UNIVERSITY

INDUSTRY

BRIDGE THE GAP !

CILS

CERTIFICATE IN INDUSTRIAL LIFE SCIENCES

IMPROVING THE EMPLOYABILITY OF GRADUATES WITH A UNIVERSITY DEGREE IN LIFE SCIENCES

UNIVERSITÉ DE GENÈVE

FACULTÉ DES SCIENCES

Certificate in Industrial Life Sciences (CILS)

General organization of the Certificate in Industrial Life Sciences (CILS)

Courses will be given over a 6 month period by – or in collaboration with – experts from various companies active in the field of Life Sciences.

The topics covered by this certificate include:

- *Introduction to the pharmaceutical industry*
- *Drug discovery*
- *Drug development and clinical trials*
- *Biostatistics in drug development*
- *Quality control management*
- *Patenting procedures*
- *Development of predictive medicine*
- *In vivo models*
- *Ethics*

> Once validated, these courses will provide 24 ECTS (European credits)
> Students will also be required to produce a portfolio on a theme related to the courses that they have received during the CILS program. This personal portfolio will be evaluated by industrial experts (CILS partners, Advisory Board) and will provide 6 ECTS
> **In total the CILS program corresponds to** **30 ECTS**

Although not a requirement of the CILS program, the students are strongly encouraged to develop their professional skills by undertaking some form of practical training / internship in a non-academic institution in addition to the coursework. The Career Center of the University of Geneva (Career Center; https://www.unige.ch/dife/carriere/) will help in the organization of these traineeships.

CILS program: Courses

The course content of the CILS program is designed to evolve according to the priorities and interests of the companies active in the field of Industrial Life Sciences and will be reassessed every year by the Advisory Board.

Course name	Responsible	Contributors	Dotation
1. INTRODUCTION TO THE PHARMACEUTICAL INDUSTRY	Pr. L. SCAPOZZA	*Dominik HOTZ,* **Leader Pharma / Life Sciences Consulting, PricewaterhouseCoopers (PwC)** *Dr Bodo BAUMEISTER*, **Partner in PwC's Life Sciences Consulting practice in Switzerland**	50 hrs 5 ECTS
2. DRUG DISCOVERY AND DEVELOPMENT : AN INDUSTRIAL PERSPECTIVE	Pr. Y. KALIA	*Dr Marco Prunotto,* **Principal Senior Scientist, Roche**	20 hrs 2 ECTS
3. DRUG DEVELOPMENT AND CLINICAL TRIALS	Pr. L. SCAPOZZA	*Dr Sabine Latour*, **Director, Global Market Access , Debiopharm;** *Dr Andres McAllister*, **AM Consulting;** *Dr A. Naik,* **Senior Consultant, Triskel Integrated Services**	24 hrs 2.5 ECTS
4. INTRODUCTION TO BIOSTATISTICS: REAL LIFE EXAMPLES IN CLINICAL RESEARCH AND DEVELOPMENT	Geneva School of Economics and Management (GSEM)	*Dr Francois Curtin,* **CEO, GeNeuro SA** *Dr David Warne,* **Consultant Biostatistician**	24 hrs 2.5 ECTS
5. BIOTECHNOLOGY DEVELOPMENT	Pr. J. GRUENBERG	*Dr Walter Ferlin,* **NovImmune**	13 hrs 1.5 ECTS
6. PERSONAL GENOMICS & PREDICTIVE GENETICS	Pr. JC MARTINOU	*Dr Goranka Tanackovic* **CEO, Gene Predictis** *Pr Daniel Kraus*, **Innovation Law, University of Neuchatel**	10 hrs 1 ECTS
7. THEORY into PRACTICE: CREATING a SUCCESSFUL BUSINESS in Life Sciences	Pr. JC MARTINOU	*Dr Jurgi Camblong,* **CEO, Sophia Genetics**	10 hrs 1 ECTS
8. QUALITY BY DESIGN (QBD) TO ENSURE PRODUCT QUALITY and OPERATIONAL EXCELLENCE (Lean 6 Sigma)	Pr. Y. KALIA	*Michael Bowley,* **Associate VP Technical Support, Compliance, Ferring** *Jérôme Repiton,* **Director, Global Operational Excellence, Ferring** *Julien Boccadoro,* **Process Development Manager, Ferring**	15 hrs 1.5 ECTS Ferring, on site
9. PHARMACEUTICAL PROJECT AND PORTFOLIO MANAGEMENT	Pr. Y. KALIA	*Dr Andrew Sadler,* **Director of the Project Management Office and Portfolio management, Ferring**	6 hrs 0.5 ECTS
10. PATENTING PROCEDURES AND INTELLECTUAL PROPERTY	Pr. L. SCAPOZZA Pr. JC MARTINOU	*Pr Daniel Kraus*, **Innovation Law, University of Neuchatel** *Dr Laurent Miéville,* **Director, Unitec** *Dr Kamran Houshang Pour,* **Patent Expert at Swiss Federal Institute of Intellectual Property (IGE/IPI)** *Dr Pascal Weibel* **Head Patent Examination at IGE/IPI**	20 hrs 2 ECTS
11. PRE-CLINICAL IN VIVO MODELS	Pr. I. RODRIGUEZ	*Dr Fabienne CHABAUD* **Coordinator RESAL** Resal module-1 theory course	20 hrs 2 ECTS
12. ETHICS IN RESEARCH	Pr. D. SPRUMONT	*Pr. Dominique SPRUMONT,* ***Deputy*** **Director Swiss School of Public Health, Director of CER-VD**	24 hrs 2.5 ECTS
13. FINAL PERSONAL PROJECT	Dr B. KAUFMANN Pharma Sciences	Literature report : (i) review on topics proposed during the lectures with an oral presentation (ii) written summary of insights gained during the site visits to companies (iii) poster presentation	6 ECTS
		Total	**30 ECTS**

INFORMATION on TEACHING MODULES

Course 1. Introduction to the pharmaceutical industry

Lecturer:

Dominik HOTZ, Leader Pharma / Life Sciences Consulting, PricewaterhouseCoopers (PwC)
Dr Bodo BAUMEISTER (Partner in PwC's Life Sciences Consulting practice in Switzerland @ PricewaterhouseCoopers – PwC - Switzerland)

Course Outline:

The objective of this course is to gain an overview of the pharmaceutical & biotech industry, its history, structure and challenges and the organisational structure of pharmaceutical companies. Starting with an overview of the industry, the course will explore some of the most pressing challenges the industry faces. During the final session 2 executives from the industry will discuss the opportunities and challenges they are facing with the participants.

Schedule:

- Day 1: Industry Overview: History, Industry Structure, Challenges and Organisational Structures
- Days 2-4: Challenges Facing the Industry: Case Studies
- Day 5: Meet the Industry

Preparation Needed:

- Day 1: None
- Days 2-4: Prepare Case Studies: 20 hours
- Day 5: Prepare Interview with Industry Executives: 1 hour

(Please note: The date of Day 5 may change depending on the availability of the industry executives participating; any change in the date will be discussed with the participants to ensure that everyone can attend.)

Agenda (may be subject to modifications):

5 one-day sessions, on each session the course will take place between 10am-1pm and 2-5pm.
50 hours in total (30 hours teaching – 20 hours home work)

Date	*Session #*	*Time schedule*	*Location*
Tue 19 02.2019	1	10 :00-17 :00	CMU room S3
Fri 15.03.2019	2	10 :00-17 :00	CMU room S3
Fri 05.04.2019	3	10 :00-17 :00	CMU room S3
Fri 10.05.2019	4	10 :00-17 :00	CMU room S3
Fri 24.05.2019	5	10 :00-17 :00	CMU room A04.2906

Evaluation mode:

Attestation (delivered based on attendance and active participation during the course

ECTS dotation:

5 credits (ECTS) (including preparatory work)

Course 2. Drug discovery & development: an industrial perspective

Lecturer:

Dr Marco PRUNOTTO (Senior Clinical Development Scientist at Roche, Basel)

Course Outline:

- Strategy and Trends in Pharma today;
- A therapeutic area under the microscope;
- Explore serendipity: phenotypic drug discovery back into the game

Agenda (may be subject to modifications):

5 sessions of four hours each, 20 hours in total

Date	*Session #*	*Time schedule*	*Location*
Thu 21.03.2019	1	13 :00-17 :00	CMU room A04.2906
Mon 01.04.2019	2	13 :00-17 :00	CMU room S4
Mon 29.04.2019	3	13 :30-17 :30	CMU room S3
Mon 13.05.2019	4	13 :00-17 :00	CMU room S3
Tue 21.05.2019	5	09 :00-13 :00	CMU room S3

Evaluation mode:

Attestation (delivered based on attendance and active participation during the course)

ECTS dotation:

2 credits (ECTS)

Course 3. Drug development: regulatory aspects and clinical trials

Lecturers:

Dr Andres McALLISTER (MD, PhD consultant at AM Consulting)
Dr Aarti NAIK (Senior Consultant, Triskel Integrated Services)
Dr Sabine LATOUR (Director Global Market Access at Debiopharm)

Objectives:

To give the students an introduction to the main topics linked to setting up *the clinical evaluation of a drug* and preparing *a dossier to be submitted to regulatory agency for approval*.

Course Outline:

- Session 1 Introduction (Andrés Mc Allister)
- Session 2 Pharmacovigilance/safety (Andrés Mc Allister)
- Session 3 Clinical protocols 1 (Andrés Mc Allister)
- Session 4 Clinical protocols 2 (Andrés Mc Allister)
- Session 5 Clinical study/organization 1 (Sabine Latour)
- Session 6 Clinical study/organization 2 (Sabine Latour)
- Session 7 Regulatory aspects of drug development and approval (Aarti Naik)
- Session 8 Regulatory aspects of drug development and approval (Aarti Naik)
- Session 9 Clinical study/organization 3 (Sabine Latour)
- Session 10 Clinical study/organization 4 (Sabine Latour)

Endpoints for single modules:

Pharmacovigilance /safety:

The students understand how the clinical safety profile of a drug is defined during premarketing and postmarketing periods
The students understand the aims and the methods of passive pharmacovigilance vs. proactive pharmacovigilance (pharmacoepidemiology).

Clinical study/organization:

The students know how a controlled clinical study is planned, performed and monitored
The roles of the different actors, including the hospital pharmacist, are discussed
The students know what is meant by Good Clinical Practice (GCP)
The students know what a patient consent form is (informed-consent documents)

Regulatory aspects of drug development and approval: The students will:

- understand the role of regulatory agencies in the development, approval and post-marketing lifecycle of medicines
- learn about fundamental European legislation governing the use of medicinal products in humans
- understand how medicines are approved in Europe and about different licensing procedures available in Europe
- learn about the content and format of a dossier ("marketing authorisation application") necessary for obtaining approval for medicines from regulatory agencies

Agenda:

6 days, 24 hours in total.

Date	*Session #*	*Time schedule*	*Location*
Thu 21.02.2019	1&2 (AMcA) – 4hrs	13 :30-17 :30	CMU room A04.2713
Thu 14.03.2019	3&4 (AMcA) - 4hrs	13 :30-17 :30	CMU room A04.2713
Thu 28.03.2019	5&6(SL) – 4hrs	13 :30-17 :30	CMU room A04.2713
Thu 11.04.2019	7&8 (AN) – 4 hrs	13 :30-17 :30	CMU room B01.2426 (Renold)
Thu 09.05.2018	9&10 (SL) – 4hrs	13 :30-17 :30	CMU room A04.2713
Thu 16.05.2019	Wrap-up session (AMcA) – 4hrs	13 :30-17 :30	CMU room B01.2426 (Renold)

Evaluation mode:

certificate of attendance and case study presentation during wrap-up session

ECTS dotation:

2.5 credits (ECTS)

Course 4. Introduction to Biostatistics: Real Life Examples in Clinical Research and Development (Geneva School of Economics and Management – GSEM – University of Geneva)

Lecturers:

Dr François CURTIN (Pharmacovigilance, Corporate Medical Director)
Dr David W. WARNE (Consultant Biostatistician)

Objectives:

The course offers an introduction to different aspects of biostatistics focusing on how biostatistics is used in drug development and health care research. Students will see how biostatistics can be applied to medical and pharmaceutical research to respond to critical questions of medicine and biology. The course should elicit the interest of students to pursue further study in the field of biostatistics or to consider starting a Professional career in this applied field of statistics.

With six blocks, the course discusses topics of biostatistics, which are key to support the development of new drugs and to explore medical questions from a statistical perspective. The course highlights some statistical issues and underlines the role of applied statistics in drug development and health care research. It builds on the theoretical concepts taught earlier during the Master's programme or during an introductory statistics course focusing on the practical application of biostatistics.

Course outline:

- **Module 1: Overview of Biostatistics:** we introduce the clinical development of new drugs and describe the need for the clinical trial methodology to support this development; some trial examples are discussed.
- **Module 2: Trial Design I -** Different experimental designs of clinical trials (parallel, cross-over, cluster, sequential, adaptive trials) are presented with their main statistical methodologies, advantages and issues.
- **Module 3: Trial Design II -** Operational and technical issues related to the performance of clinical trials are presented along with the main regulatory texts related to clinical studies. Technical points such as randomization of patients, sample size and power calculations are introduced.
- **Module 4: Trial Analysis I -** The analysis of biostatistical data with emphasis on specific estimators and statistical models frequently used in trials, including survival analysis, are presented. The methodology to analyse data in pharmaceutical trial is discussed, as well as related issues such as missing data.
- **Module 5: Trial Analysis II** - Analysis, review of data and monitoring of results are discussed. Alternative approaches such as Bayesian models and equivalence/non-inferiority studies are presented.
- **Module 6: Other Applications of statistics in medicine**: Some other applications of biostatistics useful for the understanding of disease causation (epidemiology), the synthesis of studies (meta-analysis) and the effect of medications over large populations (pharmaco-epidemiology) are discussed.

Agenda (should not be subject to modifications):

6 x 4hrs modules, Wednesday from 08:15 to 12:00, 24 hours in total

Date	*Session #*	*Time schedule*	*Location*
Wed 20.02.2019	1	08 :15-12 :15	UniMail, room M3220
Wed 13.03.2019	2	08 :15-12 :15	UniMail, room M3220
Wed 27.03.2019	3	08 :15-12 :15	UniMail, room M3220
Wed 10.04.2019	4	08 :15-12 :15	UniMail, room M3220
Wed 08.05.2019	5	08 :15-12 :15	UniMail, room M3220
Wed 22.05.2019	6 **+ EXAM**	08 :15-12 :00	UniMail, room M3220

Evaluation mode:

based on continuous assessment + final exam **on May 22nd**

ECTS dotation:

2.5 credits (ECTS)

Course 5. Biotechnology development

Lecturers:

Dr Amanda PROUDFOOT
Dr Emmanuel MONNET
Dr Nicolas FISCHER
Giovanni MAGISTRELLI
Dr Adrian HAINES
Dr Vanessa BUATOIS
Dr Laetitia SORDE
Dr Hasnaà HADDOUK
Dr Robert NELSON
Dr Krzysztof MASTERNAK
Dr Walter FERLIN

Course Outline:

- Overview of the steps for drug development (2h, EM)
- Therapeutic antibody formats and discovery platforms (2h, NF)
- Toolbox to streamline the identification of Antibody Drug Candidate (1h, GM)
- Manufacturing antibodies (1h, AH)
- Preclinical drug development: *in vitro* and *in vivo* pharmacology (2h, VB)
- Introduction to bioanalysis and clinical sample testing (1h, RN)
- Immunogenicity of biotherapeutics (1h, LS)
- Non-Clinical Safety Requirements before First in Human (2h, HH)
- Harnessing innate and adaptive anticancer immunity with anti-CD47 antibodies (2h, KM)
- Title to be determined (1h, AP)
- Bringing an antibody program from a concept to patients (2h, WF)

Agenda (may be subject to modifications):

11 sessions, 13 hours in total

Date	*Speaker*	*Time schedule*	*Location*
Mon 25.03.2019	EM	10 :30-12 :00	CMU, room A04.2910
Tue 26.03.2019	NF	08 :30-10 :00	CMU, room A04.2910
Tue 26.03.2019	GM	10 :30-11 :15	CMU, room A04.2910
Tue 26.03.2019	AH	11 :30-12 :15	CMU, room A04.2910
Mon 08.04.2019	VB	08 :30-10 :00	CMU, room A04.2711
Mon 08.04.2019	RN	10 :30-11 :15	CMU, room A04.2711
Mon 08.04.2019	LS	11 :15-12 :00	CMU, room A04.2711
Mon 08.04.2019	HH	13 :30-15 :00	CMU, room A04.2711
Tue 09.04.2019	KM	14 :30-16:00	CMU, room B04.1520
Tue 09.04.2019	AP	09 :00-10 :00	CMU, room B04.1520
Tue 09.04.2019	WF	10 :30-12 :00	CMU, room B04.1520

Evaluation mode:

Written examination - case study analysis / multiple choice

ECTS dotation:

1.5 credits (ECTS)

Course 6. Personal genomics & predictive genetics

Lecturers:

Dr Goranka TANACKOVIC (CEO, Gene Predictis)
Pr. Daniel KRAUS (Professor of Innovation Law at University of Neuchatel)

Course Outline:

- Overview of the personalized/precision medicine today (prognostic aspects, diagnostic aspects and therapeutic aspects with challenges and achievements in all three of them, new tendencies) (3h)
- Development of precision medicine product (starting form a case study and analyzing different aspects of product development: idea, proof of concept, clinical validation, regulatory requirements, reimbursement, how to bring such a product to the market) (3h)
- Regulatory and legal aspects (2h)
- Case studies preparation (2h, homework)

Agenda (may be subject to modifications):

3 sessions, 11 hours in total (9 hours teaching – 2 hours home work)

Date	*Session #*	*Time schedule*	*Location*
Tue 14.05.2019	1 (4h) (GT)	08 :30-12 :00	CMU room S3
Tue 14.05.2019	2 (4h) (GT)	13 :00-17 :00	CMU room S3
Wed 15.05.2019	3 (2h) (DK)	10 :15-12 :00	CMU room S3

Evaluation mode:

Attendance certificate (delivered based on attendance and active participation during the course)

ECTS dotation:

1 credits (ECTS)

Course 7. Theory into practice: creating a successful business in Life Sciences

Lecturer:

Dr Jurgi CAMBLONG (CEO, Sophia Genetics)

Course Outline:

This course will address various aspects linked to Entrepreneurship such as leadership, project management, financing, marketing & communication. Parallels between PhD and Enterprise projects will be discussed.
Reference books, to be read before beginning of this course: ***The Lean Startup*** *by Eric RIES, 2011, Crown Publishing Group (USA) and* ***Patrick Aebischer*** *by Fabrice Delay, 2015, Favre Sa.*

Agenda (may be subject to modifications):

2 sessions, 10 hours in total

Date	*Session #*	*Time schedule*	*Location*
Thu 11.04.2019	1 (4h)	08 :30-12:30	CMU, A04.2713
Fri 12.04.2019	2 (6h)	08 :30-12:30 + 14.30-16.30	CMU, A04.2713

Evaluation mode:

Active participation during course sessions.

ECTS dotation:

1 credits (ECTS)

Course 8. Quality by Design (QbD) to ensure product quality

Lecturers:

Michael BOWLEY (Associate VP Technical Support, Compliance at Ferring)
Jérôme REPITON (Director Global Operational Excellence at Ferring)
Julien BOCCADORO (Process Development Manager at Ferring)

Course Outline:

The goal of product development is to design a manufacturing process suitable for routine commercial manufacturing that can consistently deliver a product that meets its pre-defined quality attributes and the patient needs. Since quality cannot be tested into products, quality should be built-in by design. This approach is commonly named Quality by Design or QbD.

Topics:

- QBD (3h)
- Lean 6 Sigma (3h)
- Home readings (estimated to 4h)
- Site visit (5h)

Agenda (may be subject to modifications):

2 sessions, 15 hours in total, including homework and on-site visit

Date	*Session #*	*Time schedule*	*Location*
Wed 03.04.2019	1 (3h, JB)	08:30-11:30	CMU room S3
Thu 04.04.2019	2 (whole day on site, 3h course JR)	08:30-11:30 +13.00-18.00	@ Ferring's, Saint-Prex

Evaluation mode:

Attendance certificate (delivered based on attendance and active participation during the course)

ECTS dotation:

1.5 credits (ECTS)

Course 9. Pharmaceutical project and portfolio management

Lecturer:

Dr Andrew SADLER (Director of the Project Management Office and Portfolio Management Ferring)

Course Outline:

- Pharmaceutical project and portfolio management (to be completed)

Agenda (may be subject to modifications):

2 sessions, 6 hours in total

Date	*Session #*	*Time schedule*	*Location*
Mon 01.04.2019	1 (3h)	08:30-11:30	CMU room S4
Tue 02.04.2019	2 (3h)	08:30-11:30	CMU room S4

Evaluation mode:

Attendance certificate (delivered based on attendance and active participation during the course)

ECTS dotation:

0.5 credits (ECTS)

Course 10. Patenting procedures and intellectual property

Lecturers:

Dr Laurent MIEVILLE (Director UNITEC, University of Geneva)
Pr. Daniel KRAUS (Professor of Innovation Law at University of Neuchatel)
Dr Khamran HOUSHANG POUR (Patent expert at Swiss Federal Institute of Intellectual Property)
Dr Pascal WEIBEL (Head Patent Examination, Swiss Federal Institute of Intellectual Property)

Course Outline:

- Basics of intellectual property
- The different ways to submit a patent
- Patenting strategies
- Patents as information source, royalties, copyright, IP, etc
- «Publish or perish» or «publish and perish»: what must be patented or not? How to protect your research? How to maximize your chances to value your findings?
- Basic knowledge of protective rights, and patenting legal aspects
- Technology transfer issues, commercial aspects
  Practical session: each participant brings a real case as exercice.
- Patents in their context

Agenda (may be subject to modifications):

6 sessions, 20 hours in total (16 hours teaching + 4 hours home work)

Date	***Session #***	***Time schedule***	***Location***
Thu 28.02.2019	1 +2 (DK)	09:30-12:30 and 13 :30-16 :30	CMU room A04.2906
Fri 01.03.2019	3 (KH/PW)	10 :15-12 :00	CMU room S3
Fri 01.03.2019	4 (KH/PW)	13 :15-15 :00	CMU room S3
Tue 16.04.2019	5 (LM)	10:15-12:00 and 13:15-15:00	CMU room S3
Mon 29.04.2019	6 (KH)	09:30-13:00	CMU room S3

Evaluation mode:

Attendance certificate (delivered based on attendance and active participation during the course)

ECTS dotation:

2 credits (ECTS)

Course 11. Pre-clinical in vivo models

Lecturer:

Dr. Fabienne CHABAUD (CHUV, RESAL)

Course outline :

The course is divided in two parts: part 1 – theory, and part 2 – practice (restricted access).
The CILS students will only follow the part 1: theory course (unless previously validated)

Module 1- THEORY:

Introductory Course in Laboratory Animal Science
Course fees: 100 CHF

Agenda (should not be subject to modifications):

1 session over 2.5 days, 20 hours in total

Date	*Time schedule*	*Location*
Mon 25.02.2019	08 :00-12 :30 and 13:30-17:00	CMU room A04.2906
Tue 26.02.2019	08 :30-12 :30 and 13:30-17:00	CMU room A04.2906
Wed 27.02.2019	08 :30-13 :30 (including exam)	CMU room A04.2906

Evaluation mode:

Exam on last day

ECTS dotation:

2 credits (ECTS)

(Module 2- PRACTICAL COURSE)

Introductory Course in Laboratory Animal Science

The practical course is restricted to students/trainees who have professional activities using laboratory animals. Practical teaching transversal / transferable competences (OPTIONAL)
Course fees: 1'000 CHF

Course 12. Ethics in Research

Lecturer:

Pr. Dominique SPRUMONT (President of CER-VD, Director of PhD program "Santé, médecine et société" (SMS) - "Health, Medicine and Society", Institut de droit de la santé, University of Neuchâtel)

Course topic:

To provide the students with the bases of ethics related to research or clinical trial management.

Learned skills and content

Module 1: Introduction to Research Ethics: is an introductory module that presents the basics of research ethics evaluation and the broader context of research ethics. It is designed for anyone intimately or remotely involved with research involving humans. **Duration: 2h**
Objectives: At the end of Module 1 course participants will**:**

- be able to identify values and concepts of ethics relevant to the conduct of research involving humans
- be able to identify and consult relevant normative documents
- be able to understand the importance of ethical evaluation in the promotion of the highest ethical standards and the protection of humans who participate in research
- understand the role and mandate of research ethics committees

Overview: Module 1 has 4 parts including 15 questions in all.
You must get the correct answer before moving ahead. At the end of this module, a certificate is available for participants who got 70% correct answers on their first try.

Module 2.1: Research Ethics Evaluation: focuses on the training needs of members of Research Ethics Committees (RECs) and any support function. It is also relevant to other stakeholders in the field such as researchers and their teams, or students of faculties who train researchers, who develop research projects and/or who conduct research. Module 2.1 addresses elements that should be considered when assessing if research is ethically acceptable. **Duration: 2h**
Objectives: At the end of Module 2.1 course participants will:

- Understand the role of research ethics committees in the promotion of ethical research and the protection of research participants;
- Understand the roles and responsibilities of members of research ethics committees; and
- Be able to contribute to research ethics evaluation based on the application of principles of ethics and relevant normative documents.

Overview: Module 2.1 is divided into 4 parts and has 24 questions in all.
You must get the correct answer to each question before moving ahead. At the end of this module, a certificate is available for participants who got 70% correct answers on their first try.

Module 3.1: Informed consent **Duration: 2h**

Objectives:
At the end of Module 3.1 all participants will

- understand the importance of informed consent for participation in research on humans;
- know when the requirement of individual informed consent can be waived

At the end of Module 3.1 researchers will

- know how to seek informed consent from competent potential research participants
- know how to seek informed consent for potential research participants who are unable to give consent;

At the end of Module 3.1 research ethics committee members will

- be able to evaluate the informed consent provisions in a study protocol;
- be able to evaluate a consent form.

Overview: Module 3.1 has 5 parts including 12 questions in all.
You must get the correct answer before moving ahead. At the end of this module, a certificate is available for participants who got 70% correct answers on their first try.

Module 3.2: Good Clinical Practice (GCP-E6(R2) 2016) : This module is a current and comprehensive guide to the elements and principles of Good Clinical Practice (GCP) quality standards for clinical trials. This module is complementary to Modules 1, 2.1 and 3.1 of the TRREE Training program. Those modules need to be completed prior to beginning this one. **Duration: 6h**

Intended audience: The GCP module is relevant to anyone carrying out clinical trials and will be valuable for investigators, nurses, pharmacists, certain members of Ethics Committees, clinical trial monitors, staff working in pharmaceutical companies or in Contract Research Organization.
Pre-requisite: Modules 1, 2.1 & 3.1

Overview: Module 3.2 GCP: 37 questions & a Quiz with 25 questions. The system will automatically save completed material and allow you to continue at a later time.

Fee for the Delivery of the 3.2. *Good Clinical Practice* (GCP) module TRREE Certificate
TRREE's philosophy is based on the right to education and provides free on-line access to e-learning modules. However, the maintenance of the programme and the steady control of its quality, in particular through a regular update of its content, are not without a cost. In order to sustain and bolster the programme, we are therefore introducing a 50 Swiss Francs fee for the delivery of the official Certificate for the 3.2. *Good Clinical Practice* (GCP) module. This amount will be collected **only from participants from high income economies** (as identified in the 2016 World Bank's list). We thank you for your understanding and your support that will allow us to continue providing a high quality, accurate and up-to-date training programme in research ethics and regulation worldwide. **Access to the training module itself remains free. Only the delivery of the GCP module Certificate will be charged.**

Agenda (may be subject to modifications):

12h – 20 h (e-learning sessions, homework, readings…) + lectures 5.5h.

Date	*Topic*	*Time schedule*	*Location*
Tue 12.03.2019	Introduction	10:00-12:00	CMU room S4
Between 12.03 and 20.05.2019	TREE e-learning modules to be completed		
Mon 20.05.2019	Conclusion – acquired knowledge assessment	09:00-12:30	CMU room S3

Evaluation mode:

online evaluation of self-learning modules + wrap-up session on May 20th

ECTS dotation:

2.5 credits (ECTS)

Course 13. Final personal project

Responsible: Dr. Béatrice KAUFMANN (Pharmaceutical Sciences, Faculty of Sciences, University of Geneva)

The final personal project is a personal piece of work based on the acquisitions obtained across the various courses and during the site visits. Each student is free to select the topic that attracts his-her interest in Industrial Life Sciences, as well as the way he-she wants to build his-her personal project.

Three modes of presentation are requested:

- a written report – it can also be a media document –
- few slides for a flash talk
- a poster for discussion.

For pedagogical advice, *Catherine HUNEAULT* (Unige Career Center) is also available.

Evaluation mode:

- *Written report in English by default (other language possible after discussion with the board) that will be evaluated by experts selected by the CILS board*
- *Oral flash-talk presentation and poster presentation during final CILS symposium*
- *Evaluation: evaluation by the board of the certificate*

ECTS dotation:

6 credits (ECTS)

One Day Site Visits

Covance	**(Meyrin)**	02.05.2019 and 09.05.2019 (morning)
Ferring Pharmaceuticals	**(St Prex)**	April 4th 2019 (whole day)
Tradall (Bacardi-Martini)	**(Meyrin)**	April 15th 2019 (TBD)

CILS traineeships

Companies that might offer a 6 month practical training to CILS students

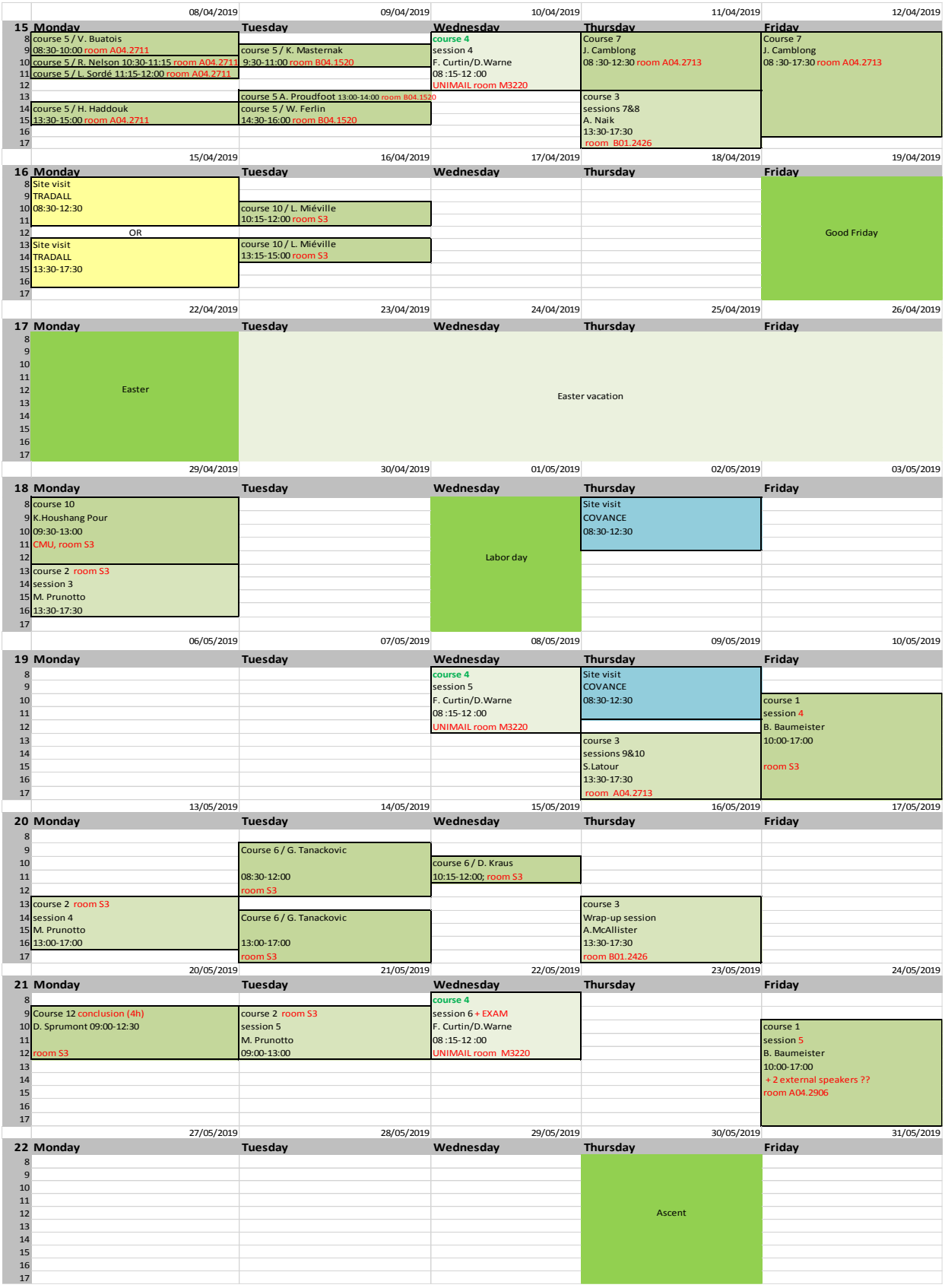
Adipogen International	**(Epalinges)**
Covalab Biotechnology	**(Lyon, France)**
Debiopharm	**(Lausanne)**
Ferring Pharmaceuticals	**(St Prex)**
Firmenich	**(Geneva)**
Galenica	**(Bern)**
Gene Predictis	**(Lausanne)**
Givaudan	**(Vernier)**
Menicon	**(Geneva)**
Merck Serono	**(Vevey)**
Nestlé Health Sciences	**(Epalinges)**
NovImmune	**(Geneva)**
Pierre Fabre	**(Saint-Julien-en-Genevois)**
Quartz Bio SA	**(Geneva)**
Quotient BD	**(Eysins)**
Shire	**(Neuchâtel)**
Triskel	**(Geneva)**
UBC	**(Geneva)**

For Professional internships, contacts will be provided through the Unige Career-Center platform.

Agenda

Remark: Due to professional agenda of our lecturers, following agenda may be subject to last-minute modifications

SPRING SEMESTER	Beginning of courses: 18.02.2019, end of courses: 31.05.2019 / Venue: CMU, Building A/B, unless specified below				
	18/02/2019	19/02/2019	20/02/2019	21/02/2019	22/02/2019
8	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8			course 4 session 1		
9			F. Curtin/D.Warne		
10		course 1 session 1	08 :15-12 :00		
11		B. Baumeister	UNIMAIL room M3220		
12		10:00-17:00			
13		room S3		course 3	
14	14:30 - 15:30 INTRODUCTION CILS program			session 1&2	
15				A.McAllister	
16				13:30-17:30	
17				room A04.2713	
	25/02/2019	26/02/2019	27/02/2019	28/02/2019	01/03/2019
9	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8					
9	course 11	course 11	course 11	course 10	course 10
10	(08:00) 08:30-17:30	08:30-17:30	08:30-13:30	D.Kraus	K.Houshang Pour
11	room A04.2906	room A04.2906	room A04.2906	09:30-12:30	10:15-12:00
12				room A.04.2906	room S3
13					
14				course 10	course 10
15				D.Kraus	K.Houshang Pour/P.Weibel?
16				13:30-16:30 room A04.2906	13:15-15:00
17					room S3
	04/03/2019	05/03/2019	06/03/2019	07/03/2019	08/03/2019
10	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
	11/03/2019	12/03/2019	13/03/2019	14/03/2019	15/03/2019
11	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8			course 4		
9			session 2		course 1
10		Course 12 introduction (2h)	F. Curtin/D.Warne		session 2
11		D. Sprumont 10:00-12:00 room S4	08 :15-12 :00		B. Baumeister
12			UNIMAIL room M3220		10:00-17:00
13				course 3	room S3
14				sessions 3&4	
15				A.McAllister	
16				13:30-17:30	
17				room A04.2713	
	18/03/2019	19/03/2019	20/03/2019	21/03/2019	22/03/2019
12	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8					
9					
10					
11					
12					
13				course 2 room A04.2906	
14				session 1	
15				M. Prunotto	
16				13:00-17:00	
17					
	25/03/2019	26/03/2019	27/03/2019	28/03/2019	29/03/2019
13	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8		course 5 / N. Fischer	course 4		
9		08:30-10:00 room A04.2910	session 3		
10	course 5 /E. Monnet	course 5 / G. Magistrelli 10:30-11:15 A04.2910	F. Curtin/D.Warne		
11	10:30-12:00 room A04.2910	course 5 / A. Haines 11:30-12:15 room A04.291	08 :15-12 :00		
12			UNIMAIL room M3220		
13				course 3	
14				sessions 5&6	
15				S.Latour	
16				13:30-17:30	
17				room A04.2713	
	01/04/2019	02/04/2019	03/04/2019	04/04/2019	05/04/2019
14	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8	course 9	course 9	course 8	course 8	
9	A. Sadler	A. Sadler	J. Boccadoro	J.Repiton	
10	08:30-11:30; room S4	08:30-11:30; room S4	08:30-11:30; room S3	08:30-18:30	course 1
11					session 3
12					B. Baumeister
13	course 2 room S4				10:00-17:00
14	session 2				room S3
15	M. Prunotto			(at Ferring's, in Saint-Prex)	
16	13:00-17:00				
17					



Notes

CILS Board Members

Ecole de Pharmacie EPGL Genève - Lausanne

FERRING PHARMACEUTICALS

novimmune

QUOTIENT

Menicon

Debiopharm Group

Pierre Fabre

CARRIÈRE

CILS Partners

Because I am unique GENE PREDICTA

SOPHIA GENETICS

unitec

resal

CUSO CONFÉRENCE UNIVERSITAIRE DE SUISSE OCCIDENTALE

IGE | IPI

COVANCE SOLUTIONS MADE REAL

UNIVERSITÉ DE GENÈVE GENEVA SCHOOL OF ECONOMICS AND MANAGEMENT

unine UNIVERSITÉ DE NEUCHÂTEL

Unil UNIL | Université de Lausanne