GHENT UNIVERSITY

Course Specifications

Valid as from the academic year 2018-2019

PK-PD in pharmaceutical research (J000446)

Course size (nominal values; actual values may depend on programme)

Credits 3.0	Study time 90 h	Contact hrs	25.0 h

Course offerings and teaching methods in academic year 2018-2019

A (semester 1)	English	seminar	8.75 h
		demonstration	1.25 h
		lecture	15.0 h

Lecturers in academic year 2018-2019

Vermeulen, An	FW03	lecturer-in-charge

Offered in the following programmes in 2018-2019	crdts	offering
Master of Science in Drug Development	3	A

Teaching languages

English

Keywords

Pharmacokinetics, pharmacodynamics, drug development, systems pharmacology, translational PKPD modeling, PBPK, pharmacometrics, in vitro/in vivo correlation, pediatric drug development, population modeling

Position of the course

In view of the importance of preclinical and clinical pharmacology in drug research and the increasing importance of quantitative pharmacology, it is important for the students to get acquainted with the PKPD principles that are being applied throughout the different phases of the drug development process. This will provide them with a better insight into the day to day application of PKPD in an industrial pharmaceutical discovery- and development environment.

Contents

The course will provide an overview of the PKPD principles that are being applied in the different phases of drug research, leading towards a more rational and better informed decision making. More specifically, the following aspects will be covered: system and receptor pharmacology (discovery phase), translational PKPD modeling and PBPK (preclinical phase), population PKPD modeling, including the role of biomarkers and surrogate endpoints (phase 1-3), disease progression modeling (phase 1-3), in-vitro/in-vivo correlation techniques that are being applied during the development of slow release formulations (IVIVC), product differentiation and –positioning (meta-analyses), pediatric drug development, the types of PD models with a focus on indirect response models.

Initial competences

Successfully mastering the basic principles of pharmacokinetics.

Final competences

1 Being able to correctly interpret and evaluate scientific package inserts of drugs, and more specifically the aspects related to PBPK en PKPD modeling.

2 Master the principles of population analyses and being able to apply and interpret them based on analyses published in the scientific literature.

3 Based on information available for an adult patient population, being able to make dose and dose regimen recommendations for a correct treatment of children.

4 Understand and define the underlying physiological differences between children and adults, and indicate their importance for the application of PKPD.

5 Being capable of defining the different types of IVIVCs and know how to apply them in support of batch release specification setting.
6 Capable of listing the different types of PKPD modeling techniques and mastering the underlying principles, as well as being able to explain their importance for each of the drug development phases.

7 Knowing the different types of biomarkers and being capable of distinguishing them based on an in-depth understanding of the mechanism of action of drugs.

8 Being capable of identifying and defining disease progression models and their potential applications.

9 Being able to explain the principles of treatment individualisation and personalisation and their importance for the individual patient. Explain which factors are important in this context.

10 Being able to explain the importance of animal research and of translational PKPD modeling.

Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract

This course unit cannot be taken via an exam contract

Teaching methods

Demonstration, lecture, seminar

Extra information on the teaching methods

Lectures, including demos, and seminars.
The seminars consist on the one hand of answering questions related to scientific publications and on the other hand of exercises that are solved partly using specialised software in the PC room. The students must initially try to solve the problem themselves or in close cooperation with other students, but during each seminar the solution is also provided.

Learning materials and price

Printed manual at cost price.
Optional: Clinical Pharmacokinetics and Pharmacodynamics. Concepts and applications - 4th edition. M. Rowland and T.N. Tozer. Lippincott Williams and Wilkins, a Wolters Kluwer business ~95 USD

References

EMA and/or FDA guidelines on population PK modeling, exposure response analysis, IVIVC and pediatric drug development.
Package inserts of drugs (e.g. of Invega Sustenna or Xeplion).
Dayneka NL, Garg V and Jusko WJ. Comparison of four basic models of indirect pharmacodynamic responses. Journal of Pharmacokinetics and Biopharmaceutics 1993 Aug; 21(4):457-478.
Post TM, Freijer JI, DeJongh J, Danhof M. Disease system analysis: basic disease progression models in degenerative disease. Pharm Res. 2005 Jul; 22(7):1038-49.
Danhof M, Alvan G, Dahl SG, Kuhlmann J and Paintaud G. Mechanism-Based Pharmacokinetic–Pharmacodynamic Modeling—A New Classification of Biomarkers. Pharmaceutical Research 2005 Sep; 22(9): 1432-1437.
Zhao, L Zhang, JA Grillo, Q Liu, JM Bullock, YJ Moon, P Song, SS Brar, R Madabushi, TC Wu, BP Booth, NA Rahman, KS Reynolds, E Gil Berglund, LJ Lesko and S-M Huang. Applications of Physiologically Based Pharmacokinetic (PBPK) modeling and simulation during regulatory review. Clinical Pharmacology & Therapeutics 2011 Feb; 89(2):259-267.
Other articles, as appropriate.

Course content-related study coaching

Interactive support via Minerva (e-mail) – possibility to schedule a personal appointment.

Evaluation methods

end-of-term evaluation

Examination methods in case of periodic evaluation during the first examination period

Written examination with open questions, written examination with multiple choice questions

Examination methods in case of periodic evaluation during the second examination period

Written examination with open questions, written examination with multiple choice questions

Examination methods in case of permanent evaluation

Possibilities of retake in case of permanent evaluation

not applicable

Calculation of the examination mark

Multiple choice questions: 20% of the score; open ended questions: 80% of the score