Summarized Curriculum

Postgraduate Study Course in Pharmaceutical Medicine

Current Version 2.5 published and revised by the Scientific Course Committee
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1. Introduction

The health care institutions and the pharmaceutical industry are facing a tough challenge. Due to their complex requirements in managing ethical and moral aspects, their research in innovative principles, their development of highly efficient safe drugs and their marketing, the pharmaceutical industry as well as the health institutions need highly qualified employees.

To overcome the ever increasing discrepancy between academic education and the need for abilities and competences in economic processes, the postgraduate study course in pharmaceutical medicine has been established. The basic philosophy behind the curriculum is the idea to transfer nowadays existing industrial knowledge to universities where this is missing or even not taught. By doing that, this knowledge can be focused and transferred to young academics.

The objective of this postgraduate study course is to focus on day-to-day practice, seeking to avoid lengthy adjustment phases when students begin working and to promote interdisciplinary knowledge, social skills, management skills and cost awareness.

After completing this two-year postgraduate study course in pharmaceutical medicine within the Faculty of Medicine at University Duisburg-Essen, the postgraduates will be productive qualified individuals able to deal with the complex international tasks facing health care institutions and the pharmaceutical industry.

2. General Educational Objectives

It is the basic philosophy behind this curriculum that in the pharmaceutical industry and/or health institutions each employee with academic qualifications should understand the relation between various departments and institutes, in order to fully appreciate his/her own function in these complex surroundings and contribute optimally to the research and development of a new chemical entity. To achieve this, the course presents overviews of all major topics in the pharmaceutical industry, spanning from molecular design to ideas behind mergers and strategic alliances. Skills on how to relate successfully with the media will also be emphasised. The study course will enable the students to work in research and development or authorities functions as well as related leading functions.
The general objectives of this course are:

* To give the student an integrated overview of all relevant topics within the pharmaceutical industry.

* To educate physicians and scientists in all major aspects of drug research and development, with emphasis on clinical development.

* To stimulate an insight into the pitfalls and possibilities of research and development with a new chemical entity.

* To create an educational platform that enables the postgraduate to fulfil and understand a variety of roles within the pharmaceutical industry.

* To train the student in moderation and leadership of groups; to make the student aware of various aspects of social competence within a complex organisation (learning within social context, evolutionary behaviour), broaden the view of the student on all aspects of human nature.

* To further the communicative skills of the candidate, both in the critical evaluation and assessment of medical publications and in the application of such interpretations, through an appropriate medium, to those involved in the environment.

At the conclusion of the educational programme, the student is able to demonstrate his/her ability in the following tasks:

1. to draw a study outline and write a protocol (phase I-IV),
2. to design a Case Report Form,
3. to manage clinical study projects,
4. to write a Medical Research Report and a publication,
5. to monitor a study according to 'Good Clinical Practice',
6. to interpret a programme of studies and investigations appropriate to clinical pharmaceutical problems,
7. to discuss the pros and cons of a specific 'Clinical Development Plan',

8. to have a critical appreciation of techniques, procedures, goals and results of biomedical and pharmaceutical research, in particular an understanding of the scientific methods, the reliability and validity of observations and the testing of hypotheses,

9. to adopt a problem-solving approach in (clinical) research situations,

10. to be aware of the scientific, ethical and social role of the clinical scientist in professional teams within the pharmaceutical industry or health institutions,

11. to be aware of the health economic environment and its implications for drug development,

12. to be aware of the key business functions in the pharmaceutical industry: pharmaceutical technology, production (including that of clinical trial samples), engineering, quality assurance, biometry, toxicology, clinical pharmacology and clinical development, personnel, marketing, sales, financial controlling etc.

13. to communicate confidently an appraisal of medicinal reports and publications, correlating to the contemporary economic climate of the pharmaceutical industry,

14. to be familiar with the regulatory requirements for R&D,

15. to be accustomed to GCP and international standards.

3. Participation and admission

Candidates must hold a degree in one of the following disciplines:

- natural sciences (e.g. life sciences, pharmaceutical sciences)
- medicine
  and must have
- one year professional experience
- Good English language skills.

Candidates must provide evidence of such qualifications by presenting authorized copies of diplomas.

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.
4. Study Course structure

The curriculum for the degree in pharmaceutical medicine has been organised as a 2-year postgraduate study course. The study course language is Englisch.

The study course can be followed, in principle, both by employed graduates as well as by graduates who wish to qualify for a position within the pharmaceutical industry and/or health care institutions. The programme will offer flexibility for the student to complete the course in 2 years or alternatively, to complete the course within their own time schedule.

The study course is structured into 3 modules with 18 study units:

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<tr>
<th>Module</th>
<th>Study Units</th>
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<td>Fundamental and Principles</td>
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<td>Pharmaceutical New Product Development</td>
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<tr>
<td>Patient and Markets</td>
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One study unit takes place over approximately one month and ends with a 3 days block seminar, namely Thursday, Friday and Saturday. Each study unit concludes with an examination.

The one month students preparation time for each single study unit is supported by a given reader, which contains basic and additional information and tasks about the topic to be taught and discussed during the block seminar. The main emphasis of the study course is teamwork, along with students presentations and discussions to teach the ability in competent managing. Only with the introduction of a topic, to give basic knowledge and fundamental theories to the students, frontal lectures will be given. The idea behind the didactic concept: during the block seminar the “junior expert” (student) meets the “senior experts” (lecturing team) to ask, to discuss and to prove his knowledge on a scientific basis.

5. Educational strategies and teaching methods

Although the core-content of the course will be more or less fixed, based on essential elements to be learned in the various study units, the students will be encouraged to become involved in special topics of their choice, that will be studied in addition to the core elements. This will be the basis of a thesis for the Master’s degree. Complementary to the (multidisciplinary) information-gathering educational approach the students will acquire knowledge and skills through tackling problems in workgroups. Key aspects such as methods to analyse and present problems and their solutions before groups and involvement in round-table discussions will be integrated into each study unit. In this environment, social awareness, cooperation and leadership will be encouraged as well as the ability to scrutinize and assess various
opinions. As not all needs may be reflected in the aims and objectives of the course, post-graduates will participate in a continuous restructuring process of the curriculum in order to further optimise the benefits of the course.

The teaching methods selected:

1. **Lectures**
   1.1. Core lectures giving introductions to each topic.
   1.2. Lectures of speakers from industry and academia.

2. **Small project-groups: tutorials in which the student will be trained in problem solving.**
   2.1. During selected study units role-playing exercises will be used. Candidates will assume the roles of clinical project manager, registration officer, marketing manager etc. The team will be presented with a situation, accompanied with background documentation, and will be required to figure out the next steps in a real-case and/or hypothetical project.
   2.2. The student will be expected to assume the role of the lecturer in a specific project prepared by the individual.

3. **Individualized learning with supervision where students work alone on:**
   3.1. The analysis of study material.
   3.2. An individual project.

4. **On-Site-Training (Internship), if desired.**

In between blocks the student will have various assignments to complete (distance learning). Furthermore, individual projects can be formulated to suit the needs of each individual. These projects may serve the students as a guide in preparation for a thesis.

6. **Assessment techniques**

During the study course the student will be examined after each study unit. This test will determine whether the student has acquired the knowledge and understanding from the previous study unit(s). The form of the test will be at the decision of the head lecturer within the relevant study unit after agreement with the examination board. The students will receive a certificate with their grading after every study unit.

In order to obtain the degree “Master of Science in Pharmaceutical Medicine” the students must write an individual thesis and pass the oral examination.

The final grade is made from the grades of the oral examination, the thesis and the average out of 18 study units, each to one third.
7. **Certificate**

The graduate of pharmaceutical medicine from University Duisburg-Essen will receive a certificate stating that he/she passed the final examinations in this field and has graduated as a qualified specialist in pharmaceutical medicine. The degree obtained will be “Master of Science in Pharmaceutical Medicine”.

8. **Outline of individual study units:**

   **Study Unit 1 General Introduction to the Health System and the Pharmaceutical Industry**

   The health system and the pharmaceutical industry play a key role in the generation and supply of medicinal products.

   The perceptions of health institutions and the pharmaceutical industry by the environment are often grossly different from their actual roles in society. With progress in medicine slowing down, prices of innovative products rising and higher regulatory and quality demands, a more thorough acceptance of ethical principle makes it necessary for them to transform into a more goal-driven enterprise. Organisational and managerial responses to these pressures will be discussed.

   **Objectives:** To introduce the student to the course, its main objectives, structure and content and to provide an overview of the state-of-the-art in modern health institutions and the pharmaceutical industry.

   **Topics:** Overview of structures and functions of the health care system and the pharmaceutical industry; principles of research and development; current main research areas and trends; multinational and national pharmaceutical companies, drug disasters, costs and financial systems.

   **Study Unit 2 Working in a complex organisation**

   A scientist or physician working within a complex organisation such as pharmaceutical cooperation needs various social and technical skills. Operating in the pharmaceutical industry implies the functioning of various interdisciplinary groups. It is vital to be adeptly aware of the roles of each of these individual bodies.

   **Objectives:** Basic training of the student in social competence comprising of interactions with individuals and within groups. To gain an understanding of the
relevant organisational structures, their requirements, strengths and weaknesses including organisational theories.

*Begin of the social competence training including aspects of leadership and interactions with individuals and groups as well as moderation- and presentation skills. (Social competence will be trained further in all subsequent study units.)*

**Topics:** Social interactions, cooperation, communication, stimulation, chairing meetings and moderation, learning within a social context, evolutionary behaviour during career development; grasping the fundamentals of the wide range of activities concerning the different faculties.

**Study Unit 3 Project Management**

Good project management is a critical success factor in bringing new products quickly and efficiently to market.

**Objectives:** To give the student an overview of project management methods and theories. To provide the student with an insight into the critical analysis of research and development methods including strategic decision making process. To instruct students on techniques to ensure the evaluation of the risks and chances in current projects.

**Topics:** Operation management matrix and line-management; prioritization, computer project management and planning, SWOT-Analysis, measurements for project controlling; introduction into project reporting systems; techniques to ensure the imparting of information; managerial decision-making processes; management structures of multinational and national companies, developments of strategic alliances, co-development, co-marketing.

**Study Unit 4 Clinical Systems and Data Management**

Emphasis will be placed on the scope and complexity of IT operations in the health system in a global context and the underlying reasons why IT is an essential component in the industry. To give an insight into the inter-relationship between functional components and the constraints that these impose in the workplace.

**Objectives:** To be thoroughly familiar with the modern information technology facilities from data-base research, data handling, evaluation, data storage and archiving. To provide the student with a basic understanding of the use of modern communication, media and computer skills required to process medical information within constraints of a highly regulated health system.
Topics: The use of software packages such as relational databases, linkage of packages. Data handling in clinical trials, database theory, clinical database, coding systems for datapool, data storage and archiving. System validation requirements of FDA and European Union (EU); electronic mailing, computer-related telecommunications, remote data entry, networking on company and official systems.

Study Unit 5 Drug Discovery and Development

In order to find an active drug many candidates have to be screened in pharmacodynamic models in-vitro and in-vivo. Techniques exist to unravel the relationship between chemical structure and biological activity. As a promising compound is characterised, it is also evaluated with regard to those properties that have a bearing on its ultimate and successful formulation into a stable and effective pharmaceutical product or dosage form.

Objectives: To introduce the student to all necessary steps in the discovery of a new therapeutic principle drug or biologic from synthesis or selection from nature through a complex labyrinth of multiple disciplines according to strict international regulatory requirements in order to test the drug or biologic in man. To enable the student to comprehend the relation between drug, disease and choice of formulation and to be acquainted with the requirements involved in the development of a new formulation. To acquire a knowledge of both theoretical and practical screening models, pharmacodynamic models; to assess the implication of pharmacokinetic and galenic theories in medicinal development in relation to the activity of the drug.

Topics: Steps in the discovery and modification of new medicines, which therapeutic area to explore, chemical synthesis, the use of structure/activity databases, modifying structures, chemical leads, receptor identification, receptor targeting, preclinical pharmacology; choice of formulations based on the physico-chemical properties of the compound and intended indication, testing formulations in-vitro systems, scaling-up procedures, quality assurance. Basics of GLP and GMP.

Study Unit 6 Toxicology

Since toxicology is one of the key functions during drug development, a scientist or physician working within a pharmaceutical corporation should have some basic understanding of toxicological issues.

Objectives: To give an insight into various in-vito and in-vitro toxicological study types needed to support the development of a new drug, possible implications of toxicological findings for the risk/benefit assessment. To enable the student to understand a toxicological hypothesis, to evaluate such a hypothesis and to design
specific studies addressing the problem including regulatory requirements and guidelines (FDA, EU).

**Topics:** Requirements, planning and methodology of acute, sub-chronic and chronic toxicological studies, reproductive and mutagenicity studies. No-effect dose, LD-50, maximal dose, toxicology of drugs and their metabolites. The application of toxicokinetics. Planning of toxicological studies before and during a clinical development. Guidelines on toxicological research (FDA, EU).

**Study Unit 7 Biostatistics**

This study unit describes the basic elements of hypothesis testing and simple statistical methods like one/two sample tests, confidence intervals and sample size. Statistical elements of a clinical study are presented. The analysis of binary variables and time to event analysis are explained. The general aspects of statistical analysis are discussed. A review of guidelines is presented and the interpretation of a published clinical trial is discussed.

**Objectives:** To enable the student to understand the basic aspects of medical statistics. Upon completion of the study unit, the student should be able to understand the experimental design of a study and the issues of primary versus secondary endpoints, the number of subjects (power aspects), and the approach of the most frequently used statistical procedures. Comprehension of the biometrical section of a study protocol, i.e. being familiar with basic techniques such as dealing with missing values, principles of confirmatory, exploratory, and descriptive analyses; Interpretation of a biometrical report and implementation of simple test procedures; orientative power and sample size considerations.

**Topics:** Definition of primary and secondary endpoints in clinical research, power calculations, type I and type II errors, confounding variables, measurement of outcome variables, intra- versus inter-individual data, parametric and non-parametric tests, psychometry, confidence intervals, various strategies of analysis; basic principles of planning a study with reference to design, power, and statistical aspects; the discussion of statistical significance versus clinical relevance.

**Study Unit 8 Clinical Pharmacology, Pharmacokinetics**

Each new chemical entity, NCE, must go through an extensive review before it is given to man for the first time. Legal, ethical and - most important – medical requirements have to be taken into account. The responsible scientific team has the obligation to follow international guidelines as well as standard operating procedures in order to be able to cope with the almost challenging but also important step in the
drug development process. The preclinical work done must be evaluated and it has to be decided if enough data are available to go to man.

**Objectives:** To enable the student to understand the medical, legal and ethical background of phase I studies and to design a phase I study protocol. To introduce the student to models of pharmacokinetics, the mathematical background of parametrics and comparative methods, and to define and explain pharmacokinetic parameters and prerequisites of starting phase I studies.

**Topics:** The designs of various phase I trials will be discussed as principles of absorption, distribution, metabolism and/or elimination. Interaction studies and their rationale, special patient groups. Guidelines for phase I studies (FDA, EU, Japanese Guidelines). Introduction of computer packages that facilitate the analysis of pharmacokinetic data.

**Study Units 9 & 10 Clinical Trials**

The application of a non-approved drug on human beings is one of the greatest challenges in the pharmaceutical industry. Apart from compliance with legislative requirements, tremendous personal and medical responsibility is required. Not only does the competence of the scientist in the pharmaceutical industry embody the justified call for positive clinical results but also the benefit-risk analysis and the ethical and moral implications. To meet the demands of all this, an in-depth knowledge of context and of the technical and legal aspects is necessary.

**Objectives:** To enhance the students understanding of all relevant international regulations (laws, guidelines, standard operation procedures) including ethical aspects how to perform 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.

**Topics:** Research methodology and various trial designs. Standard format for protocol, informed consent, adverse events monitoring, protocol approval procedures (internal and external), regulatory issues; company, authoritarian, and standard requirements; GCP (Good Clinical Practice) and SOP (Standard Operating Procedure); regulatory conditions in various countries.
**Study Unit 11 Managing Clinical Trials**

Managing clinical trials needs excellent knowledge of pharmaceutical medicine combined with excellent communication skills to transfer this knowledge into daily practice.

**Objectives:** To enable the student to cope with the practical focus on management of clinical trials in a multi-national environment. With intensive role plays the students and the lecturers work on key situations and important aspects of clinical drug development. The study unit finishes with a trouble shooting in which the students show their ability to practically cope with complex clinical research problems.

**Topics:** Tasks undertaken by sponsor, monitor and investigator according to GCP; clinical data management systems, validation of study sites. Quality control, audits and fraud prevention. Ethics of clinical trials, product liability, and patients insurance; Management of international clinical trials.

**Study Unit 12 Health Economics**

Escalating health care costs imply that government and health insurance organisations are becoming more and more concerned with cost-containment policies. Justifying the costs of new drugs becomes a major issue. The objective of undertaking such economic evaluation of drugs is to show decision-makers the true value of those drugs and to help provide information for their appropriate use and pricing.

**Objectives:** To give an insight into the legal, economical and ethical considerations for health care spending and 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.

**Topics:** Quality of life assessments, cost minimisation analysis, cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, QALYs, the practical use of health economics and their influence of the health care systems; principles of pricing in a competitive market; pricing in a regulated market; current trends and new procedures/technologies in health economics in the USA, UK and Europe.
Study Unit 13 Drug Safety

The drug safety is not the absence of any risk attributable to the use of the drug; it is rather a balanced viewpoint weighting the benefit of using a specific drug in a specific indication against the risk in doing so. Up-to-date knowledge as well as appropriate communication on the potential risks associated with use of a specific drug is one of the most important prerequisites for a pharmaceutical company to bring its drugs on to the market and to keep it there.

Objectives: An introduction to the principal aspects of assessing drug safety, of drug safety systems, the regulatory requirements and the authority-driven pharmacovigilance. The student will also be instructed in the importance, management, documentation and reporting of adverse events.

Topics: Definition and Classification of adverse events (AE), adverse drug reactions, casualty and risk-benefit assessment, pharmacoepidemiology. Regulatory aspects of AE in the USA and in Europe, pertaining to the development phases of the drug.

Study Unit 14 Post-Marketing Surveillance

Continuous collection and assessment of safety relevant information is one of the most important responsibilities of a pharmaceutical company. Post marketing surveillance activities comprise this aspect together with continuing research activities which serve as basis for successful promotion. Different objectives and viewpoints in drug safety and marketing departments may lead to conflicting situations within the company. Information strategy over the life-cycle of a medicinal product and management of fails and pitfalls comprise the daily routine in pharmaceutical industry.

Objectives: Demonstrating the criterion of post-registration standards of clinical studies, contemporary market indicators, drafting the target population, launching a new drug, impact of medical information strategies and product information strategies.

Topics: Safety databases, phase IV Trials, observational studies, recognition of special patient populations, safety information requirements in the USA and in Europe, life-cycle management of a pharmaceutical product, use of pharmacoeconomic studies.
Study Unit 15 Regulatory Affairs, Registration Procedures, Drug Approval

A lot of effort has been spent with harmonising regulatory requirements concerning quality, safety and efficacy in order to speed up both the development of new medicines and the review of marketing authorisation applications in the largest pharmaceutical markets of the world, i.e. the USA, the European Union. Nevertheless, each national authority asks for particular data.

Objectives: To enable the student to discern the different requirements necessary to obtain approval for studies (e.g. CTX, IND) and registration (e.g. NDA), as well as the application of the different registration procedures. To give an insight into the current situation of the international harmonisation process for the regulatory requirements, which is an effort of the international health care organisations (EU, FDA, EMEA, CPMP) and to point out its impact on the national regulatory framework.

Topics: Preparations for studies, requirements in various countries; registration in Europe, USA and Japan, CANDA procedure, the role of electronic documentation and submissions within and out of the EU.

Study Unit 16 Marketing and Sales

A key strategic system within modern organisations is the system of product/service promotion. Today’s global economic environment has forced all organisations to effectively communicate with their customers regarding their products and/or services. Survey of sales and marketing practices, constraints and promotion tools used in the pharmaceutical industry. Specific emphasis will be placed on sales and marketing to managed care organisations, ethical and social dimensions to pharmaceutical marketing and the regulatory aspects of pharmaceutical marketing.

Objectives: To enable the student to understand the key principles of marketing and sales as well as the role of strategic marketing. To give an insight into the different marketing concepts and the specific marketing tools. To underline the requirements of the international pharma-market.

Topics: Strategic marketing, market structure and competition, marketing analysis, portfolio analysis, market definitions and forecasts, POM and OTC products and shifts, influence of Health Maintenance Organisations (HMOs), interpreting and employing economic policies in the health system, assessing and drawing up medical critiques; Information Technology.
**Study Unit 17 Biotechnology**

Biotechnology has become an important aspect of pharmaceutical research and development. A number of biotechnology-derived pharmaceuticals have been introduced into the market in the recent past. In addition, biotechnology delivers essential tools for drug discovery. Therefore, it is essential to understand the potential and the limitation of biotechnology for the pharmaceutical industry.

**Objectives:** To enhance the student's understanding of the impact of modern biotechnology on therapeutical possibilities and ethics. To be aware of the specific regulations and registration requirements concerning clinical trials with biological, biotechnological and gentechnological active substances. To explain the relevance of modern biotechnology to people, health system and markets.

**Topics:** Introduction to biotechnology, specific regulations concerning clinical trials and registration, newest developments.

**Study Unit 18 Pharmaceutical Related Case Studies**

The students will learn to apply the methodology, which has been provided in previous study units to develop solutions to complex case studies, which cover typical challenges in drug development.

**Objectives:** To apply and train the acquired knowledge from all study units toward by dealing with pharmaceutical related case studies. The review, the analyse and the critique of true examples of both successful and unsuccessful development/marketing programs enhance the students skills in perceiving problem areas, as well as improving the ability to administer an appropriate solution. To educate the student in acknowledging extrinsic as well as intrinsic influences to medicinal development.

**Topics:** Design of complex case studies, collection of unbiased sample cases; the inspection of confounding and exposure influences in strategic decisions, assessing the validity of case studies, analysis and judgement of development/marketing programs.