Training Course Quality Management in Pharma and Biotech

Module 4: Quality and safety for the manufacturing of biopharmaceuticals: from cell line development to downstream processing and formulation

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

9.00 **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**

Course Leader

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Lecturers

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