

GMP In-house Training

for the Pharmaceutical,
API and Medical Device
Industry

**We offer practice-oriented
GMP training courses
in your company**

- Basic GMP
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation

GMP In-house Training Programme

Why GMP In-house Training?

Our GMP in-house training courses help your employees to put the GMP requirements into practice, to understand why they have to observe GMP rules and to develop a positive attitude towards GMP. In the discussion of topical questions, the participants become familiar with the GMP rules and solutions to concrete problems are found.



FDA and EU GMP Requirements for Training Courses

In Europe, the requirements for the GMP-compliant manufacture of drug products are laid down in the EU GMP Guide. Chapter 2 says that:

„The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.“

In the US, the CGMP Guide published by the FDA defines in 21 CFR § 211.25:

„Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee’s functions.“

Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.“

The Courses We Offer

We orientate the training courses towards the individual needs and ideas of a company. The course takes account of the specific situation in the company and of the latest GMP publications. We elaborate a training whose structure, contents and level are tailored to the target group - also considering group-dynamic effects.

In this brochure you will find some examples of the training courses we offer. Of course we will be glad to send you more proposals - just use the form on the last page for your inquiry.

The European Compliance Academy (ECA)

On the 1st of January 1999 the European Compliance Academy was founded. The European Compliance Academy (ECA) is an independent not-for-profit organisation chaired by a Scientific Advisory Board with 11 members of the pharmaceutical industry and regulatory authorities.

Every participant receives a folder with detailed training documentation.

As a **recognised institution for further education**, we issue certificates that document the participation in the training measure and that are accepted by the supervisory authorities.



Professional GMP Trainers

Our GMP trainers have been working for us as speakers over many years. Only GMP trainers who have performed successfully at our open GMP Education Courses or European Conferences can conduct in-house training on our behalf. Each special field is covered by a different trainer. In this way we ensure that you have a competent GMP trainer, no matter if the course is about current Part 11 trends or about cleanrooms for aseptic manufacture.



RICHARD BONNER

Dick Bonner was Senior Quality Advisor for Eli Lilly and Company and worked there many years in responsible positions. All in all, he can look back on 31 years of experience in the pharmaceutical industry.



DR CHRISTOPHER BURGESS

Chris Burgess is a chemist with more than 30 years' experience in the pharmaceutical industry, the greatest part of which he gathered in quality assurance and analytical R&D at Glaxo.



DR KLAUS HABERER

Industrial positions as head of microbiological QC/QA departments at Hoffmann-La Roche AG, Grenzach; Global Director of Microbiological QA/QC at Hoechst Marion Roussel AG in Frankfurt, Germany.



DR JOSEF M. HOFER

Dr Hofer headed the department International Drug Regulatory Affairs of Klinge Pharma in Munich, Germany.



DR AFSHIN HOSSEINY

Afshin Hosseiny was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.



DR BOB MCDOWALL

Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry with 2 multinational companies.



DR ANDREAS KÖNIG

Andreas König was Vice President Global Quality Operations Animal Health at Schering Plough and head of QC and QA at Fresenius Kabi.



DR JÖRG NEUMANN

Dr Neumann is a chemist and can look back on almost 20 years of experience in the pharmaceutical industry.



DR HEINRICH PRINZ

Heinrich Prinz can look back on many years working for Boehringer Mannheim (Roche Diagnostics), and Biotest AG.



DIPL.-ING. WOLFGANG RUDLOFF

Mechanical Engineer, legal expert in cleanroom technology and GMP management, worked in technical and process lead positions within Warner Lamber-Gödecke in Freiburg.



DR BERTHOLD STEMMLER

Berthold Stemmler worked for Boehringer Mannheim and Solvay Pharmaceuticals in Hannover, Germany. All in all he can look back to 30 years of industry experience.



DR HANS-PETER VOLKLAND

For several years, Hans-Peter Volkland worked in R&D and in various quality-relevant positions (QA, QC, validation and qualification).

8.00 - 8.30

Welcome and Introduction

8.30 - 9.30

Regulations in Europe

- Directives
- Guidelines
- Notice to applicants

Regulations in the USA

- CFR
- Guidances
- Freedom of Information Act

Harmonised Regulations

- WHO
- PIC
- ICH
- GHTF
- ISO

9.30 - 10.45

GMP in Manufacturing

- Quality of starting material
- Production process
- Packaging and storage
- Contract manufacturing
- Responsibilities

10.45 - 11.00 Break

11.00 - 12.15

GMP in Quality Control

- Duties of the quality control
- Different regulations in the EU and USA
- Qualified person
- Validation of analytical methods

12.15 - 13.15 Lunch

13.15 - 14.30

Documentation

- SOPs
- Batch documentation
- Quality control documentation
- GMP-compliant documentation
- Archiving

14.30 - 14.45 Break

14.45 - 15.45

Qualification and Validation

- Definition and differences
- Validation Master Plan
- Validation team
- Performance of validation
- Responsibilities

15.45 - 16.45

Change Management

- Deviation
- Change control
- Out-of-Specification
- SOP

16.45 - 17.15

Training and Self Inspection

- Performance of training
- Performance of self inspections
- SOP
- Documentation



Day 1

08.30 - 09.00 Welcome and Introduction

9.00 - 10.30

Regulatory Requirements in the Pharmaceutical Industry

- FDA CFR Parts 200, 600
- GMP Regulation, WHO, Europe
- Duties of the quality control department
- Differences between quality control and quality assurance

10.30 - 10.45 Break

10.45 - 11.45

Documentation Requirements on Qualification and Validation

- Qualification/validation policy
- Validation Master Plan
- Documents for the performance of qualification/validation
- SOPs
- Responsibilities
- Presumption for qualification/validation
- Qualification/validation report

11.45 - 13.00

Validation of Analytical Methods

- ICH Guideline
- SOPs necessary for validation
- How to write a validation plan
- Methodology and performance
- How to write a validation report

13.00 - 14.00 Lunch

14.00 - 15.15

Out of Specification (OOS)

- The Barr Case
- FDA Guideline on OOS
- Out-of-Specification SOP
- Failure Investigation
- Other departments involved

15.15 - 15.30 Break

15.30 - 16.30

Sampling

- Sampling plan
- Performance of sampling
- Pitfalls and failures of sampling
- SOP for sampling
- What to sample

16.30 - 17.15

Batch Release

- SOP for batch release
- How to document the release process
- Responsibilities

17.15 - 17.45 Discussion

Day 2

09.00 - 10.15

Stability Testing

- Stability testing plan
- Different kinds of testing
- Ongoing testing performance
- Stability report

10.15 - 10.30 Break



10.30 - 11.45

SOP/Documentation

- How to write a SOP
- Content of a SOP
- Nuts and bolts of SOPs
- GMP-compliant control of the documentation
- Archiving

11.45 - 13.00

Self Inspection/Auditing

- Inspection program
- Inspection plan
- Performance of an inspection
- Dos and don'ts
- Supervision of external contractors
- Inspection report
- Qualification of auditors

13.00 - 14.00 Lunch

14.00 - 15.00

Training

- Training Plan
- Training SOP
- Performance of Training

15.00 - 15.30 Discussion

Deviation, Failure Investigation, Annual Product Review and Change Management

Auditing / Self Inspection

8.00 - 8.30

Welcome and Introduction

8.30 - 9.30

Regulatory Requirements in Europe and the US

9.30 - 10.30

Out of Specification, OOS

- The Barr Case
- OOS Failures
- Handling of OOS results

10.30 - 10.45 Break

10.45 - 11.45

Deviation and Changes

- Differences between deviations and changes
- Occurrence of deviations and changes
- Handling of deviations and changes

11.45 - 12.45

Root Cause Analysis

- How to perform a root cause analysis
- Involvement of other departments

12.45 - 13.45 Lunch



13.45 - 14.45

Assessment of Deviation and Changes

- Risk analysis
- Outcome of the assessment
- Necessary actions related to other products and batches

14.45 - 15.00 Break

15.00 - 16.00

Trending/Annual Product Review

- Assessment and trending of changes and deviations
- Content of the report

16.00 - 17.00

Change Management System

- Change management as part of the quality management system
- SOPs
- Involvement of contract manufacturer

17.00 - 17.30 Discussion

8.00 - 8.30

Welcome and Introduction

8.30 - 9.30

Regulatory Requirements

- EU GMP Guide
- 21 CFR 211
- Harmonised requirements
- Differences between audit and self inspection

9.30 - 10.30

Audit Programme and Planning

- How to define an audit schedule
- Identify priorities

10.30 - 10.45 Break

10.45 - 11.45

Preparation for an Audit

- Communication with the auditor / auditee
- Internal and external planning of an audit

11.45 - 13.00

Realisation of an Audit

- How to prepare an audit schedule
- Performance of an audit
- Questions and answers

13.00 - 13.45 Lunch

13.45 - 14.45

Audit Report

- Wrap-up meeting
- Writing an audit report
- Follow-up of findings
- 483'er / Warning letter

14.45 - 15.00 Break

15.00 - 16.00

Nuts and Bolts of an Audit

- Failures of auditors
- Failures of auditees
- Differences between European and FDA audits

16.00 - 17.00

Qualification of Auditors

17.00 - 17.30 Discussion



08.40 - 09.00 Welcome and Introduction

09.00 - 10.00

The Regulators Requirements: What you Need to Know

- What are the Electronic Records and Electronic Signatures regulations (21 CFR 11) and what is their impact on the IT department?

10.00 - 11.00

Computer Validation - What is Required?

- The key terms defined and explained
- Roles and responsibilities defined and explained: End User, Quality Assurance and IT
- System Development Life Cycle (SDLC) planning and why is documented evidence important?
- Role of IT in the SDLC and the importance of regulatory compliance
- Aids to help validation and qualification: GAMP Guide and PDA technical reports
- Understanding:
 - How the FDA carry out inspections
 - Some typical questions you may be asked
 - The results of inspections: FDA Warning Letters and 483 Observations

11.00 - 11.15 Break

11.15 - 12.15

How do the Regulations Impact on an IT Department?

- Are your computer room facilities to standard and the environment monitored?
- Do you have procedures and documented evidence of activities?
- Do your personnel have current training records, position descriptions and CVs?
- Do you have security and access control policies?
- Understanding what the regulators want?
- What minimum written procedures are required by the regulations?
- Do you have them and do you follow them?
- What is the impact of GXP regulations on IT operations, especially on change control and configuration management?
- Do you generate of electronic records during normal operations?
- Are these managed correctly?

12.15 - 13.15 Lunch

13.15 - 14.15

Qualifying a Network and IT infrastructure

- How to define the scope and boundaries of the network to be qualified
- Documentation of components and the overall topology
- Managing the cabling contractors to ensure adequate records of activities
- Initial qualification of the network and how to proceed
- Change control and the impact of change on the networks validated applications.
- Advantages and disadvantages of common/standard operating environments for the Desktop

14.15 - 15.15

Regulatory Compliance Issues that must be Considered when Outsourcing your IT Operations

- Does the outsourcing organisation understand the regulations especially 21 CFR 11? What to do if they don't. Training and education in the context of outsourcing
- How to audit the outsourcing organisation for compliance with regulations before you sign the contract
- Case studies of auditing outsourcing
- Inputs required in the service level agreement for compliance
- When outsourcing can generate open systems

15.15 - 15.30 Break



15.30 - 16.30

Auditing IT Operations

- How to define the scope and boundaries of the audit: people, procedures, infrastructure and/or applications
- How to plan the audit: should you use a checklist?
- How to execute the audit: objective facts, not subjective views
- How to report non-compliance and design, and implement corrective actions

16.30 - 17.00 Discussion

Production of Sterile Pharmaceuticals

Day 1

9:00 - 10:00

Annex No. 1 to the European GMP Guide and other International Regulations

- Requirements and their relation to other International Guidelines for manufacturing of sterile pharmaceuticals
- FDA-guideline for submission of documentation on sterilization processes
- European Pharmacopoeia general text manufacture of sterile products
- USP chapters on sterile products

10:00 - 10:30 Coffee break

10:30 - 11:20

Principles of Sterilisation Processes

- Principles of sterilisation.
- Theory of inactivation of microorganisms
- Steam, dry heat, radiation, gassing
- Practical application of F, D and z values, Fo value
- Types of sterilization processes, Sterilization equipment

11:20 - 12:10

Sterilisation Processes Validation

- Cycle development
- Equipment qualification
- Load qualification
- Sterilization process validation

12:10 - 13:00

Classroom Exercises

- D, z, F-value calculations
- Do calculations on sterilization processes to answer prepared questions.
- Create plans for sterilization cycle development for a given list of products or products proposed from the audience.

13:00 - 14:00 Lunch break

14:00 - 14:50

Membrane Filtration

- Principles of membrane filtration
- Specific questions associated with membrane filtration sterilization
- Validation of membrane filtration
- Membrane filter integrity testing

14:50 - 15:10

Classroom Exercise

Develop plans for membrane filter selection and validation for a given list of products or products proposed from the audience.

15:10 - 15:40 Coffee break

15:40 - 16:30

Use and Evaluation of Bioindicators

- Types of biological indicators
- Application of biological indicators
- Evaluation of results

16:30 - 17:00

Classroom Exercise

Evaluate questions related to bioindicators as presented by the trainer.

Day 2

9:00 - 10:00

Aseptic Processing Validation

- International requirements
- Media fill considerations
- Media fill procedures
- Evaluation and interpretation of results
- Discussion of recent regulatory development

10:00 - 10:30

Classroom Exercise

Interpret results of media fills as shown by the trainer and develop investigation strategies.

10:30 - 11:00 Coffee Break

11:00 - 12:00

Sterility Testing and Parametric Release

- Nutrient media
- Reference strains
- Relevance of the test
- Interpretation of results
- Parametric release requirements and procedures

12:00 - 12:30

Classroom Exercise

Develop an outline of a plan for application for parametric release for a product proposed by the trainer or a participant.

13:00 - 14:00 Lunch break

13:30 - 14:30

Microbiological Laboratory Procedures

- General and selective nutrient media
- Preparation, validation and storage of nutrient media
- Characterization of reference organisms
- Storage of reference strains
- Microbiological method suitability and validation

14:30 - 15:00 Coffee break

15:00 - 16:00

Risk Analysis and Control Concepts for Sterile Product Manufacture

- Process flow chart
- Critical processing steps
- Critical control points
- Risk estimation procedures

16:00 - 16:30

Classroom Exercise

Develop an the outline of process plans for sterile product proposed by the trainer and do a risk estimation exercise.

16:30 - 17:00 General Discussion

Day 1

8.00 – 8.30

Welcome and Introduction

8.30 – 10.00

Regulatory Requirements for the Manufacturing of the Active Pharmaceutical Ingredients

- Structure of the regulations
- Europe
- USA
- Harmonisation

10.00 – 10.15 Break

10.15 – 12.15

The Quality Management System

- Regulatory requirements
- FDA's new expectations
- Maintenance of a QA system
- Key aspects of a QA system

12.15 – 13.15 Lunch

13.15 – 14.30

Risk Management, ICH Q 9

- Methods, content of ICH Q 9
- How to perform a risk assessment
- Necessary documentation
- DIN EN ISO 14971

14.30 - 14.45 Break

14.45 – 16.00

Qualification/Validation

- Regulatory requirements
- Qualification of equipment
- Documentation of qualification
- Retrospective qualification
- Requalification
- Cleaning validation
- Validation of processes
- Documentation of validation
- Retrospective validation
- Revalidation

16.00 – 17.30

Quality Control

- Regulatory requirements
- Performance of testing
- QC/QA versus Qualified Person
- Validation of analytical methods
- Stability / Retesting

17.30 – 18.00 Discussion

Day 2

8.00 – 8.30

Remarks, Questions; Proposals

8.30 – 9.30

Facility and Material Management

- Qualification of suppliers
- Supervision of suppliers
- Maintenance of equipment
- Control of incoming materials
- Storage

10.30 – 10.45 Break

10.45 – 12.45

Manufacturing of the API

- Requirements for manufacturing
- Starting material
- In-Process-Control
- PAT (Process Analytical Technology)
- Mixing up of different batches
- Reprocessing / Reworking



12.45 – 13.45 Lunch

13.45 – 14.45

GMP in Research and Development

- GMP Requirements in R & D
- Implementation of a Quality Management System
- Documentation (CTD, DMF)

14.45 - 15.00 Break

15.00 - 16.00

Documentation

- Regulatory requirements
- Documentation of the QA system
- Documentation in production, quality control, engineering, quality unit
- Annual Product Review

16.00 – 17.15

Auditing and Self Inspection

- Regulatory requirements
- Audit programme
- Audit plan
- Performance of an audit
- Supervision of contract manufacturer
- Supervision of suppliers
- Nuts and bolts of an audit

17.15 – 17.45 Discussion

GMP In-house Training Programme

Basic GMP

- Basic GMP Training
- GMP Training for Employees of Dosage Form Development

Quality Control

- FDA Compliance in Quality Control
- Stability Testing in the Pharmaceutical Industry
- GMP-Compliance in Analytical Laboratories
- Out of Specification Results

Quality Assurance

- Deviation, Failure Investigation, Annual Product Review and Change Management
- Auditing / Self Inspection
- Quality Assurance Systems Based on ISO 9001 and GMP
- Change Management - Changes and Deviations
- Good Storage Practice
- GMP and FDA Compliance in Quality Assurance Units
- Pharmaceutical Quality Systems
- Hygiene Training Course
- Cold Chain/Good Distribution Practice

IT / Computer Validation

- Regulatory Compliance for IT Professionals
- Validating Computerised Analytical Equipment and Systems
- Electronic Records and Electronic Signatures (21 CFR Part 11)

Validation/Qualification

- Qualification and Validation of Equipment and Processes in Laboratories and Manufacturing
- Basic GMP Training Qualification/Validation
- Cleaning Validation in Pharmaceutical Drug Product and API Production

Sterile Manufacture

- Production of Sterile Pharmaceuticals
- Media Fill

Solid Dosage Form Manufacture

- Tablet Manufacturing and Validation

Good Clinical Practice

- Basic Course in Good Clinical Practice

Medical Devices

- Regulatory Requirements on Medical Devices

APIs

- ICH Q7 Compliance

Regulatory Affairs

- Regulatory Structure - Regulatory Requirements for Pharmaceutical Companies
- The Regulatory aspects of Validation and Implementation of a New Technology
- Steps from Drug Development to Marketing Authorisation
- Marketing Authorisations and Post-Approval Obligations in the EU
- Quality Data in the Marketing Authorisation Application

You will find a time schedule for each training course at www.gmp-compliance.com, button Inhouse Training

We also offer in-house training courses for Qualified Persons. Please contact us for more information: info@gmp-compliance.org

We will be happy to design further GMP training courses for you on request.

If you are interested in one of our in-house training courses, please contact us and we will prepare a quotation for you.



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