

Workshop:

Regulatory Compliance - Interface between Production and Regulatory Affairs

Topics:

- EU-Guideline “Good Manufacturing Practice” – Regulatory requirements to be fulfilled for the Product Quality Review
- Workflows at the interfaces between Production and Regulatory Affairs
- Organizing the flow of Variations within the company
- Data exchange between Production, Regulatory Affairs and the subsidiaries

Objectives of the Workshop:

Regulatory compliance is the conforming of the country’s regulatory approval with the manufacturing and quality control.

- The workshop addresses practical experience on maintaining Regulatory Compliance when handling variations specializing on the flow of information between Production, Regulatory Affairs, and the subsidiaries/third parties.
- The interface between Production and the Marketing Authorization Holders will be dealt with in detail since this is topic to the amended chapter I “Quality Management” in the EU-GMP-Guideline.
- Based on many case studies the possibilities for frictionless workflows and data management will be shown, giving hints how regulatory data (e.g. Registration, Variation) may be coordinated companywide in order to automatise the creation of the regulatory data for the PQR

These and many additional topics will be addressed and discussed in an open and confidential atmosphere within your company - the external neutral view helping to examine the complex situation

Consultant:

Dr. Mónica Unger-Bady looks back on 19 years experience in a big pharmaceutical multinational company, where she established the workflows for Regulatory Compliance. Since 2007 she provides her practical experience as an independent consultant

Programm:

Use this workshop as a kick-off for a new interface-project, as advanced training or as a round-table discussion. We would like to work with you to develop a focused program that is tailored to the precise needs of your organisation.

■ **How to contact us:**

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■ **Duration:**

This Workshop is designed for 4 hours and will be carried out in-house based on individual and detailed consultation.