



QUALITY MANAGEMENT AND AUDIT IN THE BIOTECH INDUSTRY

Quality Management becomes obligatory for companies producing medical products such as drugs and diagnostics. Especially international business and approval requires certified quality management systems thus new quality managers have quite attractive job prospects these days.

For reproducible processing in biotech manufacturing and also total traceability at all stages of production quality managers in biotech industry face several important tasks and challenges.

This 1-day workshop illustrates the job of quality managers in biotech companies dealing with general regulating documents (ISO 9001), medical products (ISO 13485), analytical and calibrating services (ISO 17025) and US market approvals (510(k) procedure). Within this workshop participants will construct an own quality management system for their own fictional pharmaceutical company with different product focus. After setting up own quality management principles participants will learn how to audit other companies within a simulation of a GMP audit.

Workshop directory:

1. Introduction into quality management
2. Setup of quality management handbooks
3. How to certify quality managements
4. Case studies: quality managements of pharmaceutical companies
5. Approval of medical products based on QM systems (EU, USA, Asia)
6. Auditor Training – Audit Simulation