PME
Institute for Education
in Pharmaceutical Medicine
Knowledge to shape your future

Master of Science (MSc) in Pharmaceutical Medicine

UNIVERSITÄT
DUISBURG
ESSEN

Master of Science (MSc) in Pharmaceutical Medicine

Knowledge to shape the future

Vision

We are offering the leading European study course in pharmaceutical medicine and create a rich international educational environment. Our vision is to develop the next generation of leaders for health care institutions and the pharmaceutical industry, with a broad understanding of managing changes, innovations and new product development.

Mission

We are establishing a unique educational concept based upon a novel style of academic training combined with real life case studies, role plays and applied medicine.

Why this study course?

In our view, the programs offered in medicine and pharmaceutics by most institutions do not prepare students sufficiently to deal with the complex international tasks facing health care institutions and the pharmaceutical industry.

Entry requirements

Degree in one of the following disciplines:

___Life Sciences
___Medicine
___Pharmacy

as well as one year's professional experience
and good English language skills.

Selection procedure

The best-qualified applicants will be invited to participate in an intensive interviewing process designed to assess their motivation, social competence, level of commitment, and to confirm their basic knowledge of the field.

Educational objective

The objective of this study course is to focus on day-to-day practice, to promote interdisciplinary knowledge and to enable the participants to deal with the complex international tasks facing health care institutions and the pharmaceutical industry.

Key elements of the study course: emphasis on practice, international focus and interdisciplinary nature.

Profile

Course structure

The study course covers two years and is divided into 3 modules

___Fundamental principles and tools

___Pharmaceutical new product development

___Patient and markets

with 18 study units, taught in block seminars on Thursday afternoon, Friday and Saturday at the University of Duisburg-Essen. Each study unit concludes with an examination.

The study course can be conducted while the participant is working.

Course language

The course language is English.

Duration

After 18 study units a period of time for thesis preparation and oral examination follows.

Venue

The study units are held at the University of Duisburg-Essen, Germany.

Degree

Master of Science (MSc) in Pharmaceutical Medicine

Fees

The course fee is currently EUR 6,380 per year
(total amount EUR 12,760).
The fee includes the costs for the final examination.

Benefits

"Following my scientific training in academic institutions, this course has helped to smooth my entry into the pharmaceutical industry. The course provides an insight into various aspects of drug discovery and development and helps participants to gain an understanding of how the industry operates as a whole."
Nafsika Kronidou-Horst, Ph. D.

"Already the first modules enriched my work in the pharmaceutical industry. Because of this it is worth for me to attend the study course despite the high workload as a medical manager in a pharmaceutical company."
Dr. med. Katja Pütter

"Future success requires visionaries with interdisciplinary knowledge."
Norbert Wilhelms

Content / Study Units

Study Unit 1

General Introduction to the Health System and the Pharmaceutical Industry

"State of the art" in research and development, regulatory affairs, marketing and sales, current research areas and trends.

Study Unit 2

Working in a Complex Organization

Understanding organizational theory, design and behavior, working in groups and teams, developing social skills and cross-cultural awareness.

Study Unit 3

Project Management

Project Management methods and theories with insight into critical analysis of research and development, including strategic decision-making processes.

Study Unit 4

Clinical Systems and Data Management

The use of state-of-the-art communication, media and computer skills required to process clinical data and information within the constraints of a highly regulated health system environment.

Study Unit 5

Drug Discovery and Development

All the steps required for the discovery of a new therapeutic principle drug or biologic agent from synthesis or selection from nature through the complex labyrinth of multiple disciplines according to strict international regulatory requirements in order to test the drug or biologic agent in man.

Study Unit 6

Toxicology

Various types of in-vivo and in-vitro toxicological studies needed to support the development of a new drug, possible implications of toxicological findings for the risk/benefit assessment, regulatory requirements and guidelines (FDA, EU).

Study Unit 7

Biostatistics:

Basic principles of planning a clinical study with references to the most frequently used statistical procedures. Familiarization with the implementation of statistical test procedures, explanatory power and sample size considerations, various strategies of analysis and the interpretation of a biometrical report.

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Study Unit 8

Clinical Pharmacology, Pharmacokinetics

The medical, legal, ethical and organizational prerequisites for initiating phase I studies. Study designs, interaction studies, special populations for the evaluation of pharmacokinetics and pharmacodynamics. Mathematical concepts of parametrics and comparative methods. German and international regulations. Interactive implementation of this knowledge.

Study Units 9 and 10

Clinical Trials I and II

Knowledge of all relevant international regulations (laws, guidelines, standard operating procedures) including ethical aspects of how to conduct clinical trials. Strengths and weaknesses of alternative study types, design of a trial protocol and legal issues to achieve the primary objective of clinical development: global marketing authorization on competitive indications.

Study Unit 11

Managing Clinical Trials

Practical focus on management of clinical trials in a multinational environment. With intensive role-plays the students and the lecturers work on key situations and important aspects of clinical drug development. The study unit includes lectures and troubleshooting exercises in which the students show their ability to cope practically with complex clinical research problems including financial, quality and legal aspects.

Study Unit 12

Health Economics

Legal, economical and ethical considerations for health care spending and resource allocation decisions; the basics of health care economics – role, instruments, practical use; valuation of new technologies; integration of health economics into pharmaceutical R&D process; health economics and pricing decisions.

Study Unit 13

Drug Safety

The principal aspects of drug safety systems, the regulatory requirements and authority-driven pharmacovigilance.

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Study Unit 14

Post Marketing Surveillance

Safety database, Phase IV trials, observational studies, recognition of special patient populations, safety information requirements in Europe and in the USA, market competitiveness, positioning and comparison for driving market share.

Study Unit 15

Regulatory Affairs

The regulatory framework, clinical trial applications, quality related elements of registration dossiers, application procedures, the role of different regulatory agencies, arbitration, hearings and appeal procedures, post-approval applications for variations and changes, international harmonization of regulatory requirements.

Study Unit 16

Marketing and Sales

Key principles of marketing and medical marketing, specifically the role of strategic marketing, marketing concepts, the specific marketing tools and requirements of the international pharma market.

Study Unit 17

Biotechnology

Impact of modern biotechnology on therapeutic possibilities and ethics, specific regulations concerning clinical trials and registration, newest development, relevance to people, health system and markets.

Study Unit 18

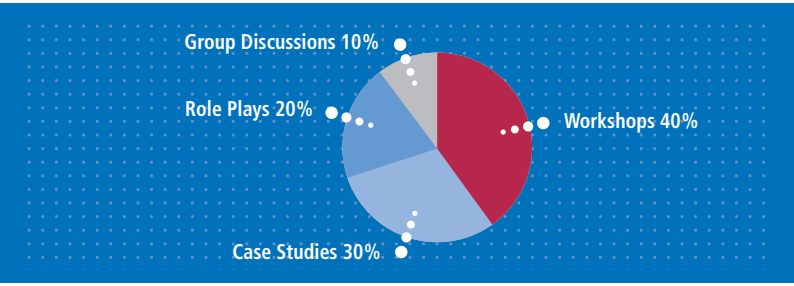
Pharmaceutical-related Case Studies

Application of all of the key concepts from all study units to real-case studies; review, analysis and critique of true examples of both successful and unsuccessful pharmaceutical development/marketing programs.

Structure

Course concept

For each study unit the participant has a one-month preparation time based on a given "Reader" which contains basic and additional information and tasks about the topic to be taught and discussed during the block seminar. The participant studies the "Reader" and becomes a "junior expert". During the block seminar the "junior expert" (participant) would meet the "senior experts" (lecturing team) to ask, to discuss and to demonstrate his knowledge on a scientific basis.



Teaching methods

The main emphasis of the study course is teamwork, along with participation, presentations and discussions to teach ability in competent management. Classic lectures will be given only for the introduction of a topic, to present basic knowledge and fundamental theories.

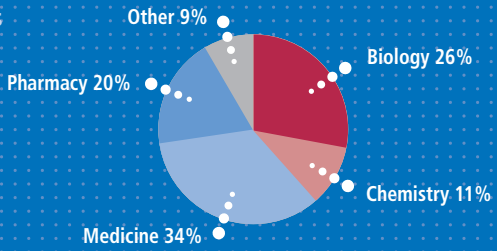
Lecturers

Participants will interact with lecturers from Belgium, France, Germany, Spain, Switzerland, the UK and the USA. They are key thought and opinion leaders. They work in health care institutions and the international pharmaceutical industry.

Students

They are all proud of being part of such an engaged, dedicated group with a high sense of commitment. 90 percent of our students made a career step. The majority of our students are graded with "excellent" or "very good".

Special Fields



Characteristics of the students (1997-2005)

Mean age (in years)	33
Gender (m/f)	52/48
Overall average final grade	1.8
Participation while the student is working	94 %
Doctorate	52 %
State doctorate	8 %
Being abroad	49 %
Minimum one career step during the study course	90 %

Scientific Course Committee (SCC)

The Scientific Course Committee (SCC) is charged with the overall responsibility of the success and applicability of the study course. The Scientific Course Committee consists of highly experienced scientists and subject matter experts actively employed in different disciplines. The main obligation of this board is to ensure that the content of the study course is state of the art.

University of Duisburg-Essen

The examination to reach the degree of "Master of Science (MSc) in Pharmaceutical Medicine" is approved by the University of Duisburg-Essen. It is located in the center of a region with the highest number of universities in Europe and is one of the biggest in the country. About 30,000 students are registered.

PME Institute for Education in Pharmaceutical Medicine

PME has the obligation to offer a comprehensive learning package, combining a university's hands-on oriented education with an innovative, on-the-job professional training. The institute is responsible for the organization and the realization of the study course units. It is the central interface which builds the connecting link for all involved persons.

Schedule

Usually a new study course starts every two years in April (2007, 2009, 2011, …).

Further information

www.uni-duisburg-essen.de/medizin/pharmaceutical_medicine, www.pme-institute.com, office@pme-institute.com

Location plan

___Via A 2:
Take the exit Essen / Gladbeck – Towards Essen turn right into B 224. From the crossroad "Gladbecker Straße / Grillostraße" keep following the signs towards "Universitätsklinikum".

___Via A 42:
Turn right at the B 224 onto "Gladbecker Straße" towards Essen. From the crossroad "Gladbecker Straße / Grillostraße" keep following the signs towards "Universitätsklinikum".

___Via A 40:
Take the exit Essen-Holsterhausen – If you are driving from the direction of Dortmund turn left, if you are driving from the direction of Duisburg turn right. At the end of the exit keep following the signs "Universitätsklinikum".

___Via A 52
Take the exit Essen-Rüttenscheid – At the end of the exit keep following the signs "Gruga" and then "Universitätsklinikum".

PME

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