„GxP“ Information Course

Instructors:

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Moderator:

Steffen Biernath, GMP Academy

Date: November 22, 2021

Time: 16:00-19:00 h

Location: online event

Outline:

GMP/GDP

The globally established systems of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) of medicinal products for human use serve to ensure the safety, efficacy and quality of medicines.
A brief introduction to the world of pharmaceutical regulation in these areas covers the main laws and ordinances in Germany, the EU and the USA. Questions about why such regulations were created and how they develop are also answered. The terms and the handling of the rules is not difficult and requires science and last but not least a healthy portion of common sense.
The course introduces the essential regulations with focus on the rules of the EU and gives an outline of the topics and requirements for pharmaceutical manufacturers and sales organizations.

GLP/GCP

Good Laboratory Practice (GLP) is a quality management system that is used in certified laboratories. It is necessary, among other things, for the analysis of drugs in the development stage (animal (in vivo) and cell (in vitro) studies), but also for environmental safety tests. In this part of the course, the 10 basic principles such as the requirements for personnel, apparatus and measurement results are explained.
Good Clinical Practice (GCP) encompasses the ethical and scientific quality requirements for conducting clinical trials on humans. After an overview of the different phases of drug testing and approval, the most important terms and the content of the guideline are explained. GCP is relevant for pharmaceutical companies and the contract research laboratories and clinics involved.
A short introduction (45 minutes) to the pertinent GxP regulatory framework (GLP/GMP/GCP/GDP) will be given and in additional 45 minutes GxP examples for biologics from early stage drug development to post market will be presented.