GMP Documentation Management: Requirements and Best Practices

Alessandro Regola

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

Monday 18th November 2019 at 16.00 GMT (17.00 CET)

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About the Speaker

Alessandro Regola is currently a free-lance consultant in Pharmaceutical Sciences with main activities in the areas of cGMP and Pharmaceutical Quality System, and in optimisation or problem solving/trouble shooting. He graduated from the University of Milan in Medicinal Chemistry and Pharmaceutical Technology and has extensive experience in the pharmaceutical industry. He spent ten years working for several different companies in R&D, first in organic synthesis of small molecules and then in pharmaceutical technology. He switched to drug product manufacturing, obtaining significant experience in GMP and Quality Systems applied to dosage forms ranging from sterile products to oral solids and semisolids. His last job in the pharma industry was as head of Quality Unit of the Garbagnate and Segrate sites of Bayer Health Care Manufacturing in Milano which included responsibility for Quality Assurance and Quality Control. He regularly collaborates with Academic and Professional Societies and holds lectures and presentations at University and Industry / Regulatory Meetings.

Overview of Webinar

The presentation will cover the GMP requirements and the practical implementation of a management system for quality related documentation. After an introduction referencing the relevant GMP norms and guidances, the different types of documents will be described with their function in the Quality System and their requirements. Paper and electronic based systems will be described with their peculiarities. The presentation will continue with a description of the most frequent deficiencies in documentation management, including some examples of Authorities' observations during inspections (observations from FDA, EMA and MHRA inspections will be presented). Finally, some best practices will be presented, combining GMP compliance and efficiency in documentation management and recommended by the speaker based on his experience.

Leaning Outcomes

By the end of this presentation, you will:

1. Understand norms and guidelines requirements for documentation management
2. Understand documentation types used in the pharma industry and their characteristics
3. Be familiar with the Authorities' interpretation of requirements and most frequent observations during inspections
4. Be informed about best practices combining GMP compliance and efficiency in documentation management

To Join the Webinar

Please register for the event by filling out the form at https://docs.google.com/forms/d/e/1FAIpQLSeZrwjsRu1FQLdCruDikL2tRMYK4ck_oQTlmhNMQULn9XZv_Q/viewform. Further instructions will then be sent by e-mail.

Continuing Education:

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