Drug/Device Product Development and Regulation - Europe and US

August 22 – September 30, 2022

# COURSE INFORMATION

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# Course Overview

**Course Description:** The health care industry is knowledge-intensive, complex, globalized and highly regulated. This industry is comprised of drugs, biologics, biotech, medical devices and diagnostics. Advances in biotechnology, medical technology, and information technology give new hope for treating diseases never imagined before. To bring these advances from the laboratory bench to the patient bedside requires training and experience that are not available in academia. This course is intended to fill that gap. It is a six-week interactive course, involving intensive self-study and teamwork. The course will bring you close to your future workplace. Experienced instructors will introduce you to the fundamentals of drug/device development, and the requirements for regulatory and quality compliance. You will have exposure to the requirements in Europe and the US in terms of the approach, the attitude to risk-taking, and managing cultural divide. This can be extrapolated to Asia, Africa and Latin America as you will develop a mind frame to handle the shift.

The world's regulatory, clinical and chemistry, manufacturing and controls (CMC), and medical technology arena is indeed complex, science-based and constantly changing. This graduate-level course covers the steps in the development and commercialization of drugs, biotech products and medical devices. It is designed to introduce regulatory and clinical professionalism to students having little or no exposure to industry. In addition, it will provide the "real world" knowledge and skills to develop solutions to multi-national regulatory and clinical problems.

This course will explore development strategy and regulations in their current status in many of the key areas of the world today. It will provide students with greater comprehension of the following main areas:

1. The basic concepts of drug / device development.
2. Regulatory and quality requirements in Europe and the USA.
3. Project Management, Intellectual Property, and managing cultural Diversity.
4. Skills in interacting with those in the profession and impinging professions in international environments.
5. Exposure to the multitude of current and emerging professions in the healthcare industry.

You will learn and apply your knowledge concurrently enabled by case studies. We will focus more on Europe and US, where it is likely you will have your first and most frequent interaction(s). This course will strengthen your confidence during the first and subsequent exploration of the work world to land in the right job. It will also serve as a resource for the future when you may be called upon to work internationally.

**Course Goals & 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.

# Enrollment Information

Registration and Payment

You will need at least a Bachelor degree in any area of Life Sciences to register to the course.

Registration deadline: August 1, 2022

Course fee: 200 CHF for EPFL members, 400 CHF for non-EPFL members

[Educate4Life ‒ SV ‐ EPFL](https://www.epfl.ch/schools/sv/school-of-life-sciences/innovation/catalyze4life/educate4life/)

# Course Materials

There is no required text for this course. The readings come from the Internet and are listed by week under "Weekly Activities." You will also find these readings under "Class Library", organized by topic.

The following text is optional:

**Textbook**: *Fundamentals of International Regulatory Affairs, 4th Edition (e-book)*

**Publisher**: Regulatory Affairs Professionals Society, 2018

**ISBN:** 978-1-947493-17-9

# Course Structure and Conduct

In-person attendance on dates of open sessions is mandatory, exceptions are only in case of illness. Inability to attend will entail deduction of 2 points per session.

**Course Assessment and Grading Table 1: Summary of Grade Points**

|  |  |
| --- | --- |
| **Assignments** | **Points** |
| Weekly Quizzes (3 @ 10 pts each) Weeks 1, 2, 3 | 30 points |
| Weekly Quizzes 4, 5, 6 | 30 points |
| Team Case Study Project   * Individual Case Study Report (14 pts) * Team Case Study Presentation (14 pts) * In-person attendance to the open sessions (12 pts) | 40 points |
| **Course Total:** | **100 points** |

**Table 2: Grading Scale**

|  |  |  |  |
| --- | --- | --- | --- |
| **A** = 100-95 | **B+** = 89-87 | **C+** = 79-77 | **D+** = 69-67 |
| **A-** = 94-90 | **B** = 86-84 | **C** = 76-74 | **D** = 66-64 |
|  | **B-** = 83-80 | **C-** = 73-70 | **D-** = 63-60 |
|  |  |  | **F** = 59 or < |

**Table 3: Course Due Dates**

This course runs from 22/08/22– 30/09/22.

|  |  |  |
| --- | --- | --- |
| **Week** | **Due Date** | **Deliverable\*** |
| Week 1: The Drug Development Process | 24/08/22 | Choice of Track, Team Case Study Project (TCSP): Sign up for a team |
|  | 25/08/22 | “Meet with Your Instructors” Zoom session” |
|  | 25/08/22 | Team formation |
|  | 26/08/22 | Choose a team leader |
|  | 04/09/22 | Quiz 1 |
|  |  |  |
| Week 2: The Device Development Process | 01/09/22 | “Meet with Your Instructors” session (ungraded) |
|  |  |  |
|  | 11/09/22 | Quiz #2 |
| Week 3: Quality Management Principles |  |  |
|  | 15/09/22 | “Meet with Your Instructors” session |
|  | 18/09/22 | Quiz #3 |
| Week 4: Intellectual Property | 25/09/22 | Quiz #4 |
| Week 5: Project Management | 02/10/22 | Quiz #5 |
| Week 6: Managing Cultural Diversity in Technical & Scientific Professions | 09/10/22 | Quiz #6 |
| Individual Case Study Report  Team Presentation | 15/10/22  10/11/22 |  |

# Academic Honesty

Any cheating or plagiarism may result in failing this class.

[Plagiarism and illegal copying ‒ Internal trainings ‐ EPFL](https://www.epfl.ch/campus/services/internal-trainings/language-centre/pedagogical-approach/plagiarism-and-illegal-copying/)

Examples of Plagiarism include but are not limited to:

* + Using sources verbatim or paraphrasing without giving proper attribution (this can include phrases, sentences, paragraphs and/or pages of work)
  + Copying and pasting work from an online or offline source directly and calling it your own
  + Using information you find from an online or offline source without giving the author credit
  + Replacing words or phrases from another source and inserting your own words or phrases
  + Submitting a complete piece of work you did for one class to another class

# Respect for Diversity

It is this program's intent that students from all diverse backgrounds and perspectives be well-served by this course, that student learning needs be addressed, and that the diversity that students bring to this class be viewed as a resource, strength and benefit. It is our intent to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let your instructor or program administrators know of ways to improve the effectiveness of the course for you personally or for other students or student groups.

# Estimated time commitment

It is expected that students will spend approximately 14-16 hours per week on a 1-unit four-week course, including viewing course presentations, reviewing readings and resources, interacting with fellow students and the course instructor, and completing assignments and activities.

# Interacting with your instructor

If you have additional questions, email me and I will answer as quickly as possible. If you do not get an immediate answer, please wait; I attempt to respond to all email requests within 24 hours.

I will make my best effort to grade student work within a week of the assignment due date.

Make sure to let me know how you're doing. It is much better to ask early and get help if you need it.

**Enjoy your course!**