Training of Max Planck Institute for Infection Biology Berlin

Day 1

08.45 – 09.00 h Welcome, presentation of the speakers and the timelines, expectation of the participants

9.00 – 10.30 What are the regulatory requirements to be followed for the manufacturing of drugs?

- Content and structure of the regulations for the manufacturing of drugs in respect to development, production, registration and distribution
    - Germany
    - Europe
    - USA

10.30– 10.45 Break

10.45 – 12.30 What does GMP means – „Why do I need to know GMP in the pharmaceutical environment?“

- History of GMP
- Topics of the regulations
- Scope of application of the guidelines
- Importance for the manufacturing and quality of a drug
- Content and application in respect to internal regulations (Guideline <-> internal SOPs)
- Legal responsibilities
    - Head of production
    - Head of quality control
    - Officer of pharmacovigilance
    - Officer of information
    - Salesman
    - Qualified Person

12.30 – 13.30 Lunch

13.30 – 14.30 Research and Development and GMP

- Manufacturing of investigational drugs
    - Good Clinical Practice
- Pharmacological and Toxicological testing
    - Good Laboratory Practice
- GMP and analytical testing
- Project management and GMP

14.30 – 14.45 Break

14.45 – 16.45 Production, quality control and quality assurance

- Main topics of the processes
- Differences in regulations
- Responsibilities in respect to quality of the drug
- Teamwork to receive qualitative products

16.45 – 17.00 Open questions

Day 2

08.45 – 09.00 h **Welcome, presentation of the speakers and the timelines, expectation of the participants**

9.00 – 10.30 Risk analysis, qualification of buildings, rooms, equipment; validation of processes

- Regulatory requirements
- Definition of the terms
- How to execute qualification
- How to execute validation
- Risk analysis as a basic requirement;
    - Tools of risk management
    - FMEA
    - HACCP
    - FTA
- Steps in qualification
    - Installation Qualification
    - Operation Qualification
    - Performance Qualification
- Steps in validation
    - Manufacturing
    - Cleaning
    - Analytical Methods

10.30– 10.45 Break

10.45 – 12.30 Hygienic requirements

- Hygienic requirements for different products
- Requirements for the rooms
- Air-look system. HVAC-system
- Sterile Products
- How to realise sterile products
    - Sterilisation by heat
    - Chemical sterilisation
    - Sterilisation by irradiation
    - Aseptic processing
- Hygienic requirements for
    - Personnel
    - Rooms

12.30 – 13.30 Lunch

13.30 – 15.00 ATMP's, Protein Engineering, Tissue Engineering

- Definition and main requirements
- Differences in manufacturing
    - Cellcultur
    - Neo-antigens
    - Genetically mutations
- Main topic in the pharmaceutical area
- Expectations from the authorities

15.00 – 15.15 Break

15.15 – 16.45 Medical devices, Combination products

- Definition of drugs, medical devices, and combination products
- Diagnostic products
    - In vitro diagnostics und „in vivo“ diagnostics
- Differences in the regulatory requirements
- Registration of medical devices in Europe
- How to handle combination products

16.45 – 17.00 Open questions

Short description of the course

The course held from 15th to 16th, November 2017 will deal with the presentation of the main requirements for the manufacturing of drugs for presenting them on the market. Special aspects on important aspects will be discussed to demonstrate that detailed requirements are to be fulfilled before the registration of the products can be requested.

Drugs are not anymore only chemical substances but meanwhile based on different starting materials such as cell culture, genetically modified cells and neo-antigens together with special expectations on the quality e. g. sterile products. To receive the high quality of drugs it is necessary to fulfill detailed expectations e. g. on rooms, personnel-behavior and toxicological and pharmacological requirements. All of these aspects will be discussed to demonstrate the complexity of drugs and what are the requirements to be fulfilled.

Beside this medical devices will become more and more interesting in the presentation of drugs mainly used in combination of theses. The course will also give a short abstract how to manufacture, register and combine medical devices with drugs.

People from all different natural sciences who will join in the near future the pharmaceutical industry will learn what are the expectations on their work and what are the characteristic differences between university/free research and the regulated environment in the pharmaceutical industry. At the end of the presentation they will have a much more clearer picture what are the expectations and where to go to.