MODULE 4

Quality Management in Manufacturing of Biopharmaceuticals

From cell line development to downstream processing and formulation

Three days of training on manufacturing biopharmaceuticals and how this relates to quality aspects.

15 – 17 NOV '21

€ 1.795
*ex. VAT**

Biopharmaceuticals are the next generation of medicines. As they originate from live cells, there are several quality concerns and significant technical challenges during development, manufacturing and testing. This module provides participants with a solid understanding of the manufacturing of biopharmaceuticals, and critical aspects to understand during development.

This three-day training provides insight into the development of biopharmaceuticals and how this relates to quality aspects. We will consider the critical steps of developing cell lines, upstream and downstream processes, and commercial manufacturing up to protein analysis. Stability, comparability, contamination and immunogenicity will be discussed, as they require special attention compared to API's of non-biological origin.

WHAT YOU WILL LEARN

- How biopharmaceuticals are produced and what the differences are between small and large (biopharmaceutical) molecules, including the key process units for cell line development, upstream and downstream processing and how they impact product quality;
- How to apply critical process parameters (CPP) and critical quality attributes (CQA) for biopharmaceuticals to achieve a robust process;
- How relevant test methods are best applied and what their limitations are;
- Up-to-date information on relevant ICH guidelines and knowledge where to find EMA and FDA guidance for biopharmaceuticals;
- The knowledge to achieve a compliant QP release of biopharmaceutical products according to the appropriate expectations.

CONTENT OF THIS MODULE

- Introduction to biotechnology;
- Upstream process development for biopharmaceutical products;
- Cell line development and cell bank preparation;
- Purification survey of unit operations and process integration;
- Design of an industrial process for purification of biologicals;
- Development, tech transfer and commercial manufacturing of monoclonal antibodies by cell culture;
- Pathogen safety;
- Protein analytics of biopharmaceuticals;
- Critical attributes and comparability studies;
- Quality challenges for Advanced Therapy Medicinal Products (ATMP);
- Biosimilars: a new class of licensed biotech products;
- Immunogenicity and formulation of biopharmaceuticals.

COURSE LEADER MODULE 4

Drs. A.C.A.J. (Aad) van de Leur (Byondis B.V.) is working at Byondis BV (formerly Synthon Biopharmaceuticals BV). In his present function of COO he is responsible for all Biopharmaceutical operational activities. This includes process development activities from cell line to Drug Product Development and related analytical development as well as manufacturing and supply of IMPs with a focus on monoclonal Antibodies and Antibody Drug Conjugates (ADCs). Before starting at Byondis, he worked for over 23 years at different Biotechnology departments at Diosynth and Organon/ Schering-Plough including Cell Culture and Purification Development, Manufacturing and Project Management.

For more information, program, trainers and registration:

The *Quality Management in Pharma and Biotech* course, first developed in 1997 and previously organized by a.o. BODL and PAOFarmacie, has successfully given hundreds of (aspiring) Qualified Persons and other quality professionals a solid basis to fulfill their essential role in the pharmaceutical industry and hospital pharmacies.

COURSE SETUP

Expert knowledge and real-life case studies are combined to form an ideal learning experience. Professionals from industry, academia and national regulatory authorities such as Dutch IGJ will share their wealth of experience and knowledge during the course. The course is highly interactive. The program is offered as a combination of self-study prior to each module, theory and practical case studies.

TARGET AUDIENCE

Professionals in pharmaceutical, biotechnological and medical device industries, Professionals in institutions and Contract Research Organizations (CRO's), Hospital pharmacists and Postgraduate students.

The course is aimed at (young) professionals in non-clinical and clinical development of new medicinal products, manufacturing, packaging, Quality Control, Quality Assurance or Regulatory Affairs who are dealing with complex quality systems. The target audience needs to gain an in-depth understanding of these systems to improve quality management in their own organization. The course is an international training program in English and requires, at minimum, a Bachelor's Degree level.

CERTIFICATES & ACCREDITATION

You will receive a certificate of attendance after attending a module. Additionally, you are offered the possibility to achieve full completion of the modules through an examination. The examination sessions will be scheduled twice a year. In combination with a university degree in, e.g. pharmacy, biology, chemistry or (bio) pharmaceutical sciences and with relevant practical experience, successful completion of all modules of the training course forms a good starting point to apply for a Qualified Person (QP) status.

PCS will apply for accreditation for each individual module with hospital pharmacists professional association NVZA.

COURSE FEE

The fees are excluding 21% VAT. The fee includes hotel accommodation, course notes, drinks, lunches and dinners. In the event of cancellation we refer to the general terms of condition of PCS (www.pcs-nl.com). Discount when following all four modules: 20%. Master and PhD students receive a discount of 25% per module, and an extra 20% discount when following all four modules.

WHERE

All modules are organized in the area of Utrecht, The Netherlands.

INTERESTED?

Go to www.pcs-nl.com/training or scan the QR code for more information about the modules, the program, trainers, pricing and registration.

PHARMACEUTICAL CONSULTANCY SERVICES ACADEMY

Houttuinlaan 4
3447 GM Woerden

T +31 (0)182 503 280
E courses@pcs-nl.com

www.pcs-nl.com
www.linkedin.com/company/pcswoerden

PHARMACEUTICAL CONSULTANCY SERVICES ACADEMY

TRAINING COURSE

Quality Management in Pharma and Biotech 2021

Four modules offering an integrated approach to quality management in pharma and biotech industries, as well as in hospital pharmacies, to safeguard the quality of their products.

There is the possibility to either attend individual course modules best suited to complement your education or experience, or you can benefit from the integrated approach by subscribing to all four modules simultaneously.

MODULES

MODULE 1 Quality Management — 7 – 8 APR & 10 – 11 MAY '21
The role of the Qualified Person

MODULE 2 Quality Management in Drug Development — 14 – 16 SEP '21
From quality by design to clinical studies

MODULE 3 Quality Management in Sterile Manufacturing — 4 – 6 OCT '21
A thorough discussion on sterility assurance challenges

MODULE 4 Quality Management in Manufacturing of Biopharmaceuticals — 15 – 17 NOV '21
From cell line development to downstream processing and formulation

MODULE 1

Quality Management

The role of the Qualified Person

Four days of training exploring the role and responsibilities of the Qualified Person in the pharmaceutical industry and hospital pharmacy.

7 – 8 APR & 10 – 11 MAY '21

€ 2.195 ex. VAT*

The Qualified Person watches over product quality while taking patient safety and product availability into account. This requires an in-depth understanding of the QP's role and responsibilities.

This four-day training provides insight into an integrated approach on quality management as a good business practice in the pharmaceutical and biotechnological industries and hospitals to safeguard the quality of their products. There will be focus on the role and responsibilities of the Qualified Person (QP) as well as on international legislation, guidelines, common challenges and best practices.

WHAT YOU WILL LEARN

- Basic principles of quality management from a regulatory and business perspective;
- Applicable GMP regulations and expectations across the product life-cycle;
- Current regulatory developments and their business impact, e.g., new regulations, the Falsified Medicines Directive (serialization) and significant issues that may impact the business (data integrity, drug shortages and supply chain integrity), and the significant impact of behavior and culture;
- Specific regulatory responsibilities of senior management, functional leaders, the Qualified Person and Responsible Person.

CONTENT OF THIS MODULE

- Quality Management as a good business practice across the product life-cycle:
  - Basic Principles of Quality Management;
  - The specific regulatory role and responsibility of Senior Management, the Qualified Person and the Responsible Person;
  - Quality Management System elements: deviation management, change control, validation & qualification, training and qualification of personnel, customer complaint management, audit systems, third party operations including risk management and data integrity;
  - Trending and management reviews;
  - Lean Manufacturing and Quality Management;
  - Similarities and differences between local (small) organizations and global (large) organizations;
  - Current regulatory developments and inspection highlights;
  - Inspection Readiness: How to manage a regulatory GMP inspection.
- The critical impact of culture and behavior on compliance;
- QP experiences:
  - Industry, hospital environment, international setting;
  - Real-life challenges: APIs, excipients, QP declarations, the Falsified Medicines Directive (FMD), drug shortage prevention.
- Real-life case studies:
  - Including participation in a team to work out a case study in the period between the first and second course sessions.

COURSE LEADER MODULE 1

Dr. D.E.M.M. (Désirée) Vendrig (Vendrig in Pharma) is a pharmacist by education and holds a PhD in Natural Sciences. She started her career in the pharmaceutical industry as Head of the R&D QC Laboratory at Solvay Pharmaceuticals (now Abbott). After 10 years as a Senior GMP Inspector for the Dutch Inspectorate for Healthcare and Youth, Désirée fulfilled various Global Quality Management positions at Teva and was a registered QP and RP. Nowadays, Désirée is an independent GxP consultant.

For more information, program, trainers and registration:

MODULE 2

Quality Management in Drug Development

From quality by design to clinical studies

Three days of training on drug development: from quality by design to clinical studies

14 – 16 SEP '21

€ 1.795 ex. VAT*

The development of a new therapeutic product is a complicated and expensive process that may take up to 12 years (or more!) before hitting the shelves. Insight into applicable quality management systems, GxPs, and regulatory expectations will help participants minimizing delays and provide clarity on the decisions made along the way.

This three-day training provides insight into the regulatory requirements for drug development from both the viewpoint of regulatory authorities as well as inspection bodies. We will explore the development of a new Active Pharmaceutical Ingredient (API), following the principles of Quality by Design. Then non-clinical development is discussed, including toxicology, up to clinical development and manufacturing, referring to GLP, GCP and GMP requirements and regulatory guidelines.

WHAT YOU WILL LEARN

- The basic concepts of quality, nonclinical- and clinical drug development;
- Find, interpret, and understand the relevant GxP guidelines and identify the key regulatory requirements for products in development;
- Identify the location of quality, nonclinical- and clinical data in the Common Technical Document (CTD).

CONTENT OF THIS MODULE

- API – Profile of lead compound: R&D steps and R&D data;
- Medicinal chemistry - Quality in lead finding and optimization;
- Pharmaceutical formulations (incl. development, quality management and GMP);
- Drug development in Dutch hospital pharmacies;
- Regulatory requirements - quality, clinical and nonclinical (incl. CTD, Clinical Trial Applications);
- GLP and nonclinical development program;
- Execution of a GLP compliant study;
- GMP during nonclinical and clinical development;
- Clinical development and GCP:
  - Clinical Phase I, II and III.
- Perspective of the Dutch Inspectorate for Healthcare and Youth (IGJ);
- Real-life case studies.

COURSE LEADER MODULE 2

Dr. A. (Ineke) Jonker-Hoogerkamp (Eagle Pharma Consult) graduated in pharmacy, followed by a PhD in pharmacokinetics. She has extensive experience in regulatory affairs including regulatory aspects of global drug development, market approval and regulatory compliance of human medicinal products and medical devices. Ineke held senior regulatory positions in Organon and Genzyme. She worked for over 10 years as director of the Regulatory Affairs division of the consultancy company Xendo. Currently Ineke works as independent consultant in regulatory affairs and drug development.

Drs. J.J. (Jan-Jaap) Scherpbier (Sonsbeek Pharma Consultancy B.V.) has a pharmacy degree and started his career in the pharmaceutical industry in both analytical and formulation development for a generic drug company. His next roles were related to regulatory affairs, mainly in the area of Chemistry, Manufacturing and Controls (CMC) for both the generic and innovative industry (Teva, Chiron, Organon, Schering-Plough, MSD). Jan-Jaap is now an independent consultant in the areas of drug development and regulatory affairs from a CMC perspective.

For more information, program, trainers and registration:

MODULE 3

Quality Management in Sterile Manufacturing

A thorough discussion on sterility assurance challenges

Three days of training on sterility assurance challenges in the pharmaceutical industry and hospital pharmacies

4 – 6 OCT '21

€ 1.795 ex. VAT*

The sterility of a pharmaceutical product can only be assured when a series of control measures are in place. The sterility test applied to the finished product does not guarantee sterility as only a small part of the batch is tested. Participants will gain a thorough understanding of the relevant regulatory requirements, sterility assurance measures, sterility assurance concepts, which helps to develop a critical attitude towards the development and manufacture of sterile products.

This module focuses on process design and control for manufacturing of sterile pharmaceuticals. The challenging environment in production requires expertise in microbiology and control systems specific for sterile manufacturing. Implementation of this expertise in the design and control of processes is crucial. Contamination factors and environmental control both influence several steps in the production process and will be discussed extensively

COURSE LEADER MODULE 3

Drs. J.H.A. (Jos) Mathôt (Mathôt Pharma Support) is a pharmacist by education and has over 35 years of experience working with sterile pharmaceuticals and aseptic production. Jos was Site Leader of a GE Healthcare sterile radiopharmaceutical manufacturing site. He has been active in CEN and ISO working groups concerning sterilization and sterility with special attention for aseptic production.

For more information, program, trainers and registration:

WHAT YOU WILL LEARN

- Thorough understanding of the design and control factors related to the sterility assurance of sterile pharmaceutical products;
- The principles of specific sterility related subjects, such as monitoring, cleaning and disinfection, sterilization, and validation;
- The guidelines and common practices, and to distinguish facts from myths;
- A critical attitude towards sterility assurance in sterile manufacturing.

CONTENT OF THIS MODULE

- Microbiology and implications for sterility;
- Sterile manufacturing set-up;
- Process and facility:
  - Sterilization (steam, dry heat, filtration and other);
  - Cleaning and disinfection;
  - Cleanroom behavior;
  - Pharmaceutical water systems and utilities.
- Control:
  - Environmental and water monitoring;
  - Sterility assurance in practice;
  - Validation and qualification (aseptic and analytical methods, operator qualification).
- Releasing the sterile product: The role of the QP in assuring the quality of sterile pharmaceuticals;
- Real-life case studies.