University of Basel

Faculty of Medicine

European Center of Pharmaceutical Medicine

CAS/DAS in Pharmaceutical Medicine
MAS in Medicines Development

2021–2023

ECPM®
European Center of Pharmaceutical Medicine

ADVANCED STUDIES

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Under the auspices of
EUCOR the European Campus
IFAPP, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine
Accredited by SwAPP, Swiss Association of Pharmaceutical Professionals and SGPM, Swiss Association of Pharmaceutical Medicine
Recognized as PharmaTrain Centre of Excellence

eucor The European Campus

IFAPP Pharmaceutical Medicine

SwAPP Swiss Association of Pharmaceutical Professionals

sgpm ashmp

Foederatio Pharmaceutica Helvetiae FPH

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE OF EXCELLENCE

Invitation

The European Center of Pharmaceutical Medicine (ECPM) is dedicated to being the leading university institute for medicines and drug development in Europe. The institute was founded in 1991 to cover the training needs of specialists working in drug development. It belongs to the department of Public Health of the Medical Faculty at the University of Basel and operates with partners worldwide. It is accredited as IMI PharmaTrain 'Centre of Excellence' and acknowledged by the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and the respective country associations.

We offer you a range of different training programs that provide a holistic understanding of the drug, medicines or device development process from discovery to the benefit of patients including key concepts in clinical trials, regulatory science and marketing.

Our education and training focus is on Advanced Studies and Continuing Professional Development (CPD). In conformity with the Bologna system, you can obtain a Certificate (CAS) or Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine or a Master of Advanced Studies (MAS) in Medicines Development. A successful course completion with a DAS degree is acknowledged by the Swiss Associations of Pharmaceutical Physicians/Professionals to gain specialization.

The programs are targeted at representatives from the pharmaceutical industry, service industry, academic and government decision- and policymakers who already have a good understanding of the basics of drug development and will benefit from a more in-depth, comprehensive and systematic immersion into modern medical product and device development, regulation and market introduction.

Participation in the ECPM training programs provides the opportunity to integrate work and education, to discuss with experts face-to-face or online, to gain in-depth knowledge and enhance your expertise while building a professional network, and to put this into perspective with your own career plan.

An international faculty of experts from academia, pharmaceutical and biotechnology companies and regulatory authorities carry the teaching responsibility.

We cordially invite you to participate in the ECPM course and very much look forward to meeting you soon!

Prof. Thomas D. Szucs
Director

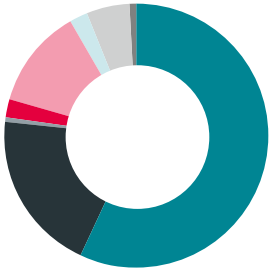
Dr. Annette Mollet
Head of Education & Training

Vivienne Rassaerts
Course Director

Life Long Learning
Deepen your expert knowledge and build an international network

Workplace of students

(2019 – 2021)



Big Pharma top 20	76
Small to Medium Size Pharma	26
CRO	1
Regulatory Authority	3
University Hospitals	16
University	3
Governmental Bodies, Associations	7
Banking	1
Total no of students	133

Mission

Our mission is to establish the best international training platform that provides and enhances the knowledge, expertise and skills needed to perform modern discovery, development, regulation and marketing of medical products. An outstanding faculty teaches integrating cutting-edge concepts and best practices to enable the development of efficient, economical, high quality and safe medical products for the benefit of the patients and the society. We are constantly innovating to offer Swiss excellence combined with a global perspective.

Definition of Pharmaceutical Medicine

The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine defines Pharmaceutical Medicine as the following:
"Pharmaceutical Medicine is the scientific discipline for the discovery, development, evaluation, registration, monitoring, and medical marketing of medicines for the benefit of the patients."

Target Audience

Our courses are targeted at representatives from the pharmaceutical industry, service industry, academic and government decision- and policy-makers who already have a good understanding of the basics of drug development and will benefit from a more in-depth, comprehensive and systematic immersion into modern medical product and device development, regulation and market introduction.

Postgraduate Modular Training Platform

Our postgraduate modular training platform provides the opportunity to discuss with experts face-to-face, build an international network and integrate work and further continuing education, in order to transfer knowledge between theory and real world experience. According to the definition of the European Commission, lifelong learning is «all learning activity undertaken throughout life that serves to improve knowledge, skills and competence».

Following a graduate Bachelor or Master title, there are three postgraduate levels that can be achieved: the first postgraduate level is the CAS (Certificate of Advanced Studies, 10-20 ECTS), the second is the DAS (Diploma of Advanced Studies, 30 ECTS) and finally the MAS (Master of Advanced Studies, at least 60 ECTS).

Syllabus: IMI Pharma Train

Training in Pharmaceutical Medicine covers all aspects of pharmaceutical medicine and drug development sciences with an international scope as defined by the PharmaTrain syllabus. This includes the discovery and development of new medicines, biopharmaceutical sciences, clinical pharmacology and trial methodology, good clinical practice and ethics, pharmacovigilance and epidemiology, biostatistics, regulatory affairs, health economics, project management, marketing and new therapeutic approaches.
For details please see www.pharmatrain.eu or ecpm.ch/education-training/syllabus

Learning Outcomes

On successful completion of training in pharmaceutical medicine, students should be able to demonstrate an understanding/knowledge of the following:

- The process of drug development and how to incorporate and apply the latest innovative biopharmaceutical development strategies, methodologies and tools
- The principal steps in drug discovery, target identification and non-clinical research
- The pertinent issues involved in the undertaking of clinical research and development
- The regulation of medicines in the various global markets, including ethical and legal provisions
- The management of drug safety issues pre- and post-marketing authorization

- The management of all lifecycle activities (regulatory and marketing) of a medicinal product
- The principles of health economics and their application in the development and marketing of medicinal products

Unique Program Features

- Deepen your knowledge in the essentials of the medical product lifecycle – from molecule to the marketplace
- Understand the trends in global pharmaceutical development and health care environment
- Expose yourself to new innovative methods, tools and strategies and apply them in your daily work
- Become a leader and integrator for medical product development
- Create a global professional network.
- Prepare for the next career step

- Enhance your CV by acquiring a Certificate/ Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine and take it to the next step with a Master of Advanced Studies (MAS) in Medicines Development
- Gain a Swiss specialty recognition for MDs or a SwAPP diploma

University of Basel

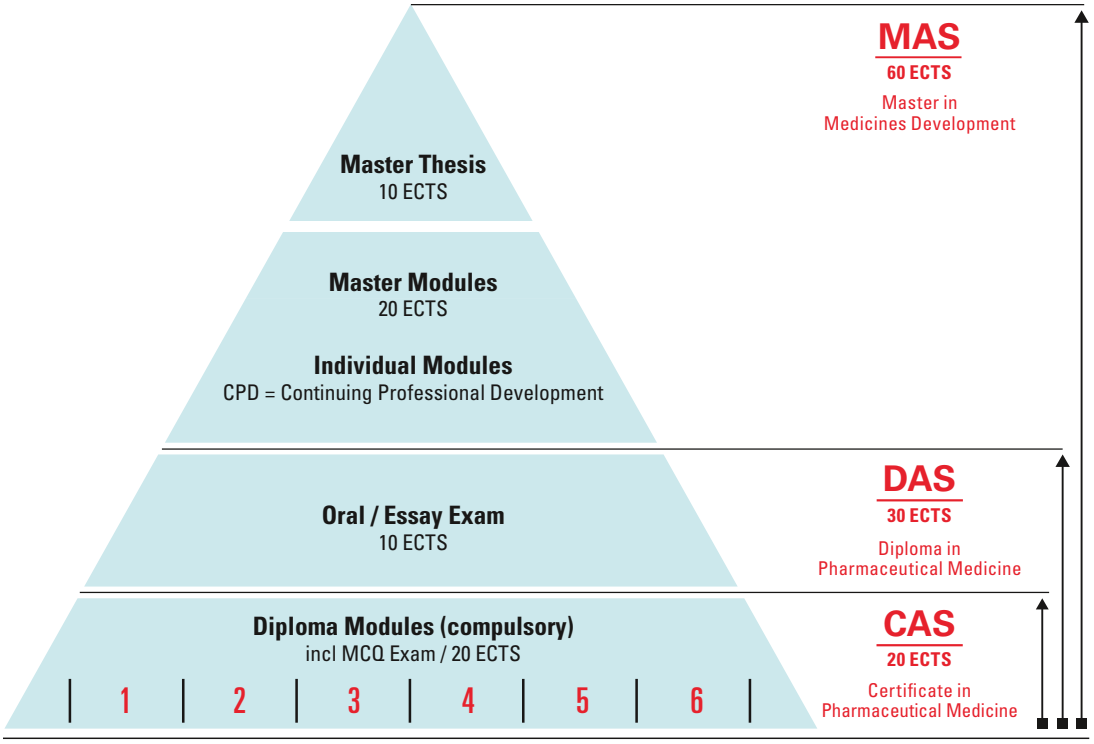
The University of Basel is Switzerland's oldest university and has been educating talents since 1460, for instance the physician and alchemist Paracelsus. Leading higher-education rankings such as the "Academic Ranking of World Universities" place the University of Basel among the world's 100 best universities. Within the German-speaking countries it is one of the top ten. Life Sciences are the main focal area at the University of Basel, closely linked with Basel's status as a center of pharmaceuticals and biotechnology.

Graduates

CAS
since 1991
1252

DAS
since 2001
618

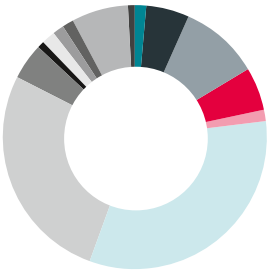
MAS
since 2015
9



Degrees and Examination
Study in an international network

Educational background of students

(2019 – 2021)



Bachelor, Master of Arts	2
Bachelor of Science	7
MSc Life Science	13
MSc Pharmacy	7
MSc Communication, Business	2
PhD	43
MD	36
MD, PhD	6
MD, MPH	1
Life Science Engineering	2
Business Engineering	2
Economics	2
MBA	9
Nursing	1
Total no of students	133

Overview of the Postgraduate Degrees

In conformity with the Bologna system three postgraduate degrees are offered.

Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine – 20 ECTS

To achieve a Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine by the University of Basel, it is required to successfully complete a two-year course cycle and to pass the multiple choice questions (MCQ) exam.

Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine – 30 ECTS

To achieve a Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine by the University of Basel, it is required to successfully complete a two-year course cycle and to pass the MCQ exam, as well as an oral and an essay exam. The oral examination is based on the pre-reading of a peer reviewed paper. The essay includes three one page summaries on given topics.

Master of Advanced Studies (MAS) in Medicines Development – 60 ECTS

To achieve a Master of Advanced Studies (MAS) in Medicines Development by the University of Basel, it is required to successfully acquire the DAS (30 ECTS), complete selected master modules from the Continuing Professional Development (CPD) short courses program (20 ECTS) and write a master thesis (10 ECTS). Students can enroll in both the ECPM course and the master course concomitantly. A study duration of five years is possible.

The master modules can be chosen by preference from the ECPM or from other course providers/ partner universities, which offer training relevant to drug development sciences and the IMI PharmaTrain syllabus. Learning outcomes of the modules are assessed individually upon completion of each module to achieve the credit points. We strongly recommend that you contact the ECPM course directorate to ensure courses will be accredited before enrolling in a course at other universities.

The Master thesis topic ideally relates to the candidates' area of work or special interest and may either be suggested by the participant or discussed and developed further with the course directorate. Please note that the topic of the thesis must be approved by the course directorate before initiation. Once the above steps have been taken, the thesis may be started at any time. The written report covers the work performed within the scope of the thesis. The text should not exceed 40 pages. The thesis (including preparation for the final examination) should be completed within four semesters based on part-time study. The final thesis must be handed in two months before the final examination.

Swiss Specialist in Pharmaceutical Medicine (FMH and SwAPP)

Participants, who successfully completed a DAS, can apply as an MD for a Swiss Specialist in Pharmaceutical Medicine Diploma offered by the FMH (Swiss Association of Medical Doctors – www.sgpm.ch) and as an MSc or PhD for a SwAPP (Swiss Association of Pharmaceutical Professionals – www.swapp.ch) Diploma.

Final Examination

To take the examination and receive a title from the University of Basel, at least 80% onsite course attendance is required. The final examination is a closed book exam and will be performed on iPads onsite on the university campus. We use the BeAxi software for e-assessments and if you would like to familiarize yourself with the software, a test version is available. Participants who choose to accomplish the DAS can take all three exams on one day, or split the exams on two days. For the FMH title, it is mandatory to take the exams on two days, as the MCQ exam has to be passed first, before the oral and essay exams can be taken.

The Bologna Process and the European Higher Education Area

The Bologna Process is a mechanism promoting intergovernmental cooperation between 48 European countries in the field of higher education. It seeks to bring more coherence to higher education systems across Europe. The system established the European Higher Education Area to facilitate student and staff mobility, and to make higher education in Europe more attractive and competitive worldwide.

European Credit Transfer and Accumulation System (ECTS)

The European credit transfer system (ECTS) is a learner-centered system for credit accumulation and transfer, based on the principle of transparency of the learning, teaching, and assessment processes and harmonizes the European title system.

	CAS	DAS	MAS	Swiss Specialist in PM or SwAPP Diploma	CPD
6 Diploma Modules	■	■	■	■	□
MCQ Examination	■	■	■	■	□
Oral/Essay Examination	□	■	■	■	□
Single or individual modules	□	□	■	□	■
Master thesis	□	□	■	□	□
Practical work experience	□	□	□	■	□
ECTS Credits	20	30	60	30	1–5
Title	Certficate of Advanced Studies (CAS) in Pharmaceutical Medicine	Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine	Master of Advanced Studies (MAS) in Medicines Development	Specialist Title → Application with Professional Association	Certificate of Attendance

ECPM Course and Modules
From Molecule to Marketplace

Course Structure

The ECPM course program consists of 24 face-to-face teaching days divided into six modules over a period of two years (four days from Monday to Thursday), including team involvement in mentored, case-oriented breakout sessions. In addition, approximately eight hours of distance learning per module is required in order to prepare for the case studies. The course language is English.

Two Parts form the ECPM Course

1. ECPM Course Modules
The focus of the ECPM course modules is on teaching the basics of drug development. Upon completion of the six modules, students can choose to take a multiple choice questions (MCQ) exam, resulting in a CAS in Pharmaceutical Medicine. In order to qualify for a DAS in Pharmaceutical Medicine, students will need to take the MCQ exam, as well as an oral and an essay exam.

2. Continuing Education Seminars – 'Frontiers in Drug Development'
While the first three days of each module of the ECPM course focus on teaching the basics of drug development, the fourth day is conducted as a seminar, dedicated to new trends and developments in drug development science. It is possible to book the 'Frontiers in Drug Development' seminar separately as continuing professional education. The seminar is open to our alumni and other interested scientists. For participants of the ECPM course, the seminars are mandatory.

Course Dates

Module 1	Global Drug Development and Pharmaceutical Business Environment	06.09. – 09.09.2021
Module 2	From Non-Clinical Testing to First-in-Human	07.02. – 10.02.2022
Module 3	Planning, Collecting and Managing Clinical Data	20.06. – 23.06.2022
Module 4	Clinical and Safety Data Evaluation and Biostatistics	05.09. – 08.09.2022
Module 5	Global Registration and Approval Process	06.02. – 09.02.2023
Module 6	Integrated Product Development, Healthcare Marketplace and Marketing	19.06 – 22.06.2023
Final Examination	Multiple Choice	22.08.2023
	Oral / Essay	22.08.2023 or 12.09.2023

September 6 – September 9, 2021

Global Drug Development and Pharmaceutical Business Environment

1

Module 1

Content

Principles and organization of global pharmaceutical research and label driven product development. Future directions of global pharmaceutical, health economics and business environments, and implications for drug selection, drug development, regulatory and business evaluations. Innovation in discovery and development as a response to medical and market needs. Health economics and disease management and their application in the changing healthcare environment. Patenting of new chemical and biological compounds.

Key topics

- Discovering, modifying, assessing and patenting new chemical and biological compounds
- System biology and principles of translational research
- Target identification and validation
- Introduction into the drug development process and the healthcare environment
- Drug development for special populations
- Project and portfolio management techniques

Learning outcomes

At the end of this module the student should be able to outline the:

1. Principal discovery and validation steps in drug development
2. The elements, functions and the management involved in the translational research and integrated development of a new drug
3. Principles of patenting new chemical and biological compounds

Djordje Filipovic, Global Head of Learning Pharmaceuticals, Novartis Ltd., Basel, Switzerland

"The pharmaceutical industry is driven by the purpose to deliver innovative new treatment options for the benefit of patients. We require the best talents with an agile mindset, a focus on life-long learning and the ability to rapidly link innovation and implementation. With its 30 years of experience, the ECPM delivers a state of the art continuing education and training platform in pharmaceutical medicine that highly supports pharmaceutical talent development."

2

Module 2

February 7 – February 10, 2022

From Non-Clinical Testing to First-in-Human

Content

Prioritizing areas of therapeutic interest and target product profile. Principles for target identification, understanding of combinatorial chemistry and drugability of new compounds. Exploring possible new drugs by means of preclinical safety and efficacy testing. The choice and the predictive value of animal testing for toxicity data as well as the principles of ADME, possibilities and opportunities of computer assisted modeling on the way to proof of concept. Procedures and databases for pharmacovigilance and pharmacoepidemiology surveillance. Pharmaceutical engineering and choice of formulation.

Key topics

- Non-clinical testing for chemical and biological compounds, including pharmacology (ADME) and toxicology
- Development, testing and formulation of chemical and biological compounds
- Non-clinical testing requirements prior to First-in-Human studies
- Molecular and cellular basis of toxicological reactions
- Genetic and genomic factors in drug development and drug response
- Transition from non-clinical to First-in-Human studies
- Clinical pharmacology and application to clinical development

Learning outcomes

At the end of this module the student should be able to outline the:

1. Value of non-clinical testing programs and their integration into the overall drug development plan
2. Steps in the pharmaceutical development of a drug substance
3. Principles of clinical pharmacology and their application to clinical development
4. Requirements, planning and regulations of non-clinical and First-in-Human studies

Gabriele Hintzen, Translational Project Lead, Affimed GmbH, Heidelberg, Germany

"On one hand, the ECPM gives you an excellent overview of all aspects of drug development and the pharmaceutical business, on the other hand, you have the opportunity to expand your network with experts from the faculty as well as amongst the other students. The course has a long-lasting impact on my career and personal development."

June 20 – June 23, 2022

Planning, Collecting and Managing Clinical Data

3

Module 3

Content

The planning, the choice of different trial designs, the randomization modes and the choice of endpoints are discussed. The different aspects of the conduct of a trial, i.e. study monitoring, principles of good clinical practice (GCP), adverse event monitoring (risk/benefit assessment) and data management are demonstrated. A basic introduction to biostatistics is given.

Key topics

- Early studies in patients: dose-finding / proof of mechanism studies
- Confirmatory clinical development plan
- Different types of clinical studies, including placebo controlled studies
- Planning and managing clinical trials
- Planning of clinical trial supplies for test substance and comparators
- Legislative requirements and Good Clinical Practice (GCP) in the clinical trial process
- Investigator and site recruitment, investigative site management and conflict resolution
- Statistical considerations in the design of clinical trial protocols and analysis of clinical trial data
- Procedures for clinical trial data collection and data management

Learning outcomes

At the end of this module the student should be able to outline the:

1. Management of early studies in patients and their impact on the drug development plan
2. Principles and practical relevance of ethical and legal issues in biomedical research
3. Design of various types of clinical studies and statistical methods used
4. The confirmatory clinical development plan including the role of relevant study committees
5. Key issues involved in the conduct of a clinical study in terms of Good clinical Practice (GCP)

Diane Jorkasky, Expert Consultant, NDA Partners; Member of Board of Directors, Altimmune Inc., Devon, PA, USA

"The ECPM course envelops participants in an active, diverse and comprehensive learning experience in the drug development journey – from the chemical in the flask to the drug on the market."

4

Module 4

September 5 – September 8, 2022

Clinical and Safety Data Evaluation and Biostatistics

Content

The different tests and methods of biostatistics are discussed. The application of different trial designs is simulated, within-trial decisions, data management, extraction, manipulation and storage of data.

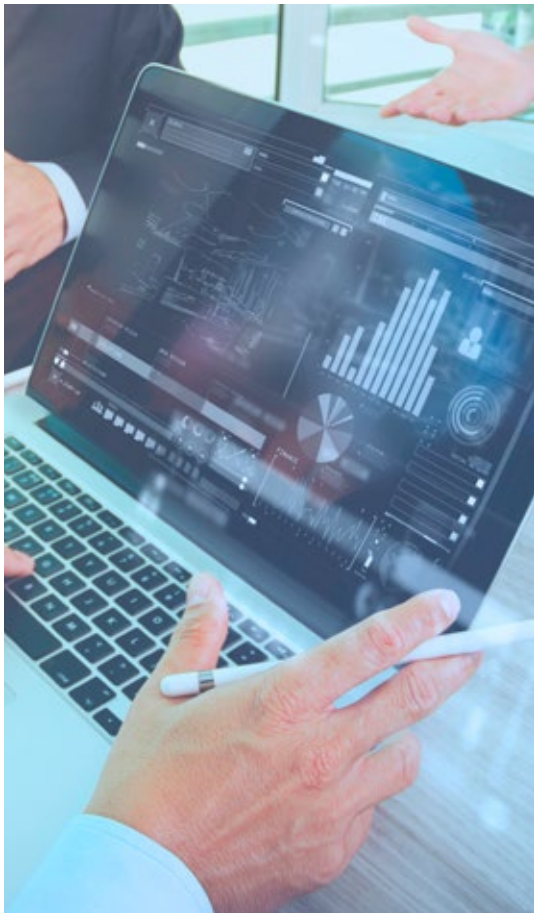
Key topics

- Development of a clinical trial protocol and the investigator drug brochure (IDB)
- Quality management issues in clinical trials
- Legal and ethical provisions for protection of clinical trial subjects
- Statistical methods used in clinical research
- Collection and evaluation of adverse event data in clinical trials
- Drug safety monitoring board and other relevant study committees
- Evaluation and interpretation of clinical trial results

Learning outcomes

At the end of this module the student should be able to outline the:

1. Development of a clinical trial protocol and the role of the investigator drug brochure (IDB)
2. Evaluation and interpretation of clinical trial results
3. Main statistical methods used in clinical data analysis
4. Collection and evaluation of adverse event data in clinical trials



Antoine Diserens, Financial Analyst of Health Care Sector, Rahn+Bodmer Co., Zurich, Switzerland

"As an Equity Analyst covering Health Care companies ECPM gives me a broad overview, which helps me where to focus on in my analysis. It provides me with a comprehensive understanding of what happens in ten years of developing a drug from preclinical trials to market launch."

February 6 – February 9, 2023

Global Registration and Approval Process

5

Module 5

Content

Overview of mechanisms and regulatory management systems in Europe, USA and Asia. Requirements of a regulatory application, documentation and collaboration between developers and regulators. Special regulatory procedures, strategies and crisis management.

Key topics

- Regulation of pre- and post-approval of medicines at EU and global level
- Regulatory activities within a pharmaceutical company
- Labelling requirements
- National and international bodies responsible for medicines regulation and their procedures
- Appeal and Referral
- Off-label/unlicensed use of medicines
- International Council for Harmonisation (ICH)
- Common technical document (CTD)
- Special Interest Area Community (SIAC)
- Pharmacovigilance: Classification of adverse events/reactions
- Safety reporting requirements pre- and post-approval
- Benefit/risk assessment and pharmacoepidemiology throughout the lifecycle of a medicine

Learning outcomes

At the end of this module the student should be able to outline the:

1. General principles of medicines and medical devices regulation (both pre- and post-approval)
2. Principles and management of drug safety and pharmacovigilance
3. Role of pharmacoepidemiology in the lifecycle management of a medicine

Dr. Claus Bolte MD MBA, Head Marketing Authorization and Executive Board Member, Swissmedic, Bern, Switzerland

"ECPM provides a comprehensive curriculum with a first-class faculty for all those who want to shape the future of pharmaceutical medicine and also use this premium platform for access to an extensive global network."

6

Module 6

June 19 – June 22, 2023

Integrated Product Development, Healthcare Marketplace and Marketing

Content

Principles of project and portfolio management, including aspects of planning, project evaluation and decision making. Management structure and organization of clinical development. Team work and performance assessment. Interaction between project teams and business. How to place a new drug successfully into the market.

Key topics

- Principles and regulations of drug marketing
- Good Promotional Practice: ethical and legal principles pertaining to marketing activities
- Health economics and health technology assessment (HTA)
- Patient organizations
- Life cycle management
- Strategic considerations of portfolio management

Learning outcomes

At the end of this module the student should be able to outline the:

1. Principles and practice of the quality system of drug lifecycle activities
2. Ethical and legal principles of market introduction of a drug
3. Principles and practical application of health economics and health technology assessment (HTA) within the healthcare marketplace

Dr. Chandra P. Leo, Investment Advisor, HBM Partners, Zug, Switzerland

"For a rigorous and comprehensive overview of key topics and important trends in drug development and associated disciplines, the ECPM courses are second to none. Leading industry experts as faculty and real-life case studies will help you to establish a solid foundation, or to refresh and expand your existing knowledge."

Teaching Framework
Combine onsite training with online follow-up

Teaching Principle

The ECPM course follows the IMI PharmaTrain Syllabus for postgraduate education in Pharmaceutical Medicine and aims for the highest academic standard based on Bloom's Taxonomy of Educational Objectives. The learning process includes didactic teaching and places a great emphasis on interactive participation. Each module includes the following activities:

Lectures
Selected faculty from industry, academia and regulatory authorities provide state-of-the-art lectures spanning both the basics of drug development as well as current trends in important drug, diagnostic and therapeutic areas as well as related issues.

Lectures focus on interactive learning, in-depth discussions and break-out groups, where participants work on case studies that complement the lectures in each module. To ensure that the curriculum is aligned with trends in pharmaceutical medicine, the ECPM consults with an advisory board of external specialists on a regular basis.

Students are provided with a summary, slides and reference list of each lecture. In addition, a short summary or review article embracing the topic will be made available.
The course language is English.

Case Studies
Participants work in small interdisciplinary teams on 'real life cases'. Problems are analyzed and discussed together with faculty members. Participants try to reach a common strategy, which is then presented and defended in a roundtable discussion. Documents and background literature of the case studies are made available prior to each course module. We expect students to read the materials in advance, in order to be able to actively participate in the discussion.

Gray Book
A special feature is the availability of the online book "Grays Medicines Development" by Dr. Julian Gray. It summarizes the key aspects of the Pharma-Train syllabus representing the whole drug development process.

Frontiers in Drug Development Seminars
The Frontiers in Drug Development Seminars take place on day four of each course module. They are an integral and mandatory part of the course.

Teaching Evaluation

We use an evaluation software, which guarantees anonymization of the data. Student input is highly appreciated as this helps us deliver a high quality education and identify areas for improvement.

Course Material

All students are provided with electronic access to the teaching material a few days before each ECPM course module. Additionally, students can buy a printed course binder including summaries, reference list and the slides of each lecture. The cost of the printed course binder is CHF 500. The binder will be provided on the first day of each module.

Participants

The majority of our students has a higher degree such as an MSc, MD, PhD, PharmD etc. and between three to five years of relevant work experience gained in the pharmaceutical and biotech industries or service industry (e.g. consultancy, CROs), in clinical research or while working for governmental policy-makers in integrated medical product development, regulation and market introduction fields.

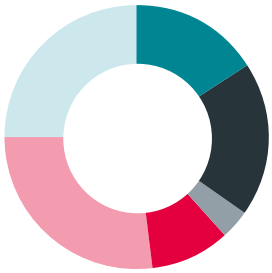
Participants of the ECPM course represent many different countries and working places worldwide. The variety of background offers a great opportunity to network and to learn from your peers.

Mr. Magdy Atta, Director Business Development

"The ECPM course is very valuable as we learn by doing and not only by listening: The integrated case studies help us to think about the information we heard, discuss it among the team and then share and discuss our range of solutions within the class. It's great to work with highly experienced course participants. Their different backgrounds make the discussions and sharing of different perspectives and experiences very enriching."

About the ECPM
The leading university institute for Pharmaceutical Medicine

Teaching Faculty



Big Pharma	18
Small and Medium Sized Enterprises	21
CRO	4
Regulatory Authorities	11
Academia/University Hospitals	30
Consultants	28

About the ECPM/Organizers

The European Center of Pharmaceutical Medicine (ECPM) or Institute of Pharmaceutical Medicine is dedicated to being the leading university institute for medicines and drug development in Europe. The ECPM belongs to the Department of Public Health of the Medical Faculty at the University of Basel and operates with partners worldwide. The institute was founded in 1991 to cover the training needs of specialists working in drug development. It comprises an education and training department (est. 1991) and a research department (est. 2003). The ECPM course was established in partnership with EUCOR, the European Confederation of the Upper Rhine Universities Medical Schools of the Universities of Basel, Freiburg i. Br. and Strasbourg together with the pharmaceutical industry.

University Network

A consortium of 21 European universities, 15 pharmaceutical companies of the European Federation of Pharmaceutical Industries Association (EFPIA), 11 learned societies (associations and agencies), three advisors and the EU performed a project (2009 – 2014) under the public private partnership of the IMI (Innovative Medicines Initiative) concerned with education and training in medicines development. The ECPM was the managing entity and the achievements of the project included: shared training syllabus, shared examination standards, mutual recognition of learning outcomes and credit points (see www.pharmatrain.eu).

The ECPM has established an international network and collaboration with courses in drug development and regulatory sciences. Its partner courses at Peking University Research Institute and the University of San Francisco Hub in Washington DC share the same teaching principles and quality label. This unique global collaboration offers the possibility to start training at one site and continue or successfully achieve the diploma at one of the sister courses in Basel, Beijing and Washington DC.

Teaching Faculty

The ECPM teaching faculty consists of about +150 international experts in regulatory sciences, medical product discovery and development, product evaluation and business practices. Lecturers and tutors will be drawn from academia, regulatory agencies (such as EMA, FDA and local agencies), pharmaceutical, diagnostic and biotechnology industry, coverage and reimbursement entities, professional societies and national institutes.

Advisory Board

The ECPM advisory board is composed of key stakeholders in medicines development representing academia, the pharmaceutical industry, regulatory authorities, the ECPM teaching faculty as well as representatives from the EUCOR medical schools and other partner universities. The advisory board members represent a critical sounding board and think tank and meet on an annual basis to review past year results. The aim of the advisory board is to advise on new strategies for the future, to ensure that the ECPM training and research cover the latest trends and developments in medicines and drug development and supports the institute to evolve its course offer to meet customer and market needs.

Communication Channels

The ECPM main communication channel is the website, available at www.ecpm.ch, which contains detailed information and background on the institute, the ECPM training & education and research team, the courses and studies offered and the research projects conducted. Several newsletter editions are sent throughout the year with updates on activities, which are also posted on the ECPM Linkedin Group that in addition offers ECPM participants, faculty and alumni to connect and network. The ECPM Annual Report provides and in-depth overview of the training & education activities, the ongoing research projects and scientific publications published throughout the year.

Organizational Information
Conduct your postgraduate studies at the University of Basel

Tuition Fees ECPM Course CAS/DAS/FMH

The tuition fee for the entire course amounts to CHF 14'750. A reduced fee of CHF 13'750 applies to continuing training centers "Weiterbildungsstätten" of SGPM (Swiss Society of Pharmaceutical Medicine) and SwAPP (Swiss Association of Pharmaceutical Professionals) and for companies who register more than 10 participants. The special fee for non-profit organizations is CHF 9'000.

The tuition fee includes online course material, lunches, coffee breaks and a welcome aperitif per module, access to the online media library and the fee for the multiple choice questions (MCQ) exam (Certificate of Advanced Studies).

Not included are the printed course materials, which are provided for CHF 500 and can be booked optionally. For the oral/essay examination (Diploma of Advanced Studies) CHF 750 will be charged. The registration for the oral/essay examination is binding and the fee is non-refundable.

The entire tuition fee is payable on confirmation of attendance by June 30, 2021. Upon request, the payment may be made in two instalments, first payment on June 30, 2021 and second payment on June 30, 2022.

Tuition Fees MAS

After starting the ECPM course you can register for the Master degree at any time and start collecting additional credit points. The maximum study time to qualify for the Master Degree is five years. The tuition fee is a follows:

- ECPM course (6 modules; 30 ECTS; CHF 14'750 or the applicable reduced fee)
- Master Modules can be either chosen from the ECPM Continuing Professional Development (CPD) short courses program or from other Universities (20 ECTS; tuition fee depends on the courses chosen and the course provider)
- Master Thesis, Final Exam and Master Diploma (10 ECTS; CHF 3'500)

	CAS	DAS	MAS	Swiss Specialist in PM or SwAPP Diploma	CPD
6 Diploma Modules	14'750	14'750	14'750	14'750	
Groups and training centres	13'750	13'750	13'750	13'750	
Non for profit organisations	9'000	9'000	9'000	9'000	
Printed course material (Optional)	500	500	500	500	
MCQ Examination Retake	– 500	– 500	– 500	– 500	
Oral/Essay Examination Retake	na	750 750	750 750	750 750	
Single or individual modules	na	na	650 – 3000	na	650 – 3000
Master thesis			3'500		
Total	14'750	15'500	about 25'000 depending on choice of modules	15'500 plus registration with professional association	na

Tuition fees in CHF / Prices 2021 (can be subject to change)

Nationalities of students
(2019–2021)
33

Number of students
(1991–2020)
2033

Beatrice Schmid
Course organisation and Administration

Admission Criteria

In order to enroll in the ECPM course, applicants must have a higher university degree, such as a Master's, MD, PharmD or PhD. The ECPM course is a postgraduate education program designed for pharmaceutical industry, regulatory and university professionals to improve their skills. Applicants should have a primary interest in medical product discovery, development, regulation and the healthcare system. The program is particularly aimed at professionals who are involved in the drug development process and have already at least one to two years working experience. Applications sur dossier are possible on an individual basis.

Application Dossier

Applications together with a one or two-page curriculum vitae and a copy of the university diploma (or a certified English or German translation) should be submitted. Applications are reviewed by the course directorate and will be confirmed on an ongoing basis. Please refer to the deadline for the course you enroll in. As enrollment is limited, prospective participants are encouraged to apply well in advance.
A strong command of English is necessary to comprehensively follow the course.

Registration

Please register online at ecpm.unibas.ch/DAS for the ECPM course. For the Master of Advanced Studies please register at ecpm.unibas.ch/MAS.

If you have questions regarding your registration, please do not hesitate to contact Beatrice Schmid
Phone +41 61 207 19 50
E-mail ecpm@unibas.ch

Deadline for Registration

The next ECPM course cycle will start in September 2021 and will end in June 2023. Deadline for registration is June 30, 2021.

Registration as Student of the University of Basel

Participants applying for the Certificate of Advanced Studies (CAS) will not be registered as students at the University of Basel. Participants who register for the Diploma of Advanced Studies (DAS) / Master of Advanced Studies (MAS) will be registered as students at the University of Basel. To obtain the student card a separate form will be provided by the university. The student registration is included in the tuition fee.

Cancellation Policy

In case of cancellation by August 31, 2021, the tuition fee less CHF 750 for administrative expenses, will be returned. Notification of cancellations must please be in writing and emailed to: ecpm@unibas.ch.

Participants who do not attend the course on the scheduled dates are considered no-shows and will be invoiced the full course fee.

Course Venue

The course will take place on the campus of the University of Basel.

Travel and Accomodation

Participants should book their own travel arrangements and hotel rooms.

Participants of the 15th ECPM Course Cycle (2019–2021).

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