

CAS

Certificat de formation continue
Certificate of Advanced Studies

Industrial Pharmacy Quality Management

January > June 2025

Distance and Face-to-face Training & Modular Training



FACULTY OF SCIENCES
PHARMACEUTICAL SCIENCES



GRIP pharma



UNIVERSITÉ
DE GENÈVE



Direction

- **Prof. Yogeshvar Kalia**, School of Pharmaceutical Sciences, Faculty of Sciences, University of Geneva

Steering Committee

- **Prof. Yogeshvar Kalia**, School of Pharmaceutical Sciences, Faculty of Sciences, University of Geneva
- **Prof. Gerrit Borchard**, School of Pharmaceutical Sciences, Faculty of Sciences, University of Geneva
- **Dr. Magali Zeisser-Labouebe**, School of Pharmaceutical Sciences, Faculty of Sciences, University of Geneva
- **David Limal**, OM Pharma, Head of Quality Management
- **Nathalie Wardé**, D4P-pharma, General Manager & Founder

Coordination

- **Florence von Ow Lesniewski**, School of Pharmaceutical Sciences, Faculty of Sciences, University of Geneva

Speakers

Professors and staff at University of Geneva and experts from the pharmaceutical industry, including executives from pharmaceutical companies located in French-speaking Switzerland.

Partnership: Swiss Society of Industrial Pharmacists (GSIA - SSPI – SSIP); *Groupement romand des industries pharmaceutiques*



Quality management is essential for any industrial activity. The objective of this CAS is to provide high-level training in effective quality management that addresses the specific needs of the pharmaceutical, biotech and medical device industries.

Effective management of quality is critical and it plays a key role in many diverse functions. These range from the selection of suppliers, identification and control of product and process specifications, qualification of equipment, quality of drugs and excipients, documentation procedures and training of personnel.

The pharmaceutical industry (including biotech and medical device sectors) is a key economic driver in Switzerland. It is a highly regulated industry that is subject to a series of international directives and rules that define how the quality of a product can be assured throughout its lifecycle from inception through to commercialization. Despite its importance, there are currently no training programmes available in Switzerland that address the specific needs of the pharmaceutical industry with respect to the management of quality.

This CAS, developed by the University of Geneva, in close collaboration with the Swiss Society of Industrial Pharmacists and the *Groupement Romand de l'Industrie Pharmaceutique* (GRIP-Pharma) has been created to address this unmet need. This collaboration between academia and industry suggests that the course content will focus on the themes that are considered to be lacking from existing programmes.

The University of Geneva is ideally positioned to offer this training for four reasons:

1. The School of Pharmaceutical Sciences is recognised as one of the leading centres of pharmaceutical excellence in Europe.
2. Switzerland is a life sciences hub for dozens of leading companies in the healthcare sector.
3. External experts come from companies that are based in Western Switzerland.
4. Courses are delivered in English and with a modular structure in order to respond to international demand while accommodating for different learning journeys.



Audience

- Professionals in the pharmaceutical industry (including biotechnology), as well as participants who need to expand their knowledge in the field in order to pursue a career in a branch of quality management in industry.
- Holders of a Master's degree in pharmacy, biotechnology, chemistry, life sciences; holders of a Bachelor's degree (chemistry, biotechnology); holders of a Bachelor's degree or Master's degree in chemistry/biotechnology.

Objectives

- To acquire detailed and thorough knowledge about Quality Management throughout the drug's life cycle
- To understand the regulatory and normative health industry contexts in which Quality Assurance is used
- To learn and master the tools of Quality Assurance
- To adopt a method of analysis and use problem-solving strategies to enable the presentation of results to different audiences
- To apply the lessons to concrete situations in the workplace through the use of case-studies

Programme Structure

- 3 thematic modules and an individual project
- 105 teaching hours
- 105 distance learning hours
- 210 independent study hours
- 14 ECTS
- Blended learning

Learning Methods

- Lectures
- Flipped classrooms
- Case studies
- On-site visits
- Use of computer software/games
- Individual research work



The programme has three teaching modules:

1. Development of pharmaceutical formulations
2. Regulatory management and audits
3. Operational quality, qualification and quality control) and a final module comprising an individual project.

The objective is to combine conventional teaching, distance learning and individual study. The teaching modules will be distinct standalone packages that can be followed individually by students not able to follow the complete course.

Learning Outcomes

- Possess a good knowledge of Quality and its application in the pharmaceutical industry
- Master the legal framework for pharmaceutical product marketing and the relationship between the holder of the marketing authorization and operators
- Master the qualification and validation processes as well as Quality Control operations
- Able to manage an inspection and establish an appropriate CAPA (Corrective and Preventive Actions)
- Able to manage suppliers and service providers from a Quality perspective to ensure patient safety
- Able to analyse, judge and determine the quality attributes in a development project in order to develop innovative solutions at a complex level
- Able to assume executive functions in the analysis, systematization, and resolution of complex problems in new contexts, with theory-based solutions
- Able to effectively respond to arguments as well as to develop, justify and negotiate alternative solutions to different groups of interlocutors within the framework of Quality
- Know how to run autonomously, assess and integrate knowledge relevant to Quality management in health industries
- Able to define their own training objectives, to develop their scientific and practical skills independently and to transpose the knowledge acquired to other contexts



Assessment

Evaluation by module and for the individual project.

Individual Project

An individual project is to be completed during the CAS and/or at the end of the theoretical period of the CAS. The participants select a topic related to quality in the health products industry (the specific topic may vary depending on the participant's interests and professional practice) and must prepare a written report and oral presentation on the subject.

Diploma Awarded

Participants who pass the assessment requirements and successfully complete all modules and the individual project will be awarded a CAS in Industrial Pharmacy - Quality Management by the Faculty of Sciences of the University of Geneva.



Practical Information

Admission criteria

- Hold a university master's degree, a university bachelor's degree, a bachelor's or master's degree from a university of Applied Pharmaceutical Sciences or a degree deemed equivalent
- Have at least some professional experience related to the Certificate programme
- Have a good command of oral and written English (B2 Level)

Applicants must submit a complete application package to be considered for admission. The Steering Committee reserves the right, under certain conditions, to select candidates who do not meet the stated admission criteria.

Number of participants: 15

Application

Online application may be submitted before **15 December 2024**

- www.unige.ch/formcont/cours/industrial-pharmacy

Single PDF file containing: cover letter, CV and letter(s) of support recommendation and a copy of the highest degree.

Fees

- CHF 7'500.-
- CHF 2'000.- for individual modules

Schedule and Location

- 9:00 – 17:00 with a lunchbreak and breaks in the morning and afternoon
- University of Geneva – School of Pharmaceutical Sciences, CMU – 1 rue Michel Servet, 1211 Geneva.

Contact

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Partnership

Société Suisse des Pharmaciennes d'Industrie (SSPI-GSIA)

Groupement Romand de l'Industrie Pharmaceutique (GRIP-Pharma)

