UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Program studiów

Wydział:	Wydział Farmaceutyczny
Kierunek:	Drug Discovery and Development
Poziom kształcenia:	drugiego stopnia
Forma kształcenia:	stacjonarne
Rok akademicki:	2020/21

Spis treści

Charakterystyka kierunku

Informacje podstawowe

Nazwa wydziału:	Wydział Farmaceutyczny
Nazwa kierunku:	Drug Discovery and Development
Poziom:	drugiego stopnia
Profil:	ogólnoakademicki
Forma:	stacjonarne
Język studiów:	angielski

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. Studia odpowiadają na potrzeby branży farmaceutycznej w zakresie specjalistów zajmujących się poszukiwaniem nowych rozwiązań terapeutycznych. Kształcenie zapewnia studentom specjalistyczną wiedzę w obszarze nauk farmaceutycznych, w szczególności związaną z poszukiwaniem nowych substancji aktywnych, nowych postaci leków oraz oceną ich właściwości fizyko-chemicznych, farmakodynamicznych i farmaceutycznych.
Absolwent kierunku Drug Discovery and Development jest przygotowany do prowadzenia prac badawczo-rozwojowych nad nowymi lekami w firmach zajmujących się wytwarzaniem leków oraz w zespołach badawczych poszukujących nowych leków i metod terapii, jest także przygotowany do systematycznego rozwijania swoich kompetencji w tych obszarach.

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 procesie dydaktycznym stosowane są nowoczesne metody dydaktyczne 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

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 są włączani w realizację szerszego nurtu prac badawczych.
Moduły zajęć powiązane z prowadzonymi badaniami naukowymi w dziedzinie nauk farmaceutycznych, służące zdobywaniu przez studenta pogłębionej wiedzy oraz umiejętności prowadzenia badań naukowych to m.in. Principles of Medicinal Chemistry, Diseases States and Pharmacotherapeutic Strategies, Principles of Pharmaceutical Technology, Molecular ADME and In vivo Pharmacokinetics, Introduction to Drugs Safety and Toxicology, Molecular Screening Systems, Introduction to Animal Models of Disease States, Chemistry in Pharmaceutical Sciences, Biology in Pharmaceutical Sciences oraz Master Project. Także moduły oferowane w ramach zajęć fakultatywnych prowadzone są w powiązaniu z realizowanymi badaniami naukowymi.

Opis infrastruktury niezbędnej do prowadzenia kształcenia

Zajęcia dla studentów kierunku Drug Discovery and Development realizowane są w całości w budynku Wydziału Farmaceutycznego UJ CM przy ul. Medycznej 9 w Krakowie, o powierzchni całkowitej 10500m2, w tym ok. 2540 m2 przeznaczonych do zajęć dydaktycznych. W budynku dla studentów dostępne są 2 sale wykładowe - każda na 100 do 120 studentów, 1 salę konferencyjną, 6 pracowni komputerowych - posiadające ogółem ponad 40 stanowisk do pracy, 11 sal

seminaryjnych - mieszczących od 20 do 40 osób, 18 specjalistycznych laboratoriów oraz sal ćwiczeniowych. Wydział posiada specjalistyczne laboratoria chemiczne oraz laboratoria przemysłowe. W budynku Wydziału poza salami dydaktycznymi znajdują się również pokoje zakładów i katedr, dziekanat, pomieszczenia administracyjne, pomieszczenia samorządu studenckiego, laboratoria naukowe (w których m.in. realizowane są badania związane z pracami magisterskimi). Budynek dostosowany jest do osób niepełnosprawnych, przed wejściem głównym znajdują się odpowiednie podjazdy, wewnątrz budynku są windy, a większość sal usytuowana jest na poziomie wysokiego i niskiego parteru. W budynku działa sieć internetowa, dostęp do internetu możliwy jest za pomocą wewnętrznej sieci Wi-Fi dostępnej poprzez sieć routerów, połączenia realizowane są również za pośrednictwem EDUROM.
System biblioteczno-informacyjny UJ CM obejmuje Bibliotekę Medyczną wraz z 4 agendami bibliotecznymi. Biblioteka Medyczna pełni funkcję głównej biblioteki Uniwersytetu Jagiellońskiego - Collegium Medicum i stanowi kompleksowe centrum informacyjne z zakresu nauk medycznych oraz dziedzin pokrewnych. Biblioteka Medyczna udostępnia literaturę z zakresu medycyny, farmacji, pielęgniarstwa i nauk pokrewnych, takich jak biologia, chemia, psychologia obejmującą:

- księgozbiór Biblioteki liczący około 300 000 woluminów druków zwartych, z czego część funkcjonuje jako kolekcje poszczególnych katedr oraz zbiory dydaktyczne bibliotek instytutowych.

- kolekcję e-booków dostępnych online za pośrednictwem katalogu liczącą 6680 pozycji.

- 50 baz online (np. Medline-PubMed, Scopus, Web of Science) oraz obszerną kolekcję czasopism - ok. 7435 tytułów dostępnych online oraz ponad 300 czasopism polskich i 75 zagranicznych w wersji drukowanej, dostępnych w Czytelni Czasopism i bibliotekach instytutowych.

Dodatkowe usługi oferowane przez Bibliotekę:

- program Mendeley (wersja instytucjonalna) do zarządzania bibliografia,

- korzystanie ze zbiorów innych bibliotek drogą wypożyczenia międzybibliotecznego. Zgodnie z warunkami licencji Biblioteka Medyczna oferuje zdalny dostęp do swoich e-zasobów pracownikom, doktorantom i studentom UJ CM z sieci komputerowej UJ CM oraz spoza niej poprzez system HAN.

Studenci i pracownicy UJ CM mają również dostęp do zasobów Biblioteki Jagiellońskiej, która ma status biblioteki narodowej. Ponadto Wydział Farmaceutyczny korzysta z zasobów zarówno Collegium Medicum UJ obejmujących m.in. Centrum Dydaktyczno-Konferencyjne przy ul. Św. Łazarza w Krakowie, jak również sale konferencyjne w budynku przy ul. Św. Anny 12, jak i Uniwersytetu Jagiellońskiego, w szczególności z kompleksu Auditorium Maximum przy ul. Krupniczej w Krakowie.

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	76
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 spełnienia łącznie następujących warunków 1) zaliczenia wszystkich przedmiotów obowiązkowych i fakultatywnych określonych w programie studiów 2) zdania egzaminu dyplomowego 3) przygotowania i obrony pracy dyplomowej.

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 equipment 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 zrealizować 1 przedmiot fakultatywny na każdym roku studiów

Semestr 3

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Foreign Language in Pharmaceutical Sciences	lektorat e-learning: 31 lektorat: 14	2,0	egzamin	O	Os
Team-work Case Studies	seminarium: 30	-	-	O	Os
Elective courses semester 3				O	Os
Medicinal Chemistry	seminarium: 170 wykład: 3 ćwiczenia: 277	36,0	egzamin pisemny	F	Os
Experimental Pharmacology	wykład: 20 ćwiczenia: 400 seminarium: 30	36,0	egzamin pisemny	F	Os
Model Informed Drug Development	wykład: 45 ćwiczenia: 120 seminarium: 120 warsztat: 165	36,0	egzamin pisemny	F	Os

Semestr 4

Przedmiot	Liczba godzin	Punkty ECTS	Forma weryfikacji		
Team-work Case Studies	seminarium: 30	4,0	zaliczenie na ocenę	O	Os
Master Project	konsultacje indywidualne: 375	18,0	zaliczenie	O	Os

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

UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Foreign Language in Pharmaceutical Sciences

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2020/21, 2021/22
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** examination
ISCED classification 0231 Language acquisition	

Period Semester 1	**Examination** - **Activities and hours** foreign language course: 14, e-learning: 6	**Number of ECTS points** 0.0

Period Semester 2	**Examination** credit **Activities and hours** foreign language course: 16, e-learning: 9	**Number of ECTS points** 2.0

Period Semester 3	**Examination** examination **Activities and hours** foreign language course: 14, e-learning foreign language course: 31	**Number of ECTS points** 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*
foreign language course	14
preparation for classes	5

e-learning	6
Student workload	**Hours** 25
Workload involving teacher	**Hours** 20

* hour means 45 minutes

Semester 2

Activity form	**Activity hours***
foreign language course	16
preparation for classes	10
e-learning	9
Student workload	**Hours** 35
Workload involving teacher	**Hours** 25

* hour means 45 minutes

Semester 3

Activity form	**Activity hours***
foreign language course	14
preparation for examination	15
e-learning foreign language course	31
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	foreign language course, e-learning, e-learning foreign language course
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	foreign language course, e-learning, e-learning foreign language course
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	foreign language course, e-learning, e-learning foreign language course
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	foreign language course, e-learning, e-learning foreign language course

Course advanced

Semester 1

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
foreign language course	oral answer, test	1. attendance at all the classes 2. active participation in classes 3. obtaining pass marks for written tests and oral presentations
e-learning		

Semester 2

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
foreign language course	oral answer, test	1. attendance at all the classes 2. active participation in classes 3. obtaining pass marks for written tests and oral presentations
e-learning		

Semester 3

Teaching methods:

e-learning, language conversation classes, foreign language course

Activities	Examination methods	Credit conditions
foreign language course	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 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 foreign language course		

Entry requirements

Knowledge of English at the level of proficiency B2 of the Common European Framework of Reference for Languages. Attendance at all the classes is compulsory.

UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Team-work Case Studies

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2021/22
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	

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COLLEGIUM MEDICUM

Medicinal Chemistry

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2021/22
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** lecture: 3, seminar: 170, classes: 277	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 of mathematical modeling used for making decisions regarding drug development
C5	Understanding modern methods in organic synthesis and analysis used in the preparation of new bioactive compounds
C6	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*
lecture	3
seminar	170
classes	277
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** 277

* 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	lecture, classes, seminar

2.	Characteristics of major therapeutic groups	W1, W2, W3, U1, U17	lecture, classes, seminar
3.	Biological targets for drugs from major therapeutic groups	W3, W7, U17	lecture, classes, seminar
4.	Drugs' mechanisms of action	W3, U17	lecture, classes, seminar
5.	Structure-activity relationships in the major drug groups	W4, U17, U2, U3, K1	lecture, classes, seminar
6.	Relationships between chemical structure and pharmacokinetic properties or toxicity	W6, W7, W8, W9, U4, U5, U6, U8, K1	lecture, classes, seminar
7.	Basic metabolic pathways	W5, W7, W8, W9, U5, U6, U7, K1	lecture, classes, seminar
8.	Databases and programs allowing to determine physicochemical, pharmacokinetic, toxicological and pharmacological properties	W5, W6, W7, W8, W9, U5, U6, U7, K1, K2, K3	lecture, classes, seminar
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	lecture, classes, seminar
10.	Methods of structural modifications to optimize the desired properties of the compound	W7, W8, U6, U7, U8, K1, K2, K3	lecture, classes, seminar
11.	Selected reactions for formation of carbon-carbon bond (e.g., Heck, Suzuki, metathesis, aldol, Wittig reactions)	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
12.	Selected reactions for formation of carbon-heteroatom bond	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
13.	Methods for selective reduction and oxidation	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
14.	Peptide chemistry	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
15.	Protecting groups	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
16.	Stereochemistry in organic synthesis	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
17.	Click chemistry	W13, U14, U15	lecture, classes, seminar
18.	Analytical methods for confirming and determining the purity of compounds (NMR, LCMS, IR)	W14, U13, U16, U8	lecture, classes, seminar
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	lecture, classes, seminar
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	lecture, classes, seminar
21.	Ligand-based (pharmacophore modeling) and structure-based (homology modeling) molecular design methods	W10, W11, W12, U10, U11, U8, K1, K3	lecture, classes, seminar
22.	Methods of ligand-biological target binding energy assessment (FEP, MM-GBSA)	W10, U10, U11	lecture, classes, seminar

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	lecture, classes, seminar
24.	Virtual screening of chemical databases using pharmacophore and structural models	W10, W11, W12, U10, U11, U8	lecture, classes, seminar
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	lecture, classes, seminar
28.	Isolation and purification of compounds (extraction, chromatography, crystallization)	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
29.	Microwave-assisted reactions	W13, W14, U13, U14, U15, U16	lecture, classes, seminar
30.	Green chemistry	W13	lecture, seminar
31.	Flow chemistry	W13	lecture, 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
lecture	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

UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Experimental Pharmacology

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2021/22
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** lecture: 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***
lecture	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	lecture
2.	Influence of conformational changes of therapeutic protein targets on their activity	W1, K1, K4	lecture, seminar
3.	Relationship between receptor protein conformation and the strength of its interaction with ligand or downstream effector proteins	W1, K1, K4	classes
4.	Constitutive activity of the seven-transmembrane receptors (7TMR)	W1, K1, K4	classes, seminar
5.	Role of receptor ligands binding and dissociation kinetics in evaluation of their biological activity	W1, K1, K4	classes, seminar
6.	Signaling pathways of particular receptor subtypes: differences between individual tissues, cell types and subcellular compartments	W1, K1, K4	classes
7.	Mode of action of allosteric modulators depending on therapeutic target	W1, K1, K4	classes, seminar

8.	Functional selectivity of receptor ligands	W1, K1, K4	classes
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
10.	Cell models in preclinical studies	W2, W3, U1, K1, K4	lecture
11.	Main aspects of cultured cell biology	W2, W3, U1, K1, K4	lecture, classes, seminar
12.	Cell adhesion, proliferation and differentiation	W2, W3, U1, K1, K4	lecture
13.	Primary versus secondary cell cultures	W2, W3, U1, K1, K4	classes, seminar
14.	Acquisition of cells for culture	W2, W3, U1, K1, K4	seminar
15.	Observation of the culture and determination of culture condition, including potential infections	W2, W3, U1, K1, K4	classes, seminar
16.	Differences between finite and continuous cell lines	W2, W3, U1, K1, K4	classes, seminar
17.	Process of in vitro transformation	W3, K1, K4	classes, seminar
18.	Tissue and organotypic cultures	W2, W3, U1, K1, K4	classes
19.	Passage of suspension and adherent cells	W2, W3, U1, K1, K4	classes
20.	Cell lines representing the phenotype of various tissues	W2, W3, U1, K1, K4	classes
21.	Methods for cell viability assesment	W2, W3, U2, K1, K3, K4	classes
22.	Genetic modification of cells - gene silencing and transgene overexpression	W2, W3, K1, K3, K4	lecture, seminar
23.	Assumptions of in vitro pharmacological screening and the importance of appropriate assay throughput	W3, K1, K4	seminar
24.	Phenotypic screening vs. biological target-oriented screening	W3, K1, K4	lecture, seminar
25.	Comparison of biochemical and cell-based tests	W3, K1, K4	classes
26.	Saturation and competitive radioligand binding assays	W16, W3, U15, U16, K1, K4	classes
27.	Different types of devices enabling experimental data recording depending on the technology used in biological tests	W16, W3, U15, U16, K1, K4	classes
28.	Spectral characteristics of various fluorophores and technological requirements for their use in biological assays	W16, W3, U15, U16, K1, K4	classes
29.	Application of various imaging techniques in preclinical studies	W3, U15, U16, K1, K4	seminar
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
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
32.	Types of microbiological tests used in the search for antibacterial drugs	W3, K1, K4	lecture, seminar
33.	Basics of anatomy, physiology and histopathology of laboratory animals	W5, U4, K1, K3, K4	lecture, classes

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
35.	Basic types of animal behavior, recognition of pathological and dystrophic behaviors characteristic of particular species	W5, W6, U6, K1, K2, K3, K4	seminar
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
37.	Sources from which animals can be obtained for testing	W7, U10, K1, K2, K3, K4	seminar
38.	Principles of anesthesia and euthanasia of laboratory animals	W7, K1, K2, K3, K4	classes, seminar
39.	Rules for the selection of the appropriate size of the group and species for testing	W9, U7, K1, K2, K3, K4	classes
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
41.	Rules for the collection of biological material, its storage and the basics of biochemical determinations	U5, K1, K2, K3, K4	classes
42.	Requirements that for the compound to enter the animal testing phase	W8, U9, K1, K4	seminar
43.	Principles of the analysis of in vitro results	W16, U16, K1, K4	classes
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
45.	Basics of statistical analysis of results	W16, U16, K1, K4	classes
46.	Toxicity sources, target organs exposed to toxic effects	W11, U14, K1, K4	lecture, seminar
47.	Basic concepts such as TD50, LD50, LOAEL, NOAEL or therapeutic index	W11, K1, K4	lecture, seminar
48.	Rules for the selection of the appropriate animal species for toxicity tests	W13, U15, K1, K2, K3, K4	seminar
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
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	lecture, seminar
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

52.	Exceptional cases for which safety pharmacology studies are unnecessary	W15, U13, K1, K2, K3, K4	seminar
53.	Theoretical basics, limitations, advantages and disadvantages of ADME-Tox parameters evaluation in vitro	W4, U2, U3, K1, K2, K3, K4	lecture, seminar
54.	Experimental assays for evaluation of drug permeation through biological membranes and drug absorption	W4, U2, U3, K1, K2, K3, K4	classes
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
56.	Experimental studies of CYP-independent metabolism	W3, W4, U2, U3, K1, K2, K3, K4	classes
57.	Determining the affinity and impact on CYP isoform activity	W16, W3, W4, U16, U2, U3, K1, K2, K3, K4	classes, seminar
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
59.	Experimental determination of genotoxicity	W4, U3, K1, K2, K3, K4	classes
60.	Procedures for testing the affinity and inhibition of hERG channels	W4, U16, U3, K1, K2, K3, K4	classes

Course advanced

Teaching methods:

computer classes, problem solving method, 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 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

UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Model Informed Drug Development

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2021/22
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** lecture: 45, seminar: 120, classes: 120, workshop: 165	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***
lecture	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	lecture, classes, seminar, workshop
2.	Pharmaceutical Manufacturing & Quality Control.	W12, W7, W8, W9, U3, U4, K1, K2	lecture, seminar, workshop
3.	Principles of ADME/Tox and IVIVE.	W2, W3, W4, W5, W6, U1, U2, K1, K2	lecture, classes, seminar, workshop
4.	Clinical Trials – Scientific Background and Regulatory Requirements.	W1, W12, U4, K1, K2	lecture, seminar

Course advanced

Teaching methods:

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

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

UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

Master Project

Educational subject description sheet

Basic information

Department Faculty of Pharmacy	**Didactic cycle** 2020/21
Field of study Drug Discovery and Development	**Realization year** 2021/22
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	

Entry requirements

Completed all modules from the first two semesters of studies.