

GMP COURSE (BE) FOR ACADEMICS AND PROFESSIONALS

A HELIS Academy Programme

*Preparing for a future in
(bio)pharmaceutical
production*

HELIS Academy



Interreg 
Vlaanderen-Nederland
Europees Fonds voor Regionale Ontwikkeling

QBC
QUALITY BY DESIGN

Advipro



flanders.bio

Qpeople
validating expertise

GMP COURSE (BE) FOR ACADEMICS AND PROFESSIONALS

Preparing for a future in (bio)pharmaceutical production

Why participate?

The production of medicines is a profession with its own challenges. Medicines must meet high standards before they can be administered to patients. This means, among other things, that medicines are manufactured in a very clean environment where strict quality controls are in place. The guidelines for the production of medicines have been laid down by the EU as Good Manufacturing Practice (GMP).

This course covers the essential aspects of (bio)pharmaceutical manufacturing. Through lectures, practical lessons, workshops and guided tours, you will get a complete picture of, and good insight into all things related to GMP. Advipro has a complete training centre with a cleanroom, which means that you can immediately apply the acquired knowledge in a realistic practical environment.

Whether you are interested in a job that involves the development of analytical methods, production, quality control, quality assurance or process development, this course provides a good basis for a job in the biotech or pharmaceutical industry.

For whom?

This course is aimed at graduates (BSc, MSc, PhD and postdoc) and professionals, who have studied a subject or discipline in Life Sciences, but have no experience in the GMP production industry. With this course you will gain insight and experience in the pharmaceutical manufacturing industry. You could then qualify for jobs in production, quality control (QC), analytical method development, formulation development or quality assurance (QA).



PROGRAMME

Module 1. Introduction to Good Manufacturing Practices (GMP)

Delivering medicinal products of reliable quality is the top priority of any company active in the healthcare, pharmaceutical and cosmetic industry. Many guidelines and regulations have been developed in the past, by both the authorities as well as the industry itself. The result are the Good Manufacturing Practices (GMP) guidelines, which are the minimum requirements that a manufacturer must meet to assure production of safe and qualitative goods. This training provides an introduction to these Good Manufacturing Practices, which is essential knowledge when implementing, maintaining or monitoring activities at any manufacturing site. It covers all aspects of production, such as design of the premises, acceptance of materials, equipment, quality control, documentation and training.

Objectives

At the end of the module you

1. have a thorough knowledge of the Good Manufacturing Practices guidelines/ requirements
2. have insight in the important GMP activities and flows in any manufacturing site
3. are able to identify gaps and risks and to implement actions and systems in compliance with the GMP requirements

Module 2. Quality management system and documentation

Quality is a top priority in every pharmaceutical, medical device or life sciences company. But what is quality? Does quality only mean the delivery of a conform product? Or is it more than that? How does one guarantee the delivery of the same quality standards, day in day out? In this module an introduction is given to what exactly a quality management system is according to several rules and regulations (ISO9001, ICHQ10) and why it is essential. The different parts that together shape the quality management system are highlighted and explained as well as the link between each of these.

Objectives

At the end of the module you

1. understand where the requirements of having a QMS come from
2. can find the relevant guidelines and rules and regulations required to set up a QMS
3. can identify the different processes that compose a QMS and the links between these processes
4. have an understanding of why a good documentation system is crucial for a QMS



PROGRAMME

Module 3. Contamination control: infrastructure - staff - cleaning

In this module you are introduced to the strict requirements that apply on a controlled GMP production area in order to prevent contamination of the product. There are a lot of measures with regard to the design of the production areas, the use of materials and staff behaviour. Micro-organisms are always and everywhere, making the prevention of microbial contamination an important challenge for pharmaceutical production. Contamination sources will be highlighted. Cleaning and disinfection of the cleanrooms is important to control the growth of microorganisms. Cleanroom classification and monitoring will be discussed. You will have the opportunity to see state-of-the-art cleanrooms. During this training you are informed about the requirements that apply on entering cleanrooms and they will learn why these requirements are necessary. You will be trained in gowning procedures and behaviour in a working cleanroom.

Objectives

At the end of the module you

1. understand what the different contamination sources (production personnel, equipment) are
2. know how to classify and monitor a cleanroom
3. understand how to manage a cleanroom and preventing the introduction and growth of microorganisms
4. understand why cleaning and disinfection of cleanrooms is important to control the growth of microorganisms
5. understand the requirements that apply on entering cleanrooms and learn why these requirements are necessary
6. have experience with and practiced the gowning procedures and expected behaviour in a working state-of-the-art cleanroom

Module 4. Aseptic techniques

During this module on aseptic techniques you will be introduced to understand why aseptic processes should be performed in a certain way. You will gain hands-on experience in working GMP conform in a biosafety cabinet. You will learn to understand why aseptic processes should be performed in a certain way. The environmental monitoring of the cleanroom is also a part of this module. There will be a short introduction on biotechnological pharmaceutical products and the upstream and downstream processes.



PROGRAMME

Objectives

At the end of the module you

1. understand the GMP conditions to work in a aseptic environment
2. have insight in the environmental monitoring of a cleanroom
3. have experience working in a state-of-the-art cleanroom and biosafety cabinet
4. have hands-on experience in aseptic processing and understand the reasons behind it
5. understand upstream and downstream processes in the biotechnological pharmaceutical industry

Module 5. Quality Management System: deviations - OOS - change control

Deviations and CAPAs remain an important agenda item during audits. In many job positions in life science you will be involved in the reporting, investigation and/or monitoring of deviations. Through this module you will learn how to prepare GMP defensible documentation.

Objectives

At the end of the module you

1. understand the context and underlying relations of quality systems like deviations, OOS (Out Of Specs) and change control ('what' -'why' - "system")
2. are able to write and report deviations and other quality records in a clear and logical way
3. can perform effective root cause investigations and formulate corrective/preventive actions
4. are able to design a flow to get your changes under control, define elements of change and perform a basic impact assessment
5. can apply a method to control your changes

Module 6. Raw materials, packaging/labelling and distribution

Inspection of incoming raw materials is an essential step in the life cycle of a medicine or medical device. We walk you through the whole flow of receiving, packaging, labelling and distribution in a practical way.



PROGRAMME

Objectives

At the end of the module you

1. can recreate the flow of materials and raw material use and its handling
2. are able to identify the risks related to storage, packaging and distribution/shipping
3. understand recent regulatory expectations
4. know the packaging and receiving process through a company visit

Module 7. Validation (Facility/equipment/system qualification and Process validation)

Within the life sciences sector, you can find many validation job opportunities. Through this module you gain basic background and practical knowledge to start your first validation project. We start from the theory but dive quickly into practice.

Objectives

At the end of the module you

1. comprehend the regulatory expectations regarding facility/equipment/system qualification and process validation
2. understand the possible consequences of non- or incorrectly validated systems or processes
3. can apply the life cycle of process validation
4. are able to identify the different aspects critical for design and performance of process validation
5. are able to apply the different steps in the life cycle of equipment (V-model /ASTM/ Quality by Design)
6. have insight in which systems require qualification (and which do not)
7. can prepare qualification documents (protocols/reports) and execute/handle them correctly



PROGRAMME

Module 8. Quality control

One of the major aspects of the quality management system is controlling the quality of products. Quality control is a process to evaluate the products in order to assure that they meet the criteria and can be safely released.

In this module an overview is given of the most common test methods used for the analysis of biotechnological and chemical drugs. What are the specific needs for parenteral drugs and what to do when a result does not meet the acceptance criteria? An introduction to stability studies and sampling techniques are addressed as well.

Objectives

At the end of the module you

1. know the place of Quality Control (QC) within the Quality Management System (QMS)
2. are familiar with Pharmacopoeia
3. have an understanding of several test methods
4. know a strategy to handle "Out-Of-Specifications"
5. have a better understanding of stability studies

Module 9. Downstream processes

In this module the following matters are discussed:

- Basics of the production, basics of process impurities
- DSP steps: clarification, centrifugation, chromatography, ultrafiltration, diafiltration, virus inactivation
- Types of viruses, virus clearance, risk assessment, validation
- Development of IMP, regulations and development of products, bill of testing, batch production records
- Practical: TFF systems (ultrafiltration/diafiltration/clarification)

Objectives

At the end of the module you

1. know the different process steps that are important for the production of (bio)pharmaceutical products
2. understand basic principles of various purification techniques for use in downstream processing, including chromatography, ultrafiltration, diafiltration and centrifugation
3. understand various virus elimination and inactivation techniques
4. have experience in the operation of sealing and welding equipment



PROGRAMME

Module 10. Aseptic production filling

This module will use virtual reality to familiarize you with the following topics related to aseptic production filling:

- Gowning
- Preparations for filling
- Cleaning and disinfecting
- Routine interventions
- Unexpected interventions

In this module you will also learn more about (bio)pharmaceutical production through educational games.

Objectives

At the end of the module you

1. have experience in working with an automatic filling line
2. understand the impact of the environment on aseptic processing
3. are able to relate microbiological monitoring to operations around an automatic filling line
4. have in-depth understanding of particle monitoring
5. know which critical parameters are covered in a filling line validation and understanding why these parameters are important



ABOUT US

About HELIS Academy

The GMP course for academics is organised in the framework of the HELIS (HEalth and Life Sciences) Academy. HELIS Academy is a consortium of 10 public and private partners that strive to optimize the Life Sciences & Health cluster in the Netherlands and Flanders. The project focuses on the development and coordination of appropriate training programmes in the Life Sciences and Health sector by matching companies' job requirements and profiles to curricula and develops new training programmes where needed. Through these training programmes students and young professionals are better prepared for the labour market by training them in skills and competences that are in demand. In this way, the academy increases the industry readiness of life scientists.

HELIS Academy provides training programmes in the following domains:

1. Good Manufacturing Practices (GMP);
2. Clinical Development;
3. Data Analysis and Stewardship;
4. Business Development;
5. Technology and Life Sciences;
6. Product and Process Design.

HELIS Academy is financed by the Interreg V-programme Flanders-Netherlands, the cross border collaboration programme with financial support from the European Fund for Regional Development (EFRO).

About flanders.bio

flanders.bio is a dynamic, member driven organisation with currently more than 350 members from Belgium and abroad. We help our members to create value by organising Networking and Training Activities, supporting Internationalisation, providing Services and building Expertise. flanders.bio and its members want to be the proud advocates of a reputable global-impact ecosystem in Life Sciences.

HELIS Academy

Interreg 
Vlaanderen-Nederland
Europees Fonds voor Regionale Ontwikkeling

flanders.bio



TERMS AND CONDITIONS

Registration fee

The registration fee for the ten-day course is €2995 (excl. VAT) for non-flanders.bio members and €2745 (excl. VAT) for flanders.bio members. The registration fee for students and job seekers (private rate) is €495 (excl. VAT).

Certificate

At the end of the ten-day training, participants who have followed all modules will receive a participation certificate.

Cancellation policy

Only written cancellations will be processed. If cancelled more than 20 days prior to the first day of training, an administration fee of €45 will be charged, except for students and job seekers. In case of cancellation on or after 20 days prior to the first day of training, the full registration fee will be charged. Upon premature termination of participation to the multi-day course, registration fees will not be refunded.

No show

If you are not present at the training or do not cancel in time, the full registration fee will be charged.

Replacement

When unable to attend, a colleague can take your place. Report your hindrance and/or replacement of participation to flanders.bio as soon as possible. Replacement after the start of the training is not possible.

Performance of services

Flanders.bio and partners - QbD, Q-people, Advipro and BTF Leiden - commit to perform the agreed training (GMP course for academics and professionals) to the best of their ability. In case of insufficient participation or in case of force majeure prior to or during this training, flanders.bio has the right to cancel the course or to move it to a later time. In case of forced cancellation the registration fee will be reimbursed to registered participants. For practical reasons, the maximum number of participants is limited to 15. The minimum number of participants to commence the training is 8. When cancelled or postponed to a later date, any registration fees paid will be refunded.

Registration

Visit flanders.bio/en/events/helis-academy-gmp-course-for-academics-level-ii-belgium

