Europe and US Drug/Device Product Development and Regulations

The course starts on Monday, August 22 and ends on Friday, September 30, 2022.

"From the lab bench to the bedside – a fantastic voyage of drug/device development"

- This is a unique 6-week course on Drug/Device Development and Regulation - Europe and US.
- Students will have the real-world experience of working across classical pharma/MedTech company departments with intensive team work, discussion of week's material, enabling them to write the Case Study Reports. Expect approximately 2-3 hours of work daily.
- On successful completion, the course participants will receive a Certificate of Attendance from EPFL.
- Besides, the course participants are entitled to 2 ECTS from EPFL by applying through department channels.
- The course is hybrid with most study material online but active exposure to the "meet the instructor" sessions once a week carries points and is mandatory. The "meet-the-instructors" sessions in SV 1717 will be on:
  - Monday, August 22 from 13:30 to 15:30.
  - Thursday, August 25 from 10:00 to 12:00.
  - Thursday, September 01 from 16:30 to 19:00.
  - Thursday, September 15 from 16:30 to 19:00.
  - Thursday, September 22 from 16:30 to 19:00.
  - Thursday, September 29 from 16:30 to 19:00.

The 10 Course Goals and Objectives:

Students who successfully complete this course will be able to:

1. Understand the major steps of the drug and device development process through cross-functional teamwork and report writing with pre-set deadlines, reflecting real-life situation of challenges at work in industry.
2. Compare and contrast US and European Union regulatory and quality requirements (major markets setting best practices and standards).
3. Develop tools to interaction with regulators.
4. Understand the basics of a Quality Management System.
5. Develop a Product Profile for a drug/device product or therapy.
6. Draft the basic components of a Development Plan for a Phase 1 clinical trial, including a Preclinical Plan, a Clinical Trial Protocol, and CMC (Chemistry, Manufacturing and Controls) Plan.
7. Master the basics of early stage Project Management skills.
8. Learn the essentials of Intellectual Property Rights.
9. Learn the art of successful cross-cultural communication.

10. Feel more confident about job seeking and job interviews.

PROGRAM

WEEK 1

- Welcome by:
  Prof. Bart Deplancke, Vice Dean of Innovation, EPFL.

- Keynote lecture “Research to Business” by:
  Dr. Seng Chin Mah, Chairman of the Board, BioVersys AG.

  Dr. Seng Chin Mah is Chairman of the Board of BioVersys AG. He was previously Chief Executive Officer of the Canyon Pharmaceuticals Group AG and has over 30 years’ experience in the Pharma and Biotech industry. Prior to Canyon Pharmaceuticals, he was the Head of Development of the Integration Office during the integration of Chiron into Novartis and has previously held positions including Global Head of Clinical Safety and Epidemiology, Head of Drug Regulatory Affairs Europe. He also had oversight responsibility for Clinical Quality Assurance. Dr. Mah was also a member of the Novartis Corporate Executive Group and a member of the board of directors for Novartis Europharm Ltd. During his tenure with Novartis and Ciba, he has driven transformational programs, managed large global organizations, and achieved significant business results such as the numerous global registrations of major products including Diovan. Mah has worked extensively on both development projects and marketed products. He has held numerous research and academia positions, and is currently on the boards of several biotech companies. Dr. Mah is an award-winning CEO of a biotech - The Frost & Sullivan 2011 Product Differentiation Excellence Award in Parenteral Anticoagulants recognized Canyon Pharmaceuticals Group AG for the development and launch of Iprivask® (desirudin for injection). He subsequently effected an asset transaction of the product. He possesses deep knowledge in strategic decision-making within the Pharma and Biotech industry, late-stage clinical development & regulatory experience as well as people development skills.

- Drug Development Process, and External Case Study on Drug “Detailed structure, content and deliverables of the course.”

- Explanation of multiple-choice quizzes (20 questions x 3).

- Explanation of case studies and expectations.

- Formation of teams with case studies and identification of group leaders.

- “Drug Development Process, Preclinical, clinical, CMC. EU Regulatory Process.”
  Presented by: **Gautam Maitra**, EPFL SV, Catalyze4Life, Lausanne, Switzerland.

- "Overview of Preclinical Requirements – small Molecules and Biotech Products."
  Presented by: **Hasnaà Haddouk**, Head of Biological Sciences & Non Clinical Safety Immunology at Sobi - Swedish Orphan Biovitrum, Geneva, Switzerland.

  Currently Head of Biological Sciences & Non Clinical Safety Immunology at Sobi - Swedish Orphan Biovitrum. My specialties are Regulatory Toxicology (Board Certified), Preclinical Development (Non Clinical Safety, ADME) and Translational aspects, Bioanalytical Sciences, Regulatory support, Cross-functional activities, Projects and CRO management. I received my Ph.D. in Toxicology from Bordeaux University, and I hold a Regulatory Affairs Dual Certificate in Pharmaceuticals and Medical Devices from RAPS.

- "Clinical Trials in the EU and UK (post-Brexit)."
  Presented by: **Anne Hamel**, Senior Manager Regulatory Affairs at AC Immune SA.

  Regulatory affairs professional with over 10 years of experience in regulatory submissions and drug development. Track record of delivering successful applications in Europe and USA. Skilled in the management of clinical trials applications, leading cross-functional teams and delivering high quality regulatory documentation.
  Received a PhD degree from EPFL and completed a post-doctoral work at ETHZ.

- "FONGIT – Raising the Initial Capital"."
  Presented by: **Emmanuel de Watteville,** Head of Financing Programs

  Emmanuel joined Fongit and the Swiss CTI (now Innosuisse) as a business coach and financial expert in 2003. He has extensive experience in coaching, creating, managing, developing and financing more than 200 high-tech startups across several sectors, including the medical and information technologies. In 2008, Emmanuel founded BlueOcean Ventures, a VC firm investing in early stage Life Sciences companies. Emmanuel holds a MSc in ICT from the ETHZ and an MBA from INSEAD.

- Satellite lecture – "Preclinical Strategy for Developing Drugs in Parkinson's Disease".
  Presented by: Jan Stoehr, Head, Biology Parkinson's Disease at AbbVie Greater Boston.

  Jan Stoehr Ph.D. is currently AbbVie's Head of Parkinson's disease discovery leading the global discovery efforts for Parkinson's disease (PD) within AbbVie's Neuroscience Therapeutic area, is new to our company. He and his discovery team is located in Cambridge MA (USA) and is discovering the foundational mechanisms of PD with the goal to identify and characterize novel therapeutic targets.
  Dr. Stoehr arrived at AbbVie following a tenure as Head of non-Alzheimer's disease proteinopathies at AC Immune (Lausanne, CH), where he led a team charged with developing therapeutics and diagnostics for synucleinopathies, frontotemporal lobar degeneration and neuroinflammation. Before that he worked in academia as an assistant professor together with Nobel laureate Dr. Stanley Prusiner at the Institute for Neurodegenerative Diseases, University of California, San Francisco. During his tenure at UCSF he led studies for structural and functional characterization of protein aggregates and supported UCSF's therapeutic development efforts for neurodegenerative diseases.

Some of his pre-AbbVie projects included studies on understanding the governing principles of self-propagating tau and amyloid-β aggregates; structural and biological characterization misfolded tau and amyloid-β aggregates from familial and sporadic Alzheimer's disease patients; development of passive immunotherapies targeting alpha-synuclein and TDP-43, discovery and first in human trials of novel Parkinson's disease PET ligands.
He has published widely as both a lead and corresponding author in peer-reviewed journals, and he has presented or served as an organizer and co-chair at several international conferences.

WEEK 2

- Device Development Process, and External Case Study on Devices.

- MDR, MedTech Regulatory landscape, Three Pillars – Technology, Biology, Clinical.

- International Standards.
  Ary Saaman, Director, Device Technology Management, Alvotech Swiss AG.

  M.Sc. cum laude in Chemistry and Physics from the University of Nijmegen, The Netherlands. I was a Research Fellow of the Dutch Foundation for the Fundamental Research on Matter (FOM), and an International Fellow at SRI International in Menlo Park, California, USA. Director, Device Technology Management, Alvotech Swiss AG. Worked at Debiotech S.A. (Lausanne, Switzerland) from July 1990 through January 2021 and held various positions in the fields of research & development, quality assurance, and regulatory affairs. Was responsible for setting up and maintaining Quality Management Systems that conform to European and USA requirements, the preparation of regulatory dossiers to support market authorizations for Debiotech's devices, and interfacing with regulatory agencies, including Notified Bodies, for Debiotech.
  A member of AAMI (Association for the Advancement of Medical Instrumentation). A member of RAPS (Regulatory Affairs Professionals Society) and a founding member of the RAPS Switzerland Chapter, currently serving as the Chapter's Executive Secretary and Treasurer.

- Summary of US Regulations.
  Presented by: **Ary Saaman.**

- Explanation of multiple-choice questions (20).

WEEK 3

- Role of Quality Compliance in the Regulated Industry.

- Role of Quality and **Compliance.**
  Presented by: Claude Ammann, Claude Ammann Consulting, Epalinges, Switzerland.

Director of Claude Ammann Consulting, advising pharmaceutical and biotech companies to comply with the regulations and obtain regulatory certifications. Audit suppliers and vendors to verify their compliance with agreements and GMP, GLP and GCP regulations. Built my >30 years industrial experience at Zyma and Ciba-Geigy, both now part of the Novartis group. Was Site Manager and QA Director of different small biotech companies. Own business in 2009. A Swiss "Responsible Person" as qualified by Swissmedic.

- US FDA, International Engagement, and the US-EU Mutual Recognition Agreement
  Presented by: **Matthew Scherer**, US Food and Drug Administration, Europe Office.

  Currently the Assistant Health Attache and International Program and Policy Analyst at the FDA Office of International Programs - Europe Office in Brussels. Experienced policy advisor and consultant with a demonstrated history of working with regulators, government organizations, and industry. Have skills in the pharmaceutical, biotech, medical products and food industries, particularly in the areas of negotiations, project management, policy analysis, strategy, marketing and market research.

- Explanation of multiple-choice questions (20).

- Satellite Lecture - Biotechnology – Virus Filtration Regulatory updates.
  Presented by: **Paul Cashen**, Pall Biotech.

  Paul is the Senior Bioprocess Specialist for the United Kingdom & Ireland, specialising in small-scale development and optimisation of Downstream Processing (DSP) technologies and applications. He has over 10 years' experience in development, optimisation and scale-up of biologics, with a primary focus on Gene Therapy applications.
  He joined Pall in 2016 as a Bioprocess Specialist, focusing on early development in downstream processing, providing technical support and innovation for internal and external projects. His responsibilities include process development, troubleshooting, customer training and consultancy for all DSP applications from initial harvest to final filtration.
  Paul's academic background includes a BSc in Biomedical Sciences and an MSc in Industrial Biotechnology, both from Liverpool John Moores University.

- Satellite Lecture - Biotechnology – Virus Filtration Technology updates.
  Presented by: **Lionnel Lueginbuehl**, Pall Biotech
  Lionnel is a team manager for the Aseptic Consultancy Team for western Europe, specialising in MSAT (Manufacturing Sciences and Technology) support for pharmaceutical companies, with a primary focus on aseptic technologies (sterilizing grade and viral filtration including integrity testing) with over 14 years of experience.
  He joined Pall in 2008 as an inside sales engineer, before joining the SLS team (Scientific and Laboratory Services) as a field engineer in 2009. Since then, he has been providing trainings, expertise, process development and optimization as well as troubleshooting, interacting with operators, manufacturing leadership, QA departments and engineering at customer's production sites.
  Lionnel holds an engineer diploma in Food Technology from the University of Applied Sciences Western Switzerland in Sion.

WEEK 4

- Intellectual Property – “A key to Innovation - Intellectual Property in the 21st Century”
  Presented by: **Natalia Giovannini**, Technology Transfer Manager at EPFL.

  Natalia Giovannini is an experienced professional with accumulated successful track record in technology transfer at EPFL (intellectual property, contracting, licensing and marketing) mainly in chemistry, medtech, biotech and pharmaceutical areas. She is member of the Board of swiTT, the Swiss association of university technology transfer since 2008.

- Intellectual Property
  Presented by: **Bojana Portmann**, AVP IP and Business Development at AC Immune, Lausanne, Vaud, Switzerland.

  Dr. Portmann joined AC Immune in 2011 as Intellectual Property Manager and has held multiple roles within the IP department with increasing responsibility over the past years, during which her work was mainly focused on creating and strengthening patent portfolio for biologicals, small molecules and liposomal technology. Dr. Portmann holds a Ph.D. degree from the EPFL University in Switzerland, and a LL.M. degree, Master of Intellectual Property Law and Management (MIPLM), from the CEIPI in France. She also received a M.Sc. (Dipl.-Ing.) degree in Polymer and Chemical Engineering from the University of Belgrade in Serbia.

WEEK 5

- Project Management
  Presented by: **Stephan Proennecke.**

  Stephan has 12+ years of experience in medical device industry as Project Manager and Director of Production. Strong expertise in cross-functional team management, MD development, clinical affairs management and supply chain development in various clinical fields (e.g., nephrology, diabetes, oncology, …)
  Before working in medical industry, Stephan spent 7 years as Project Manager in the consumer electronics and 6 years in the payment services industry.
  His background is a PhD in Physics from the EPFL.

WEEK 6

- Managing Cultural Diversity in Scientific and Technical Professions
  Presented by: **Lionel Laroche**, President at MultiCultural Business Solutions Inc.

  Lionel received his education in France and the United States and started his career in Canada as an engineer. He worked with technical professionals from all over the world and in Germany and Italy on expatriate assignments. The cultural adaptation process, after immigrating to Canada and working on international assignments for multinational companies, taught him so much that he decided to use the knowledge to help professionals from all over the world to achieve career success and organizations benefit from the opportunities brought by a diverse workforce and the global market.
  Over the past fifteen years, Lionel has provided cross-cultural training, coaching and consulting services to over 20,000 people through a wide range of business, government, academic, professional and non-profit organizations in fourteen countries (Canada, the U.S.,

Bermuda, Mexico, Peru, Belgium, Switzerland, France, the UK, Turkey, UAE, Hong Kong, China and Korea).
Lionel is a thought provoking and educational speaker / facilitator who presented at over 200 conferences and venues across Canada and the United States. He is the author of two books examining the impact of cultural differences on business at the organizational and individual level entitled:

- Managing Cultural Diversity in Technical Professions
- Recruiting, Retaining and Promoting Culturally Diverse Employeess

Lionel holds a Ph.D. in Chemical Engineering from the California Institute of Technology, USA and a "Diplôme d'ingénieur polytechnicien" from the École Polytechnique de Paris, France.

- CASE STUDY – "Doing a Swiss Life Science PhD out of Tanzania – Challenges and Opportunities"
  Presented by: **Lorenz Hofer**, PhD Candidate, Swiss Tropical and Public Health Institute, Allschwil.

  Lorenz is a molecular microbiologist and parasitologist currently working on his PhD at Swiss Tropical and Public Health institute. Lorenz is also a research collaborator at Ifakara Health Institute in Tanzania, East-Africa, where he is involved in several projects on the biology of malaria transmission and capacity building for malaria cell culture.

Registration and Payment

- You will need at least a Bachelor degree in any area of Life Sciences to register to the course.
- Course fee: 200 CHF for EPFL members, 400 CHF for non-EPFL members.
- Register online. Your place will be confirmed after receipt of the payment.
- Registration deadline: August 1, 2022.

Contact

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