes	25
analysis of the research material	5
preparation for classes	10
preparation for test	15
consultations with lecturer	2
preparation of multimedia presentation	15
case analysis	3

Student workload	**Hours** 100
Workload involving teacher	**Hours** 50
Practical workload	**Hours** 33

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	1. Introduction to Pharmaceutical Biotechnology	W1, W4, U1, U2, U4, U6	lecture, classes, seminar
2.	Biopharmaceuticals	W2, W3, U3, U5	lecture, classes, seminar
3.	Technology of biopharmaceuticals development	W4, W6, W7, U4, U5, U6, U8, U9, K1	lecture, classes, seminar
4.	Bioprocessing technology	W5, W7, U7, K2	lecture, classes, seminar

Course advanced

Teaching methods:

case study, brainstorm, classes / practicals, computer classes, laboratories (labs), demonstration, discussion, problem solving method, project method, case study method, presentation, group work, seminar, lecture

Activities	Examination methods	Credit conditions
lecture	written examination	tests – scoring at least 60%
seminar	written examination	tests – scoring at least 60%
classes	written examination	tests – scoring at least 60%

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Pharmaceutical Biotechnology

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2019/20
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** elective
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	

Period Semester 2	**Examination** graded credit **Activities and hours** lecture: 15, seminar: 10, classes: 25	**Number of ECTS points** 4.0

Goals

C1	The learning objective within the module is to broaden knowledge, skills and social competences in the field of pharma biotechnology

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	Molecular biology and recombinant DNA techniques	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W12	written examination, test
W2	General principles of molecular biology techniques and the recombinant research models in vitro used in small-molecule drug discovery and development	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W12	written examination, oral examination, test

W3	General principles of the use of molecular biology and recombinant DNA techniques in biological drug development and production.	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W12	written examination, test
W4	Classification and application of biological drugs	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W12	written examination, oral examination, test
W5	Principles and perspectives of gene therapy	DDD_KDR_W03, DDD_KDR_W12	written examination, test
W6	Application of microbial/enzymatic biotransformations for the small-molecule drug discovery	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W12	written examination, test
W7	Microbial/enzymatic biotransformations used in the pharma industry	DDD_KDR_W05, DDD_KDR_W12	written examination, test
W8	Bioprocessing technology including bioreactor design and selection, system validation and optimisation, economics of bioprocesses, scale-up of up-stream and down-stream process	DDD_KDR_W05, DDD_KDR_W08, DDD_KDR_W12	written examination, test
W9	Industrial requirements for bioprocessing and biomanufacturing such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Clinical Practise (GCP) and International Organization of Standarization (ISO).	DDD_KDR_W05, DDD_KDR_W11	written examination, test
Skills – Student can:			
U1	Select molecular biology and recombinant DNA techniques depending on their use in particular areas of pharmaceutical biotechnology	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U2	Perform basic laboratory activities with microbiological and eukaryotic organisms including breeding, banking and storing	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U3	Perform basic laboratory activities with molecular biology and recombinant DNA techniques	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U4	Perform the microbial/enzymatic reaction of biotransformations including process monitoring and product purification and analysis	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U5	Use bioinformatic methods in the design of the biotechnological processes	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06, DDD_KDR_U11	written examination, test
U6	Handle and operate basic laboratory biofermentor and can keep adequate bioprocessing documentation.	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U7	Communicate with specialists in the field of: medicinal chemistry, molecular biology, bioinformatics, bioprocess engineering on the special topics related to the application of molecular biology techniques, recombinant in vitro research models and microbial/enzymatic biotransformations for the small-molecule drug discovery, development and production	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, oral examination, test
U8	Design, plan and organize a collaborative research project, focused on the use of pharmaceutical biotechnology methods in drug discovery and development	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U05, DDD_KDR_U11	written examination, test

U9	Use basic research methods (principles of work in sterile conditions, initiation of plant, algae and mycelial in vitro cultures, passaging)	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06	written examination, test
U10	Use various sources of information for independent and creative problem solving related to the subject of biotechnology research on plants, algae and higher mushrooms	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U06, DDD_KDR_U11	written examination, oral examination, test
U11	Identifiy and distinguishes research directions and methods used in biotechnology of plants, algae and higher mushrooms important from the pharmaceutical point of view	DDD_KDR_U01	written examination, oral examination, test
U12	List examples of practical solutions using plant biotechnology methods, algae and higher mushrooms used to obtain bioactive compounds	DDD_KDR_U01	written examination, oral examination, test
Social competences – Student is ready to:			
K1	Consult experts from different areas of medicinal chemistry, biology, biotechnology and pharmacy if he has difficulty solving the problem.	DDD_KDR_K01	oral examination
K2	Take care for the safety of biological medicine production and the use of molecular biology techniques, recombinant in vitro research models, microbial, plant, algae and mycelial in vitro cultures in accordance with all safety standards, GLP, GMP, etc.	DDD_KDR_K07	oral examination

Calculation of ECTS points

Activity form	**Activity hours***
lecture	15
seminar	10
classes	25
preparation for classes	15
preparation for test	10
preparation for examination	25
Student workload	**Hours** 100
Workload involving teacher	**Hours** 50
Practical workload	**Hours** 25

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Introduction to Pharmaceutical Biotechnology	W1, W2, W5, W6, U1, U10, U11, U2, U3, U4, U6, U7, U9, K1, K2	lecture, classes, seminar
2.	Biopharmaceuticals	W4, W7, W8, U10, U11, U12, U4, U5, K1, K2	lecture, classes, seminar
3.	Technology of biopharmaceuticals development	W2, W3, W4, W7, W8, W9, U10, U5, U6, U7, U8, K1, K2	lecture, classes, seminar
4.	Bioprocessing technology	W2, W3, W7, W8, W9, U12, U2, U5, U6, U7, U8, K1, K2	lecture, classes, seminar

Course advanced

Teaching methods:

classes / practicals, computer classes, laboratories (labs), demonstration, discussion, presentation, group work, seminar, lecture, lecture with multimedia presentation, practical classes

Activities	Examination methods	Credit conditions
lecture	written examination	Written exam
seminar	oral examination	presence obligatory, oral presentation, written exam
classes	test	presence obligatory, partial tests (>60%), final written exam

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Team-work Case Studies

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** graded credit
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	Examination	Number of ECTS points
Semester 3	- **Activities and hours** seminar: 30	0.0

Period	Examination	Number of ECTS points
Semester 4	graded credit **Activities and hours** seminar: 30	4.0

Goals

C1	Aims to develop understanding and appreciation of the team work role in all stages of drug discovery and development process, from target identification, active compound identification, and the submission of preclinical and clinical data to regulatory authorities for marketing approval, and post-marketing surveillance.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the current state-of-the-art and future directions in drug discovery	DDD_KDR_W03, DDD_KDR_W08, DDD_KDR_W09	oral answer, project
W2	knows examples of projects for the discovery and development of innovative and generic medicines and the accompanying challenges	DDD_KDR_W03, DDD_KDR_W08, DDD_KDR_W09	oral answer, project
Skills – Student can:			
U1	plan rationally the strategies to maximise the potency, efficacy, and safety of new drugs in preclinical settings	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U05, DDD_KDR_U07, DDD_KDR_U09	oral answer, project
U2	identify best clinical candidates	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U05, DDD_KDR_U07, DDD_KDR_U09, DDD_KDR_U10	oral answer, project
U3	plans in a global scale all stages of a new drug development	DDD_KDR_U03, DDD_KDR_U06, DDD_KDR_U09	oral answer, project
U4	present and discusses a research results both in a written and oral report	DDD_KDR_U03, DDD_KDR_U07, DDD_KDR_U09	oral answer, project
Social competences – Student is ready to:			
K1	identify and explore problems, compare and select options to overcome them	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03	oral answer, project
K2	assesses ethical, conflict of interest, and intellectual property issues involved in the DDD process	DDD_KDR_K02, DDD_KDR_K06	oral answer, project

Calculation of ECTS points

Semester 3

Activity form	Activity hours*
seminar	30
preparation for classes	30
Student workload	**Hours** 60
Workload involving teacher	**Hours** 30

* hour means 45 minutes

Semester 4

Activity form	Activity hours*
seminar	30
preparation for classes	30
Student workload	**Hours** 60
Workload involving teacher	**Hours** 30

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	An overview and the discussion of the discovery and development process for drugs currently on the market or soon to be introduced. Topics will include new drugs from various therapeutic groups.	W1, W2, U3, K1	seminar
2.	Analysis of key elements for successful DDD process.	W2, U1, U2, U4, K2	seminar
3.	Planning of individual stages of work on the drug - costs, time, potential problems and obstacles.	W2, U1, U2, K2	seminar

Course advanced

Semester 3

Teaching methods:

project method, case study method, group work, seminar, workshop

Activities	Examination methods	Credit conditions
seminar	oral answer, project	Warunki zaliczenia en

Semester 4

Teaching methods:

project method, case study method, group work, seminar, workshop

Activities	Examination methods	Credit conditions
seminar	oral answer, project	

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Medicinal Chemistry

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** elective
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 3	written examination **Activities and hours** e-learning: 135, seminar: 170, classes: 145	36.0

Goals

C1	Understanding the relationship between drug structure and its activity, pharmacokinetics and toxicity
C2	Understanding the principles of multi-parameter optimization of biologically active compounds, including therapeutic efficacy, pharmacokinetics and safety
C3	Understanding molecular modeling techniques and bioinformatics in order to propose and evaluate candidates for biologically active molecules
C4	Understanding modern methods in organic synthesis and analysis used in the preparation of new bioactive compounds
C5	Ability to discuss and effectively cooperate with specialists working in a field of drug development

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	Anatomical Therapeutic Chemical (ATC) Classification System of drugs	DDD_KDR_W02	written examination, project, test
W2	examples of pharmacophore structures in major drug groups	DDD_KDR_W03	written examination, project, test
W3	examples of drug-biological target interactions	DDD_KDR_W02	written examination, project, test
W4	basic structure-activity relationships in the main therapeutic groups and methods of their quantitative assessment (QSAR)	DDD_KDR_W01, DDD_KDR_W03	written examination, project, test
W5	representative examples of drug metabolism	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03	written examination, project, test
W6	goals necessary to achieve at each stage of drug discovery process	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05	written examination, project, test
W7	the importance of the chemical structure of a compound for its pharmacodynamic, pharmacokinetic and biopharmaceutical properties	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W03	written examination, project, test
W8	principles of design and optimization of pharmacodynamic and drug-like properties	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04	written examination, project, test
W9	methods of determination and prediction of ADME parameters and metabolism	DDD_KDR_W07	written examination, project, test
W10	basics of quantum and molecular mechanics and possibilities of their application in computer-aided drug design	DDD_KDR_W07	written examination, project, test
W11	principles and application of pharmacophore modeling and structure-based modeling (including homology models)	DDD_KDR_W03, DDD_KDR_W07	written examination, project, test
W12	methods for biologically active compounds discovery - de novo design based on atoms and fragments and virtual screening of chemical databases	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W07	written examination, project, test
W13	the most important and the most useful synthetic methods in medicinal chemistry	DDD_KDR_W06, DDD_KDR_W11, DDD_KDR_W12	written examination, project, test
W14	analytical techniques used for determination of compound’s structure	DDD_KDR_W06, DDD_KDR_W11, DDD_KDR_W12	written examination, project, test
Skills – Student can:			
U1	classify drugs according to Anatomical Therapeutic Chemical (ATC) Classification System	DDD_KDR_U07	written examination, group assessment, project, test
U2	draw chemical structures of the basic representatives of the main therapeutic groups	DDD_KDR_U04	written examination, group assessment, project, test

U3	describe basic structure-activity relationships in the main therapeutic groups	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U07	written examination, group assessment, project, test
U4	use databases with information about drugs' structure and properties	DDD_KDR_U04	booklet of practice, group assessment, project, test
U5	analyze and critically evaluate the results of physicochemical, pharmacodynamic, pharmacokinetic, toxicological tests and draw conclusions about the relationship between them and the chemical structure	DDD_KDR_U01, DDD_KDR_U03	booklet of practice, written examination, group assessment, project, test
U6	indicate fragments of compound's structure disadvantageous for its drug-like properties and propose appropriate structural modifications leading to their improvement	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U06	booklet of practice, written examination, group assessment, project, test
U7	propose appropriate methods (and indicate specialists) for the determination of basic physicochemical, pharmacological, pharmacokinetic and toxicological properties	DDD_KDR_U02, DDD_KDR_U05, DDD_KDR_U06	booklet of practice, written examination, group assessment, project, test
U8	propose work adequate for a particular stage of drug discovery process	DDD_KDR_U03, DDD_KDR_U06, DDD_KDR_U10	booklet of practice, written examination, group assessment, project, test
U9	dock the ligand to the biological target model and evaluate qualitatively and quantitatively ligand-target complex	DDD_KDR_U02, DDD_KDR_U04	booklet of practice, group assessment, project, test
U10	perform virtual screening of chemical database	DDD_KDR_U02, DDD_KDR_U04	booklet of practice, group assessment, project, test
U11	build pharmacophore and homology model	DDD_KDR_U02, DDD_KDR_U04	booklet of practice, group assessment, project, test
U12	interpret the results of the QSAR analysis	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	booklet of practice, written examination, group assessment, project, test
U13	properly document the laboratory activity/prepare laboratory documentation	DDD_KDR_U07, DDD_KDR_U08	booklet of practice, group assessment, project, test
U14	use the software and databases necessary in the work of organics chemist: programs for drawing of chemical entities, synthetic pathway design, prediction of physicochemical properties, spectral analysis	DDD_KDR_U02, DDD_KDR_U04	booklet of practice, written examination, group assessment, project, test
U15	plan and carry out chemical reactions and isolate the desired products using appropriate methods and equipment	DDD_KDR_U02	booklet of practice, written examination, group assessment, project, test
U16	use adequate methods to determine structure and purity of compounds	DDD_KDR_U02	booklet of practice, written examination, group assessment, project, test
U17	professionally and comprehensively present knowledge and research results	DDD_KDR_U07, DDD_KDR_U11	booklet of practice, written examination, group assessment, project, test

Social competences – Student is ready to:			
K1	cooperate in a group to solve complex problems in the field of drug discovery and development	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03	booklet of practice, group assessment, project, test
K2	recognize the importance of reliable knowledge and critical assessment of received content in solving cognitive and practical problems	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03	booklet of practice, project, test
K3	prioritize tasks to implement specific, self-determined goals or other projects and consult experts, if necessary	DDD_KDR_K04	booklet of practice, project, test

Calculation of ECTS points

Activity form	Activity hours*
e-learning	135
seminar	170
classes	145
preparation for classes	225
preparation for examination	50
conducting literature research	25
preparation of multimedia presentation	25
preparation of a report	25
preparation of a project	50
preparation for test	50
Student workload	**Hours** 900
Workload involving teacher	**Hours** 450
Practical workload	**Hours** 145

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Anatomical Therapeutic Chemical (ATC) Classification System of drugs	W1, U1, U2	classes, seminar, e-learning

2.	Characteristics of major therapeutic groups	W1, W2, W3, U1, U17	classes, seminar, e-learning
3.	Biological targets for drugs from major therapeutic groups	W3, W7, U17	classes, seminar, e-learning
4.	Drugs' mechanisms of action	W3, U17	classes, seminar, e-learning
5.	Structure-activity relationships in the major drug groups	W4, U17, U2, U3, K1	classes, seminar, e-learning
6.	Relationships between chemical structure and pharmacokinetic properties or toxicity	W6, W7, W8, W9, U4, U5, U6, U8, K1	classes, seminar, e-learning
7.	Basic metabolic pathways	W5, W7, W8, W9, U5, U6, U7, K1	classes, seminar, e-learning
8.	Databases and programs allowing to determine physicochemical, pharmacokinetic, toxicological and pharmacological properties	W5, W6, W7, W8, W9, U5, U6, U7, K1, K2, K3	classes, seminar, e-learning
9.	Methods used for determination, calculation and prediction of structural (log P, log D, pKa, PSA), physicochemical (solubility, permeability, chemical stability) and biochemical properties of compounds (metabolic stability, protein binding, transport)	W8, W9, U5, U7, U8, K1, K2, K3	classes, seminar, e-learning
10.	Methods of structural modifications to optimize the desired properties of the compound	W7, W8, U6, U7, U8, K1, K2, K3	classes, seminar, e-learning
11.	Selected reactions for formation of carbon-carbon bond (e.g., Heck, Suzuki, metathesis, aldol, Wittig reactions)	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
12.	Selected reactions for formation of carbon-heteroatom bond	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
13.	Methods for selective reduction and oxidation	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
14.	Peptide chemistry	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
15.	Protecting groups	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
16.	Stereochemistry in organic synthesis	W13, W14, U13, U14, U15, U16	classes, seminar, e-learning
17.	Click chemistry	W13, U14, U15	classes, seminar, e-learning
18.	Analytical methods for confirming and determining the purity of compounds (NMR, LCMS, IR)	W14, U13, U16, U8	classes, seminar, e-learning
19.	Structure and properties of proteins as biological targets (GPCRs, enzymes, ion channels and transporters) and types of interactions with ligands	W10, W11, W12, U10, U11	classes, seminar, e-learning
20.	Assumptions of classical and quantitative structure-activity relationships assessment - SAR, QSAR (classic descriptors, Hansch equation, Craig diagram, Topliss scheme), 3D-QSAR (molecular fields, CoMFA, CoMSIA	W10, U12, U3, U9	classes, seminar, e-learning
21.	Ligand-based (pharmacophore modeling) and structure-based (homology modeling) molecular design methods	W10, W11, W12, U10, U11, U8, K1, K3	classes, seminar, e-learning

22.	Methods of ligand-biological target binding energy assessment (FEP, MM-GBSA)	W10, U10, U11	classes, seminar, e-learning
23.	Principles of de novo design based on atoms and fragments – scoring the molecule's fitness and searching the chemical space	W10, W11, W12, U10, U11	classes, seminar, e-learning
24.	Virtual screening of chemical databases using pharmacophore and structural models	W10, W11, W12, U10, U11, U8	classes, seminar, e-learning
25.	Safety in a chemical laboratory	U13	classes, seminar
26.	Keeping track of laboratory work	U13	classes, seminar
27.	Conducting reactions in various conditions (anhydrous conditions, inert gas atmosphere, low/high temperature)	W13, W14, U13, U14, U15, U16	classes, seminar
28.	Isolation and purification of compounds (extraction, chromatography, crystallization)	W13, W14, U13, U14, U15, U16	classes, seminar
29.	Microwave-assisted reactions	W13, W14, U13, U14, U15, U16	classes, seminar
30.	Green chemistry	W13	seminar
31.	Flow chemistry	W13	seminar

Course advanced

Teaching methods:

case study, brainstorm, classes / practicals, laboratories (labs), demonstration, presentation, group work, computer room, seminar, participation in research, lecture

Activities	Examination methods	Credit conditions
e-learning	written examination	1. Classes attendance (lectures at least 75%, seminars and laboratories at least 90%), 2. Completion of seminars based on the results of partial tests (at least 60% from each), 3. Accepted presentation of a project, 4. Completion of laboratory classes. 5. Scoring at least 60% from written final exams for the following units: a. Structure-activity relationships in approved drugs, b. Principles of design and structure optimization of novel drug candidates, c. Principles of Molecular Modeling, d. Contemporary organic synthesis.
seminar	group assessment, project, test	1. Classes attendance - at least 90%, 2. Completion of seminars based on the results of partial tests (at least 60% from each), 3. Accepted presentation of a project.
classes	booklet of practice, written examination	1. Classes attendance - at least 90%, 2. Completion of laboratories based on the results of partial tests (at least 60% from each), 3. Accepted reports, 4. Completion of laboratory classes.

Entry requirements

Principles of Medicinal Chemistry module passed

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Experimental Pharmacology

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** elective
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 3	written examination **Activities and hours** e-learning: 20, seminar: 30, classes: 400	36.0

Goals

C1	acquire knowledge, skills and social competences in the field of conducting pharmacological research in the process of drug discovery and development, including in vitro and in vivo pharmacodynamic, toxicological and safety pharmacology studies.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	principles of molecular pharmacology significant for current drugs action and discovery of new drugs	DDD_KDR_W02, DDD_KDR_W04	written examination, oral answer, test

W2	assumptions of cell and tissue cultures in the context of their applications in preclinical drug development	DDD_KDR_W03, DDD_KDR_W04	written examination, oral answer, test
W3	concepts, definitions and theoretical assumptions of detection methods and techniques of screening in vitro in the extent useful in drug design and development	DDD_KDR_W03, DDD_KDR_W04	written examination, oral answer, test
W4	concepts, definitions and theoretical assumptions of methods and models of ADME-Tox screening in vitro in the extent useful in the preclinical development of drug candidates	DDD_KDR_W01, DDD_KDR_W04, DDD_KDR_W06	written examination, oral answer, test
W5	the basics of anatomy, physiology and histopathology of laboratory animals	DDD_KDR_W04	written examination, oral answer, test
W6	rules of dealing with laboratory animals and recognizing symptoms of pathological and distress behaviors of animals	DDD_KDR_W14	written examination, oral answer, test
W7	ethical and legal aspects of performing experiments on animals	DDD_KDR_W09, DDD_KDR_W14	written examination, oral answer, test
W8	the requirements for a compound to enter the animal testing phase	DDD_KDR_W14	written examination, oral answer, test
W9	rules of selection of the appropriate route of administration, dose, size of the group, duration of the experiment, as well as animal species for pharmacological research	DDD_KDR_W04	written examination, oral answer, test
W10	selected animal models of disease states	DDD_KDR_W14	written examination, oral answer, test
W11	sources of toxicity, target organs exposed to toxic effects and basic concepts and definitions in the field of toxicology	DDD_KDR_W03, DDD_KDR_W05	written examination, oral answer, test
W12	basic toxicological test sets required by the guidelines for new compounds	DDD_KDR_W05	written examination, oral answer, test
W13	basic sets of tests required by the guidelines, which should be performed within the safety pharmacology studies	DDD_KDR_W04	written examination, oral answer, test
W14	suggested additional tests that can be performed as a part of the safety pharmacology studies	DDD_KDR_W02, DDD_KDR_W04, DDD_KDR_W12	written examination, oral answer, test
W15	specific cases in which safety pharmacology studies are not necessary	DDD_KDR_W05	written examination, oral answer, test
W16	basics of statistical analysis of results	DDD_KDR_W07	written examination, oral answer, test
Skills – Student can:			
U1	conduct routine cell and tissue culture procedures in the extent useful in drug design and development	DDD_KDR_U02	written examination, oral answer, assignment report, test
U2	calculate pharmacological activity descriptors and ADME parameters on the basis of definitions and equations related to particular in vitro and in vivo screening techniques in the extent useful in drug design and development	DDD_KDR_U02, DDD_KDR_U04	written examination, oral answer, assignment report, test

U3	prepare and carry out selected in vitro pharmacological and ADME-Tox screening experiments in the extent useful in drug design and development	DDD_KDR_U02	written examination, oral answer, assignment report, test
U4	locate internal organs and assess the anatomy of these organs in selected laboratory animals	DDD_KDR_U05, DDD_KDR_U07	written examination, oral answer, assignment report, test
U5	collect and prepare the organs of selected laboratory animals for histopathological assessment and evaluate them using microscopic methods	DDD_KDR_U02	written examination, oral answer, assignment report, test
U6	determine both normal and pathological conditions of laboratory animals	DDD_KDR_U01	written examination, oral answer, assignment report, test
U7	choose the appropriate route of administration, dose, size of the group, duration of the experiment, as well as the species of animals for pharmacological research	DDD_KDR_U02	written examination, oral answer, assignment report, test
U8	administer the compound using various routes of administration	DDD_KDR_U02	written examination, oral answer, assignment report, test
U9	list the requirements for a compound to enter animal testing phase	DDD_KDR_U02	written examination, oral answer, assignment report, test
U10	determine from which sources animals for research can be obtained	DDD_KDR_U02	written examination, oral answer, assignment report, test
U11	select the appropriate battery of tests for new compounds using selected animal models of disease states	DDD_KDR_U02	written examination, oral answer, assignment report, test
U12	indicate the basic set of tests required by the guidelines, which should be carried out within the safety pharmacology	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U05, DDD_KDR_U06, DDD_KDR_U07	written examination, oral answer, assignment report, test
U13	propose additional safety studies based on the compound’s profile	DDD_KDR_U01, DDD_KDR_U05, DDD_KDR_U06	written examination, oral answer, assignment report, test
U14	identify sources of toxicity and organs particularly exposed to toxic drugs, as well as explain basic concepts related to toxicity	DDD_KDR_U01, DDD_KDR_U06	written examination, oral answer, assignment report, test
U15	based on acquired knowledge of the drug development path and available data, indicate when individual tests are performed and plan them in time	DDD_KDR_U02	written examination, oral answer, assignment report, test
U16	analyze mathematically and statistically research results	DDD_KDR_U04	written examination, oral answer, assignment report, test
Social competences – Student is ready to:			
K1	consult with experts in the field of experimental pharmacology in case of facing difficulties in solving certain tasks independently	DDD_KDR_K01, DDD_KDR_K02	written examination, oral answer, test
K2	show respect for the prestige associated with her/his profession and properly understood professional solidarity	DDD_KDR_K02	written examination, oral answer, test

K3	care about safety of her/his own, her/his colleagues and the environment	DDD_KDR_K07	written examination, oral answer, test
K4	independently acquire knowledge based on reliable sources and critically evaluate it	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03	written examination, oral answer, test

Calculation of ECTS points

Activity form	Activity hours*
e-learning	20
seminar	30
classes	400
preparation for classes	400
preparation for examination	50
Student workload	**Hours** 900
Workload involving teacher	**Hours** 450
Practical workload	**Hours** 400

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Molecular mechanisms of function of receptors, ion channels, membrane transporters and enzymes	W1, K1, K4	classes, seminar, e-learning
2.	Influence of conformational changes of therapeutic protein targets on their activity	W1, K1, K4	classes, seminar, e-learning
3.	Relationship between receptor protein conformation and the strength of its interaction with ligand or downstream effector proteins	W1, K1, K4	classes, seminar, e-learning
4.	Constitutive activity of the seven-transmembrane receptors (7TMR)	W1, K1, K4	classes, seminar, e-learning
5.	Role of receptor ligands binding and dissociation kinetics in evaluation of their biological activity	W1, K1, K4	classes, seminar, e-learning
6.	Signaling pathways of particular receptor subtypes: differences between individual tissues, cell types and subcellular compartments	W1, K1, K4	classes, seminar, e-learning
7.	Mode of action of allosteric modulators depending on therapeutic target	W1, K1, K4	classes, seminar, e-learning

8.	Functional selectivity of receptor ligands	W1, K1, K4	classes, seminar, e-learning
9.	Measures of pharmacological activity in vitro descriptors: Kd, Ki, Kb, eKm, IC50, EC50, kon, koff, Vmax, Bmax, Emax –meaning and estimation methods	W1, W3, U2, K1, K2, K3, K4	classes, seminar, e-learning
10.	Cell models in preclinical studies	W2, W3, U1, K1, K4	classes, seminar, e-learning
11.	Main aspects of cultured cell biology	W2, W3, U1, K1, K4	classes, seminar, e-learning
12.	Cell adhesion, proliferation and differentiation	W2, W3, U1, K1, K4	classes, seminar, e-learning
13.	Primary versus secondary cell cultures	W2, W3, U1, K1, K4	classes, seminar, e-learning
14.	Acquisition of cells for culture	W2, W3, U1, K1, K4	classes, seminar, e-learning
15.	Observation of the culture and determination of culture condition, including potential infections	W2, W3, U1, K1, K4	classes, seminar, e-learning
16.	Differences between finite and continuous cell lines	W2, W3, U1, K1, K4	classes, seminar, e-learning
17.	Process of in vitro transformation	W3, K1, K4	classes, seminar, e-learning
18.	Tissue and organotypic cultures	W2, W3, U1, K1, K4	classes, seminar, e-learning
19.	Passage of suspension and adherent cells	W2, W3, U1, K1, K4	classes, seminar, e-learning
20.	Cell lines representing the phenotype of various tissues	W2, W3, U1, K1, K4	classes, seminar, e-learning
21.	Methods for cell viability assesment	W2, W3, U2, K1, K3, K4	classes, seminar, e-learning
22.	Genetic modification of cells - gene silencing and transgene overexpression	W2, W3, K1, K3, K4	classes, seminar, e-learning
23.	Assumptions of in vitro pharmacological screening and the importance of appropriate assay throughput	W3, K1, K4	classes, seminar, e-learning
24.	Phenotypic screening vs. biological target-oriented screening	W3, K1, K4	classes, seminar, e-learning
25.	Comparison of biochemical and cell-based tests	W3, K1, K4	classes, seminar, e-learning
26.	Saturation and competitive radioligand binding assays	W16, W3, U15, U16, K1, K4	classes, seminar, e-learning
27.	Different types of devices enabling experimental data recording depending on the technology used in biological tests	W16, W3, U15, U16, K1, K4	classes, seminar, e-learning
28.	Spectral characteristics of various fluorophores and technological requirements for their use in biological assays	W16, W3, U15, U16, K1, K4	classes, seminar, e-learning
29.	Application of various imaging techniques in preclinical studies	W3, U15, U16, K1, K4	classes, seminar, e-learning

30.	Practical use of the HCS platform and flow cytometry in studies on biological activity of compounds	W16, W3, U15, U16, K1, K3, K4	classes, seminar, e-learning
31.	Differences in the setup of electrophysiological experiments taking into consideration voltage gated or ligand-gated ion channels studies	W16, W3, U15, U16, K1, K3, K4	classes, seminar, e-learning
32.	Types of microbiological tests used in the search for antibacterial drugs	W3, K1, K4	classes, seminar, e-learning
33.	Basics of anatomy, physiology and histopathology of laboratory animals	W5, U4, K1, K3, K4	classes, seminar, e-learning
34.	Rules of good practice in the care of laboratory animals (preparing animals for the procedure, rules for handling animals used in procedures adapted to a given species)	W6, U7, K1, K2, K3, K4	classes, seminar, e-learning
35.	Basic types of animal behavior, recognition of pathological and dystrophic behaviors characteristic of particular species	W5, W6, U6, K1, K2, K3, K4	classes, seminar, e-learning
36.	Ethical and legal aspects regarding the implementation of animal experiments (current regulations on the protection of experimental animals, rules for writing applications for the use of animals for testing)	W7, U10, K1, K2, K3, K4	classes, seminar, e-learning
37.	Sources from which animals can be obtained for testing	W7, U10, K1, K2, K3, K4	classes, seminar, e-learning
38.	Principles of anesthesia and euthanasia of laboratory animals	W7, K1, K2, K3, K4	classes, seminar, e-learning
39.	Rules for the selection of the appropriate size of the group and species for testing	W9, U7, K1, K2, K3, K4	classes, seminar, e-learning
40.	Different routes of administering compounds (influence of physicochemical properties of the compound on the choice of the route of administration)	W9, U8, K1, K2, K3, K4	classes, seminar, e-learning
41.	Rules for the collection of biological material, its storage and the basics of biochemical determinations	U5, K1, K2, K3, K4	classes, seminar, e-learning
42.	Requirements that for the compound to enter the animal testing phase	W8, U9, K1, K4	classes, seminar, e-learning
43.	Principles of the analysis of in vitro results	W16, U16, K1, K4	classes, seminar, e-learning
44.	Selected animal models of disease states (models of diseases of the central nervous system, cardiovascular system, infectious diseases, models in oncological research and others)	W10, U11, K1, K3, K4	classes, seminar, e-learning
45.	Basics of statistical analysis of results	W16, U16, K1, K4	classes, seminar, e-learning
46.	Toxicity sources, target organs exposed to toxic effects	W11, U14, K1, K4	classes, seminar, e-learning
47.	Basic concepts such as TD50, LD50, LOAEL, NOAEL or therapeutic index	W11, K1, K4	classes, seminar, e-learning
48.	Rules for the selection of the appropriate animal species for toxicity tests	W13, U15, K1, K2, K3, K4	classes, seminar, e-learning

49.	Basic toxicological test sets required by the guidelines for new compounds: genotoxicity, immunotoxicity, carcinogenicity, chronic toxicity, reproduction and other	W12, U15, K1, K4	classes, seminar, e-learning
50.	Rules for the selection of the appropriate route of administration, dose, group size, duration of the experiment, as well as the species of animals for the study of safety pharmacology	W13, U12, K1, K2, K3, K4	classes, seminar, e-learning
51.	Basic, required by the guidelines test sets to be performed within the pharmacology of safety - the central nervous system, respiratory system and cardiovascular system and suggested additional tests that can be performed as part of the pharmacology of safety	W13, W14, U12, U13, K1, K2, K3, K4	classes, seminar, e-learning
52.	Exceptional cases for which safety pharmacology studies are unnecessary	W15, U13, K1, K2, K3, K4	classes, seminar, e-learning
53.	Theoretical basics, limitations, advantages and disadvantages of ADME-Tox parameters evaluation in vitro	W4, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
54.	Experimental assays for evaluation of drug permeation through biological membranes and drug absorption	W4, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
55.	Evaluation of drug distribution, including determination of affinity to albumin, acid glycoprotein as well as stability in plasma and other body fluids	W4, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
56.	Experimental studies of CYP-independent metabolism	W3, W4, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
57.	Determining the affinity and impact on CYP isoform activity	W16, W3, W4, U16, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
58.	Procedures for the experimental determination of drug elimination parameters, including Clint, t1/2, Vmax i Km	W4, U16, U2, U3, K1, K2, K3, K4	classes, seminar, e-learning
59.	Experimental determination of genotoxicity	W4, U3, K1, K2, K3, K4	classes, seminar, e-learning
60.	Procedures for testing the affinity and inhibition of hERG channels	W4, U16, U3, K1, K2, K3, K4	classes, seminar, e-learning

Course advanced

Teaching methods:

computer classes, problem solving method, seminar, lecture, lecture with multimedia presentation, practical classes

Activities	Examination methods	Credit conditions
e-learning	written examination	The grade of the course according to the result of the final test
seminar	written examination, oral answer, test	Partial tests passed (> 60%). The grade of the course according to the result of the final test.
classes	assignment report	The grade of the course according to the result of the final test

Entry requirements

Knowledge, skills and competences obtained in the II semester of the I year of the DDD course. Mandatory presence at exercises and seminars.

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Model Informed Drug Development

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** elective
Disciplines Pharmaceutical science	**Examination** written examination
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period Semester 3	**Examination** written examination **Activities and hours** e-learning: 45, seminar: 120, classes: 120, workshop: 165	**Number of ECTS points** 36.0

Goals

C1	Familiarization with major routes of drugs administration. Quantified approach in dosage form adjustments for a particular route of drug administration.
C2	Acquainting with the systems for quality control and assurance for medicinal products and quantitative assessment of the impact of the production process on quality.
C3	Presentation of software and methods of analysis of clinical data in terms of bioequivalence and biosimilarity.
C4	Acquainting with dissolution methods and mathematical basis of dissolution profiles extrapolation on the results of clinical trials (IVIVC / IVIVR).
C5	Legal regulations of drug development and registration.

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	The results of in vitro and in vivo studies on absorption, distribution, metabolism, and elimination (ADME).	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W07, DDD_KDR_W08, DDD_KDR_W09, DDD_KDR_W10, DDD_KDR_W14	written examination
W2	The principles of making decisions regarding drugs development based on the results of modeling.	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W07, DDD_KDR_W10, DDD_KDR_W14	written examination
W3	The principles of search and analysis of publicly available data used to build and parameterize mathematical models; knows the available sources of information.	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W07, DDD_KDR_W10, DDD_KDR_W14	written examination
W4	Models / approaches to mathematical modeling of drug kinetics: ○ Models of individual ADME processes ○ Classic pharmacokinetic models ○ Non-compartmental analysis ○ Physiological models (PBPK) and their applications ○ Population pharmacokinetic models Toxicokinetic modeling ○ Pharmacodynamic models (PD, PKPD, QSP).	DDD_KDR_W01, DDD_KDR_W03, DDD_KDR_W04, DDD_KDR_W12, DDD_KDR_W14	written examination
W5	In vitro studies in the evaluation of the safety of the use of medicines.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W04, DDD_KDR_W12, DDD_KDR_W14	written examination
W6	Methods of assessing organ toxicity of drugs.	DDD_KDR_W01, DDD_KDR_W02, DDD_KDR_W14	written examination
W7	Problems of scaling up manufacturing processes of a drug and technology transfer, the issues of a campaign based and continuous manufacturing processes, issues of validation of the manufacturing process.	DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W12, DDD_KDR_W14	written examination
W8	Conditions for the production of medicinal products and the hygiene of the production space, the problems of GMP, GHP, and related systems HACCP, ISO9001.	DDD_KDR_W03, DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W12, DDD_KDR_W14	written examination

W9	Modern analytical methods used to study the form of the drug and the principles of their validation, compendial and non-compendial methods of dissolution testing and their importance for demonstrating bioequivalence (BE in vitro and methods for comparing profiles).	DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W12, DDD_KDR_W14	written examination
W10	The relationship between modifications of the formulation and bioavailability (extended, modified, controlled release, therapeutic systems), the concept of BCS and its meaning in the registration process (biowaiver), can analyze the dependence of physicochemical properties of API and its bioavailability, also on selected examples of quantitative relationships.	DDD_KDR_W01, DDD_KDR_W04, DDD_KDR_W05, DDD_KDR_W07, DDD_KDR_W14	written examination
W11	The differences between generic and biosimilar products, the concept of IVIVC / IVIVR and understands its use both in the registration process (biowaiver) and in the post-marketing phase (SUPAC – scale-up and postapproval changes), the physiological and pathophysiological conditions of different routes of drugs administration and the basic principles of the formulation of selected forms of drugs to be administered via different routes.	DDD_KDR_W01, DDD_KDR_W06, DDD_KDR_W07, DDD_KDR_W08, DDD_KDR_W09, DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W12, DDD_KDR_W14	written examination
W12	The structure of CTD and the content of individual modules necessary to submit marketing authorization application for a generic product, legal differences in regulations for various markets (EU vs. USA), the issues related to borderline products.	DDD_KDR_W05, DDD_KDR_W06, DDD_KDR_W09, DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W13, DDD_KDR_W14	written examination
Skills – Student can:			
U1	Mathematically analyze the results of ADME studies and draw conclusions.	DDD_KDR_U01, DDD_KDR_U03, DDD_KDR_U04	essay
U2	To analyze and interpret simulation results carried on to solve a certain problem, connect with the existing information, and based on them decide about further studies and their directions. To find proper literature data to develop a mathematical model. Critically assess the quality of data, define uncertainties and propose solutions. Defines and use in practice models describing ADME processes including: ◦ Classical PK models, ◦ NCA, ◦ PBPK models, ◦ Toxicokinetic models, ◦ PD, PKPD, QSP models. to solve real life problems.	DDD_KDR_U02, DDD_KDR_U05, DDD_KDR_U07, DDD_KDR_U10, DDD_KDR_U11	essay
U3	Indicate the differences between the laboratory, pilot and production series, to identify potential threats related to the change of production scale and to list the benefits and threats resulting from continuous production, plan the validation of selected manufacturing process based on statistical assumptions, determine sample size, indicate sampling methods and use descriptive statistics methods to analyze and present the obtained results, characterize the classes of cleanrooms used for manufacturing, determine the assumptions of individual quality assurance systems, indicate their purpose and specify the basic documents necessary to create the system.	DDD_KDR_U02, DDD_KDR_U05, DDD_KDR_U07, DDD_KDR_U10, DDD_KDR_U11	project

U4	Design dissolution tests for different drug forms and interpret the results of these tests with particular emphasis on comparing release profiles, calculate and interpret pharmacokinetic parameters of the drug using pharmacokinetic models or a noncompartmental analysis, assign a therapeutic substance to the appropriate BCS class and assess the chances of applying for biowaiver, create a basic level A IVIVC model, find and use sources of knowledge in the regulatory field (EMA / FDA / ICH guidelines, pharmacopoeias, local regulations).	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U06, DDD_KDR_U10	project
Social competences – Student is ready to:			
K1	To participate effectively in interdisciplinary scientific meetings, representing a team responsible for mathematical modeling.	DDD_KDR_K01, DDD_KDR_K02, DDD_KDR_K03, DDD_KDR_K04	no credit
K2	Cooperates with other students in conducting the experiment, analyzing results and building mathematical models, presents and defends the results of his/her work.	DDD_KDR_K05, DDD_KDR_K06, DDD_KDR_K07	no credit

Calculation of ECTS points

Activity form	**Activity hours***
e-learning	45
seminar	120
classes	120
workshop	165
preparation of a project	40
preparation for examination	20
preparation of a report	4
participation in examination	2
preparation for classes	350
conducting literature research	40
Student workload	**Hours** 906
Workload involving teacher	**Hours** 450
Practical workload	**Hours** 285

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Advanced PK/ADME & Biopharmaceutics.	W1, W10, W11, W2, U1, U2, K1, K2	classes, seminar, workshop, e-learning
2.	Pharmaceutical Manufacturing & Quality Control.	W12, W7, W8, W9, U3, U4, K1, K2	seminar, workshop, e-learning
3.	Principles of ADME/Tox and IVIVE.	W2, W3, W4, W5, W6, U1, U2, K1, K2	classes, seminar, workshop, e-learning
4.	Clinical Trials – Scientific Background and Regulatory Requirements.	W1, W12, U4, K1, K2	seminar, e-learning

Course advanced

Teaching methods:

case study, classes / practicals, computer classes, problem solving method, seminar, lecture

Activities	Examination methods	Credit conditions
e-learning	written examination	60% of maximum number of points
seminar	project	Project defense.
classes	essay	Practical exercises report.
workshop	no credit	

Entry requirements

Principles of Pharmaceutical Technology and Knowledge Based Drug Development modules passed

JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

Master Project

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2019/20
Field of study Drug Discovery and Development	**Realization year** 2020/21
Study level second-cycle program	**Lecture languages** English
Study form full-time	**Block** obligatory for passing in the course of studies
Education profile general academic	**Mandatory** obligatory
Disciplines Pharmaceutical science	**Examination** credit
ISCED classification 0916 Pharmacy	
Subject related to scientific research Yes	

Period	**Examination**	**Number of ECTS points**
Semester 4	credit **Activities and hours** tutorial: 375	18.0

Goals

C1	The aim of the seminars and master project is to prepare the scientific content for the master's thesis and to prepare the student to write a thesis and the present the thesis at the diploma exam

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	the research areas covered by master project	DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W12, DDD_KDR_W14	oral examination, project

W2	the results of recent research published in the scientific literature related to the topic of master project	DDD_KDR_W09, DDD_KDR_W10, DDD_KDR_W11, DDD_KDR_W14	oral examination, project
W3	the research areas of other participants of the course	DDD_KDR_W14	oral examination, project
Skills – Student can:			
U1	collect and compile literature data relevant to master project topic	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	oral examination, project
U2	collect and interpret the results of conducted research	DDD_KDR_U01, DDD_KDR_U02, DDD_KDR_U03, DDD_KDR_U04	oral examination, project
U3	plan the structure of the master's thesis and prepare its text	DDD_KDR_U07, DDD_KDR_U08, DDD_KDR_U11	oral examination, project
U4	prepare and give a multimedia presentation on the purpose, scope, methodology, and results of research project	DDD_KDR_U06, DDD_KDR_U07, DDD_KDR_U11	oral examination, project
Social competences – Student is ready to:			
K1	Objectively evaluate the research tools used in the research (own and others' participants of the course),	DDD_KDR_K03, DDD_KDR_K04	oral examination, project
K2	Critically analyzes the results of the research	DDD_KDR_K02, DDD_KDR_K04	oral examination, project
K3	Cares for the safety at the workplace	DDD_KDR_K07	oral examination, project

Calculation of ECTS points

Activity form	**Activity hours***
tutorial	375
preparation of multimedia presentation	20
preparation of a project	45
preparation of thesis	50
preparation for examination	50
Student workload	**Hours** 540
Workload involving teacher	**Hours** 375

* hour means 45 minutes

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Discussions with the supervisor regarding the merits of the project	W1, W2, U1, U2, U3, K1, K3	tutorial
2.	Discussions with the supervisor on statistical issues and related to the proper preparation of the manuscript	W1, U1, U2, K2	tutorial
3.	Oral presentations given by each of the course participants on various issues related to DDD covered by their individual research projects	W3, U4, K1	tutorial

Course advanced

Teaching methods:

brainstorm, discussion, project method, presentation, seminar, participation in research

Activities	Examination methods	Credit conditions
tutorial	oral examination, project	