Program
International regulations for manufacturing sterile medicines

Length :14 hours (2 days)

Training: In-house or inter-site / Face-to-face or remotely

Target audience : Head Pharmacist, Quality control managers and technicians in the pharmaceutical, biotechnology, human and animal healthcare industries.

Pre-requisites : no pre-requisite

Training accessible to people with disabilities

Teaching goals

- Understand and integrate the new regulations described in Annex 1 of the European GMPs
- Be able to implement them as part of your business
- To take into account the significant differences between the main global benchmarks in this area: European GMPs Annex 1, Guidance FDA 2004 - Sterile Drug Products Produced By Aseptic Processing, Japanese Pharmacopoeia 17th edition: 2016

Training content

- Make reference to the different international regulatory texts
- Describe the historical development of Annex 1 of European GMPs and its latest revision process
- Be able to identify the different Chapters in the last document published in Annex 1
- Recognise the different contaminants
- List the key points of each chapter 1, 2, 3 and 4 of the Draft Annex 1 of February 2020
- Identify new sections and confirm requirements for the original sections of these chapters
- List the key points of each chapter 5, 6 and 7 of the February 2020 Draft Annex 1
- Identify new sections and confirm requirements for the original sections of these chapters
- List the key points of Chapter 8 of the Draft Annex 1 of February 2020
- Identify new sections and confirm requirements for the original sections of these chapters
- List the key points of each chapter 9, 10 and 11 of the February 2020 Draft Annex 1
- Identify new sections and confirm requirements for the original sections of these chapters
- Compare American, European and Japanese regulatory texts and establish the differences for the topics covered in Annex 1

How the course is organised

Speakers:
Pierre DEVAUX, Emmanuel GOURVIL

Teaching and technical tools

- Training materials
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Questions / answers sessions
- Self-assessment using a grid

Tool for monitoring the implementation of the training results assessment

- Attendance sheets.
- Knowledge acquisition assessment test
- Training certificate.