PAOFarmacie

Netherlands Centre for Post Academic Education in Pharmacy

Module 4: Quality and safety for the manufacturing of biopharmaceuticals:

from cell line development to downstream processing and formulation thorough discussion on sterility assurance challenges

PROGRAM
11 – 13 November 2019
Hotel Bergse Bossen, Driebergen, the Netherlands

Monday, 11 November 2019
Theme*: Cell line development, upstream and downstream*

09.30: Welcome
09.45: Introduction to biotechnology: applications and elements of the biotechnological production process; quality and regulatory aspects
Aad van de Leur
11.00: Upstream process development for biopharmaceutical products
Jürgen van de Lagemaat
12.30: Lunch
13.30: Cell line development and cell bank preparation
Theory and case study
-Genetics: gene of interest; description of the starting strain(s) or cell line(s); preparation and description of the product strain or cell line; genetic stability during storage of cell bank and during production.
-Cell Bank system: preparation and description of the Master Cell Bank (MCB); testing / in-process controls; protocol for preparation of subsequent Working Cell Bank (WCB).
Nienke Vriezen
16.00: Purification survey of unit operations and process integration
Marcel Ottens
18.30: Dinner

Tuesday, 12 November 2019
Theme: *The practice*

09.00: Design of an industrial process for purification of biologicals
Michel Eppink
10.15: Development, tech transfer and commercial production of monoclonal antibodies by cell culture
-Introduction Janssen Biologics
-Upstream Processing
-Downstream Processing
-Changes, deviations and CAPA's
-Case study 1: PGCS contamination
12.30: Lunch
13.30: Part 2
-Continue case study 1: PGCS Contamination
-Technology transfer & process Validation
-Process fit to plant and platform Technology
-Case study 2: IgG retention
-CQA's, CPP's and CMA's
-Spec settings
-Case study 3: Spec settings
-Closure
Marit Heblij and Martijn Wapenaar
18.00: Pathogen safety
Olaf Stamm
19.30: Dinner

Wednesday, 13 November 2019
Theme: *Quality issues*

09.00: Protein analytics of biopharmaceuticals:relevant assays and their principles
Peter Verhaert
10.30: Critical attributes and comparability studies to be announced
11.45: Quality challenges for Advanced Therapy Medicinal Products (ATMPs)
Anna de Goede
12.45: Lunch
14.00: Biosimilars: a new class of licensed biotech products
Arnold Vulto
15.15: Immunogenicity and formulation of biopharmaceuticals to be announced
16.15: Evaluation of the course
Aad van de Leur
16.30: Close

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Quality and safety for the manufacturing of biopharmaceuticals
Faculty

COURSE LEADER

Drs. A.C.A.J. (Aad) van de Leur
Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

LECTURERS

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Delft University of Technology, Dept. of Biotechnology, the Netherlands

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Charles River Biopharmaceutical Services GmbH, Erkrath, Germany

Dr. N. (Nienke) Vriezen
Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

Prof.dr. A.G. (Arnold) Vulto
Honorary professor at the Erasmus MC, Rotterdam, the Netherlands and at the KU Leuven, Belgium

Prof. dr. P.D.E.M. (Peter) Verhaert
Founder of ProteoFormiX, Beerse, Belgium

GENERAL INFORMATION

See last page for information on registration, dates and costs is available on the website of **www.paofarmacie.nl**
Select course ***Quality Management***
For more information contact Hans Noordhuis, email address **h.noordhuis@paofarmacie.nl**

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