Pharmaceutical Consultancy Services

Quality Management MODULE 4
in Manufacturing of Biopharmaceuticals

21 to 23 November 2023

Three days on manufacturing biopharmaceuticals & quality aspects.

TARGET AUDIENCE

Professionals in pharmaceutical and biotechnological industries, Professionals in institutions and Contract Research Organizations (CRO's), Hospital pharmacists and Post-graduate students.

LEARNING GOALS

- Understand how biopharmaceuticals are produced and what the differences are between small and large (biopharmaceutical) molecules.
- Apply critical process parameters (CPP) and critical quality attributes (CQA).
- Understand how relevant test methods are best applied and what their limitations are.

RESULTS

- The knowledge to achieve a compliant QP release of biopharmaceutical products.
- Fundamental tools to achieve a robust manufacturing process and insight into how CPP's and CQA's are established using different approaches.
- Up-to-date information on relevant ICH guidelines and knowledge where to find EMA and FDA guidance for biopharmaceuticals.

CONTENTS

- 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 production 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

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GROUP DISCOUNTS APPLY, INQUIRE WHEN REGISTERING!

Quality Management MODULE 4

MODULE LEADER

Drs. A.C.A.J. (Aad) van de Leur – Byondis B.V.

Aad van de Leur is working at Byondis BV (formerly Synthon Biopharmaceuticals BV).
In his present function of COO he is responsible for all Biopharmaceutical operational activities including 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).

GENERAL INFORMATION

Educational Form	Seminar
Date	21 to 23 November 2023
Location	Area of Utrecht, the Netherlands

RELATED COURSES

Quality Management – the Role of the Qualified Person
This five-day training provides insight into an integrated approach on quality management as a good business practice.

What makes a PCS training so special?

562

More than 562 participants so far!

34

This is the 34th edition of this training.

93%

93% of participants would recommend this training to others.

8,1

The average rating for this module is 8.1 out of 10.