PIER
Pharmacists in Industry, Education and Regulatory
IRELAND

GPIE
EIPG

Data Integrity

Alessandro Regola

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

Tuesday 11th December 2018
at 16.00 GMT (17.00 CET)

Click here to register

About the Speaker

Alessandro Regola is a graduate in Medicinal Chemistry and Pharmaceutical Technology from the University of Milan. He has more than 30 years' experience in the pharmaceutical industry, having first worked in R&D of small molecule synthesis and pharmaceutical technology for both Italian and multinational companies such as 3M Healthcare and Boehringer Ingelheim. He subsequently moved to drug product manufacturing, amassing significant experience in GMP and Quality Systems related to various dosage forms, first for Schering and subsequently for Bayer, culminating in the headship of the Quality Unit of the Garbagnate and Segrate sites of Bayer Healthcare Manufacturing. He is currently a free-lance consultant in pharmaceutical services, with activity in cGMP and Pharmaceutical Quality Systems for drug product and API manufacturing, and optimisation and problem solving for formulations, processes, technology transfer, scale-up/down, regulatory dossier preparation and deficiency letter response. He collaborates regularly with Academic and Professional Societies, and is currently Secretary to the Consiglio Direttivo, of the Associazione Farmaceutici Industria, the Italian member organisation of EIPG.

Overview of Webinar

The presentation will cover the issue related to the integrity of GMP relevant data that the pharmaceutical industry has been struggling with for the past 5-7 years mainly due to violations recorded during Authority inspections to pharmaceutical (both API and drug product) manufacturing facilities. Most common and frequent compliance issues related to paper, IT or hybrid (paper+ IT) systems will be discussed. A recommended risk assessment and remediation approach will be presented, including the classification of affected system based on risk for the quality of the product and the patient health, the evaluation of the gaps and the prioritisation of corrective actions.

Leaning Outcomes

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

1. The pharmaceutical quality requirements
2. The principles of quality risk management and their applications
3. The management of investigations of deviations and complaints
4. Containment and cross contamination requirements
5. Quality culture implementation

To Join the Webinar

Please register for the event by filling out the form at https://docs.google.com/forms/d/e/1FAIpQLSe0r6j8eodIHgt2q3bYdwzcdfJXpaFUaKJt_EPhlyy9ezIb4Q/viewform. Further instructions will then be sent by e-mail.

Continuing Education:

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