

# Certificate in Industrial Life Sciences (CILS)

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Academics from the Faculty of Sciences, Life Sciences employers and the Career Center of the University of Geneva ([Centre de Carrière](#)) have put together the certificate in Industrial Life Sciences (CILS). The CILS certificate aims at enhancing the employability of students who hold a university degree in Life Sciences and the program has been designed to bridge the gap between academic and industrial life sciences.

The CILS program will provide students holding a Master or a PhD degree in biochemistry, biology, chemistry, or pharmaceutical sciences with a core training in Industrial Life Sciences (ILS), which covers a wide range array of activities including :

- ◆ Pharmaceutics
- ◆ Biotechnology
- ◆ Personal genomics and predicted genetics
- ◆ Pharmacogenomics
- ◆ Medtech

The 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.

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

Courses will be delivered by or in collaboration with experts from various companies active in the field of life sciences over a 6 months period.

The topics targeted by this certificate are the following:

- *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 produce a portfolio where they will present a report on a specific theme they have elaborated during their training. This personal portfolio will be evaluated by the Advisory Board and will provide 6 ECTS
- > In total the CILS program corresponds to 30 ECTS.

Independently of the CILS courses, the students are strongly encouraged to test and to develop their professional skills during a 6 months practical training performed in a non-academic institution after the courses. The "[Centre de Carrière](#)" of the University of Geneva will participate in the organization of these traineeships.

### **Objectives**

As a first objective, the students should acquire the basic vocabulary used in ILS, understand the different phases of product development and acquire a basic knowledge of the activities linked to these phases.

The program will encompass specific tools (e.g. in the field of Quality) as well as technical lab skills (health and safety,...) Project Management training (risk analysis...).

The CILS program is designed to help Master level students to apply for jobs in Manufacturing, Process Development, Clinical Operations, Biostatistics, Clinical Trial Services, Pharmacovigilance, Quality Control, Regulatory Affairs, Marketing.

For PhD level students, the CILS program should help to improve access to jobs in R&D, Biomarkers, Toxicology, Clinical Development, Project Management.

### **Outline of the program : Pedagogical tools, strategies**

Pedagogy will be based on case studies, on site visits and on active interactions with experts. All courses will be in English. Students will regularly prepare oral presentations and written reports. Part of the evaluation will be done on portfolio produced by the students.

### **Practical skills tested and validated in situ**

Targeted knowledge and know-how related to a specific job "category" will be acquired through a 6 months traineeship performed after the theoretical courses. The 6 months traineeships are strongly encouraged to complement the theoretical / practical courses and to validate the best practices used in the industry; they will be regulated via a convention between UNIGE and the industrial partner. Traineeships can be performed in companies located in Switzerland or abroad providing the local administrative conditions are fulfilled.

### **Acknowledgements**

The Faculty of Sciences thank the Companies that have accepted to provide advice on the content and organization of the CILS program: Debiopharm International SA (Lausanne), Ferring Pharmaceuticals SA (St-Prex), Menicon Co. Ltd. (Geneva), Pierre Fabre Immunology Centre (Saint-Julien-en-Genevois, France), Quotient BD Limited (Eysins).

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## CILS Advisory Board as founded in 2016

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(1) Industrials :	Dr. Alain BECK Hanane BENBELGACEM Paul STUART Dr. Bertrand DUCREY Dr. Mouad LAMRANI Dr. Andrew SADLER	(Senior Director Pierre Fabre) (Quotient) (Quotient) (CEO Debiopharm) (General Manager R&D Menicon) (Director Ferring)
(2) Faculty of Sciences:	Pr. Leonardo SCAPOZZA Pr. Yogeshvar KALIA Pr. Jean-Luc VEUTHEY Pr. Jean-Claude MARTINOU Pr. Jean GRUENBERG Pr. Brigitte GALLIOT	(PI, Pharmaceutical Sciences) (PI, Pharmaceutical Sciences) (PI, Pharmaceutical Sciences) (PI, Biology) (PI, Biochemistry) (PI, Biology, Vice-Dean)
(3) Unige Career Center:	Antoine ORSINI Dimitri RUIZ	(Head of Career Services) (Project manager)
(4) Unige Pedagogy Unit:	Mallory SCHAUB Catherine HUNEAULT	(Head of University Pedagogy Unit) (Pedagogy expert)

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## CILS management (2017/2018)

Pr. Yogeshvar KALIA (Pharmaceutical Sciences)	Director of the CILS program
Pr. Brigitte GALLIOT (Biology)	Vice-Dean, Faculty of Sciences
Dr. Béatrice KAUFMANN (Pharmaceutical Sciences)	Coordinator of the CILS program
Florence von OW	Administrative assistant

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## CILS course program

The 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	Hours / credits
<b>1. INTRODUCTION TO THE PHARMACEUTICAL INDUSTRY</b>	Pr. L. SCAPOZZA	<i>Dominik HOTZ, Leader Pharma / Life Sciences Consulting at PricewaterhouseCoopers (PwC)</i>	50 hrs 5 ECTS
<b>2. DRUG DISCOVERY AND DEVELOPMENT : AN INDUSTRIAL PERSPECTIVE</b>	Pr. Y. KALIA	<i>Dr Marco Prunotto, Principal Senior Scientist at Roche</i>	20 hrs 2 ECTS
<b>3. DRUG DEVELOPMENT AND CLINICAL TRIALS</b>	Pr. L. SCAPOZZA	<i>Dr Sabine Latour, Director Global Market Access Dr Andres McAllister, AM Consulting Dr Aarti Naik, Senior consultant Triskel integrated services</i>	20 hrs 2 ECTS
<b>4. BIOSTATISTICS WITHIN DRUG DEVELOPMENT</b>	Geneva School of Economics and Management (GSEM)	<i>Dr Francois Curtin, CEO GeNeuro SA Dr David Warne, Consultant Biostatistician</i>	24 hrs 2.5 ECTS
<b>5. BIOTECHNOLOGY DEVELOPMENT</b>	Pr. J. GRUENBERG	<i>Dr Marie Kosco-Vilbois CSO NovImmune</i>	20 hrs 2 ECTS
<b>6. PERSONAL GENOMICS &amp; PREDICTIVE GENETICS</b>	Pr. JC MARTINOU	<i>Dr Goranka Tanackovic CEO Gene Predictis</i>	10 hrs 1 ECTS
<b>7. THEORY into PRACTICE: CREATING a SUCCESSFUL BUSINESS in Life Sciences</b>	Pr. JC MARTINOU	<i>Dr Jurgi Camblong, CEO Sophia Genetics Course on site</i>	10 hrs 1 ECTS
<b>8. QUALITY BY DESIGN (QBD) TO ENSURE PRODUCT QUALITY and OPERATIONAL EXCELLENCE (Lean 6 Sigma)</b>	Pr. Y. KALIA	<i>Michael Bowley, Associate VP Technical Support, Compliance FERRING Jérôme Repiton, Director Global Operational Excellence at Ferring Julien Boccadoro, Process Development Manager at Ferring</i>	20 hrs 2 ECTS  Ferring on site
<b>9. PHARMACEUTICAL PROJECT AND PORTFOLIO MANAGEMENT</b>	Pr. Y. KALIA	<i>Dr Andrew Sadler, Director of the Project Management Office and Portfolio management at FERRING</i>	6 hrs 0.5 ECTS
<b>10. PATENTING PROCEDURES AND INTELLECTUAL PROPERTY</b>	Pr. L. SCAPOZZA Pr. JC MARTINOU	<i>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</i>	20 hrs 2 ECTS <sup>⊕</sup>
<b>11. PRE-CLINICAL IN VIVO MODELS</b>	Pr. I. RODRIGUEZ	<i>Dr Fabienne CHABAUD Coordinator RESAL Resal module-1 theory course</i>	20 hrs 2 ECTS
<b>12. SCIENCE, TECHNOLOGIES AND SOCIETY IMPACT</b>	Pr. S. HURST	<i>Pr. Samia Hurst, Director Ethic Institute (IEH2); Dr. Christine Clavier</i>	20 hrs 2 ECTS
<b>13. PORFOLIO / PROJECT REPORT</b>	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	6 ECTS
		<b>Total</b>	<b>30 ECTS</b>

## INFORMATION on TEACHING MODULES

### Course 1. Introduction to the pharmaceutical industry

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**Lecturer:**

**Dominik HOTZ** (Partner, Leader Pharma / Life Sciences Consulting Switzerland @ PricewaterhouseCoopers – PwC - Switzerland)

**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.)

### Course 2. Drug discovery & development: an industrial perspective

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**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

## Course 3. Drug development: regulatory aspects and clinical trials

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### Lecturers:

**Dr Andres McALLISTER** (MD, PhD consultant at AM Consulting)

**Dr Jean-Yves LE COTONNEC** (CEO, Triskel Integrated Services)

**Dr Sabine LATOUR** (Director Global Market Access at Pharmaceutical Company)

### 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:

- lesson 1 Introduction (Andrés Mc Allister)
- lesson 2 Pharmacovigilance/safety (Andrés Mc Allister)
- lesson 3 Clinical protocols 1 (Andrés Mc Allister)
- lesson 4 Clinical protocols 2 (Andrés Mc Allister)
- lesson 5 Regulatory affairs and Quality control (Jean-Yves Le Cottonnec )
- lesson 6 Regulatory affairs and Quality control (Jean-Yves Le Cottonnec )
- lesson 7 Clinical study/organization 1 (Sabine Latour)
- lesson 8 Clinical study/organization 2 (Sabine Latour)
- lesson 9 Clinical study/organization 3 (Sabine Latour)
- lesson 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).

#### *Regulatory affairs and Quality control:*

The students know the prerequisites for administering a putative drug in humans and thus starting clinical trials

The students know who gives the authorization to start clinical trials (ETHICS committee) and the prerequisites for obtaining such an authorization

The students know what is a patient consent form (informed-consent documents)

The students know the strategy to be pursued for depositing a dossier to the regulatory bodies (internal strategy for development versus strategy guided by the regulatory guidelines)

The students know what is meant by Good Clinical Practice (GCP) and the practical aspects

#### *Clinical study/organization:*

The student know how a controlled clinical study is practically planned and analyzed

The roles of the different actors, including the hospital pharmacist, are discussed

## Course 4. Biostatistics within drug development (Geneva School of Economics and Management – GSEM – University of Geneva)

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### 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.

## Course 5. Biotechnology development

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### Lecturers:

**Dr Marie KOSCO-VILLEBOIS** (CSO, NovImmune )

**Dr Amanda PROUDFOOT**

**Dr Zoe JOHNSON**

**Dr Nicolas FISCHER**

**Giovanni MAGISTRELLI**

**Dr Keith WILSON**

**Alexandre CARRON**

**Dr Vanessa BUATOIS**

**Dr Robert NELSON**

**Dr Susana SALGADO-PIRES**

**Rebeca ZORILLA**

**Dr Krzysztof MASTERNAK**

**Dr Walter FERLIN**

### Course Outline:

- Overview of the steps for drug development (2h, MKV)
- Choosing and validating a protein as a target for pharmaceutical intervention (2h, ZJ)
- Discovering a therapeutic macromolecule with an emphasis on antibodies (monoclonal, bispecific, fragments) (2h, NF)
- Generating a robust toolbox and screening approaches (1h, GM)
- Steps in manufacturing antibodies (1h, KW)
- Manufacturing a drug for market: process validation (1h, AC)
- In vitro and in vivo pharmacology studies (2h, VB)
- Testing samples from clinical trials and the notion of GCP (2h, RN)
- Nonclinical safety: toxicology and other safety considerations before entering humans (2h, SS-P)
- Pulling it all together: Project management (1h, RZ)
- Awakening the immune system to fight cancer by targeting CD47 (1h, KM)
- Targeting chemokines: successes and failures (1h, AP)
- Targeting rare diseases: The orphan story (2h, WF)

## Course 6. Personal genomics & predictive genetics

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**Lecturers:**

**Dr Goranka TANACKOVIC** (CEO, Gene Predictis)

Prof. Daniel KRAUS (Professor of Innovation Law at University of Neuchâtel)

**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 from 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)

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

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**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.*

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

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**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)
- Regulatory Affairs in the Pharma Industry (4h, with external contributor from Ferring Int. in Denmark)
- Lean 6 Sigma (3h)
- Home readings (estimated to 4h)

## Course 9. Pharmaceutical project and portfolio management

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**Lecturer:**

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

**Course Outline:**

- Pharmaceutical project and portfolio management (to be completed)
- 2 sessions, 6 hours in total

## Course 10. Patenting procedures and intellectual property

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**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 exercise.
- Patents in their context

## Course 11. Pre-clinical in vivo models

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**Lecturer:**

**Dr. Fabienne CHABAUD** (CHUV, RESAL)

**Course outline :**

The course is divided in two parts: part 1 – theory, and part 2 (optional) practice.

The CILS students who do not have already followed this course will follow the part 1: theory

**Module 1- THEORY:**

Introductory Course in Laboratory Animal Science

Course fees: 100 CHF

**Module 1- 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. Science, technologies and society impact

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**Lecturers:**

**Dr. Christine CLAVIEN** (Senior Lecturer, IEH2, University of Geneva)

**Pr. Samia HURST** (Director Institute of Ethics, History, Humanities - IEH2 - University of Geneva)

**Course topic:**

For centuries, philosophers have discussed the link between ethics and natural facts, especially those that pertain to human nature. These debates are presently taking a new turn, as neuroscience, genetics, evolutionary modeling, and cognitive sciences provide fresh insights into the biological basis of human cognition, emotion, and decision-making. Thus scientific knowledge becomes increasingly relevant to our understanding of moral judgements and behavior.

Simultaneously, new discoveries in neuroscience and genetics raise unprecedented ethical issues: e.g. related to the use of technologies and drugs that alter human cognition or character, or related to the relevance of scientific expertise for judicial decision making.

In this course, along a series of invited conferences, the students will learn how ethics is transformed by recent scientific knowledge

**Learned skills and content**

- Transpose knowledge and results from scientific fields to philosophical debates
- Understand the impact of empirical discoveries in genetics, neuroscience and medicine on classical philosophical debates (e.g. free will, mind-body problem)
- Understand the contribution of evolutionary biology and neuroscience to a descriptive understanding of human moral behavior
- Develop a critical view on the relationship between empirical knowledge on humans (e.g. brain mechanisms, behavioral tendencies) and the moral foundation of norms and values
- Explore the practical ethical implications of new scientific and medical discoveries (social implications, legal issues, emergence of new moral responsibilities, etc.).

## Course 13. Portfolio / Project Report

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

The portfolio 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 portfolio.

Three modes of presentation are requested :

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

*Evaluation: evaluation by the board of the certificate*

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## One day visits

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**3 visits to be defined**

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## CILS traineeships

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

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

**For Professional internships, Ayumi BART ([Centre de Carrière](#)) will provide contacts through the "[Centre de Carrière](#)" platform.**

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## CILS Board Members

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## CILS Partners

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