IMP manufacturing in the era of the clinical trial regulation 536/14

Luciano Gambini

Webinar for members of EIPG
in conjunction with
PIER and University College Cork

Thursday 18th November 2021
at 17.00 CET (16.00 GMT)

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About the Speakers

Luciano Gambini began his career as an analyst in R&D. He moved into Validation and Quality Assurance for the Pharmaceutical Development Department of Farmitalia Carlo Erba. At Pharmacia, later Pharmacia and Upjohn, he spent his working life in global R&D Quality Assurance setting up the internal policies for the quality of Investigational Medicinal Products (IMPs). He is currently the coordinator of the AFI (Italian Association of Industrial Pharmacists) working group on manufacture of IMPs.

The meeting will be chaired, and the subject introduced by Irene Gonzalez-Conde, Board Member of AEFI (Spanish Association of Industrial Pharmacists).

Overview of Webinar

From the 31st January 2022 the "new" Clinical Trial Regulation 536/14 and its reference documents for IMP manufacture will enter into force. The following are some of the questions arising:

- Is this a big cultural change for people involved in IMP manufacture?
- How do the interactions between GMP and GCP evolve?
- How much should the Quality System for IMP manufacture be updated?
- What are the critical differences between GMPs for IMPs and those for the commercial pharmaceutical products and which are their interactions?
- Do the responsibilities for the Sponsor and the Qualified Person remain the same?
- Particularly important for IMPs, are the labelling requirements the same?

The aim of the webinar is to provide initial answers to these questions, highlighting the differences between the current and new regulations and to propose possible solutions to cover the gaps between the old and new scenario.

Learning Outcomes

By the end of this webinar, you will be able to:

1. Understand the difference between the set of documents applicable under the EU Directive 2001/20 and those applicable under Regulation 536/14.
2. Comprehend how to update the quality system to be in compliance with the new scenario.
3. Allow the Sponsor to be aware of the new scenario in order to speed up the approval of the clinical trial.
4. Give the QPs the tools to certify the batch of IMP according to the new set of guidelines

To Join the Webinar

Please register for the event by filling out the Webinar Registration Form. **The instructions will be shown on the screen when you submit the form**, for you to keep a record of them.

Continuing Education

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.