Your benefits:
Customised to fit your company's requirements - cost-effective and flexible!

GMP/GDP In-house Training

for the Pharmaceutical, API and Medical Device Industry

NEW

We offer practice-oriented GMP/GDP training courses in your company

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

ECA Academy
Your GMP/GDP Information Source

ECA Academy
P.O. Box 10 21 68
69011 Heidelberg, Germany
info@gmp-compliance.org

www.gmp-compliance.org

Why In-house Training?

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

This is an ideal training solution and cost-effective way to train a larger number of people than you would normally want to send to an external course. We come to you at a time and date to suit your organisation.

Courses according to your Needs

The training courses are developed according to your needs and ideas. That means that they take into account the specific situation in your company and the latest GMP/GDP publications. That way your employees benefit from trainings whose structure, contents and provided knowledge level are exactly tailored to the target audience.

In this brochure you will find some examples of the training courses offered:

- Basic GMP Training
- FDA Compliance in Quality Control
- Deviation, Failure Investigation, Annual product Review and Change Control Management
- GMP Audits / Self Inspection
- Regulatory Compliance for IT Professionals
- Data Integrity
- ICH Q7 Compliance
- Good Distribution Practice
- Good Storage Practice

Of course we will be glad to send you more proposals. Please use the form on the last page for your inquiry.

Certificate of Attendance and Documentation

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

In addition, every participant receives an electronic version (pdf files) of the training documentation.


Certificate

Mr Paul Smith

Good Distribution Practice

Effective Remote Training

Have you already considered GMP eLearning with videos from pharmaceutical and API production?

In addition to in-house training courses you may also use GMP eLearning courses with real life videos. Please check www.gmp-elearning.com for more information

Professional GMP Trainers

Our 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 trainings on our behalf. Every specific field is covered by a different trainer. This way we ensure that you have a competent GMP trainer, no matter if the course is about process validation, computer validation, about cleanrooms for aseptic manufacture or any other topic.

The following list contains only a few GMP Trainers which are involved in multiple customised training courses.

DR RAPHAEL BAR
Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. Today, he works as trainer and consultant.

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

DR MARCEL GOVERDE
Mr Goverde led the QC Labs for non-sterile product testing at F. Hoffmann-La Roche Ltd. and he worked as a QC expert for microbiology at the chemical department of Novartis Pharma.

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. He also is a Qualified Person under permanent Provisions.

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

GERT MOELGAARD
Gert Moelgaard has been Vice President for Innovation & Business Development in NNE Pharmaplan.

DR BETTINA PAHLEN
During the last 15 years she worked at university, authority and in different areas of the pharmaceutical industry (R&D, manufacturing, quality control, quality assurance).

DR HEINRICH PRINZ
Heinrich Prinz can look back on many years working for Boehringer Mannheim (Roche Diagnostics), and Biotest AG in both QA and QC.

DR BERND RENGER
Dr Renger was Director of QC at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he held several positions at Mundipharma, Altana Pharma and Baxter. He also is a Qualified Person under the permanent provisions.

DR WOLFGANG SCHUMACHER
Dr Schumacher has more than 30 years experience in the pharmaceutical Industry. At Hoffmann-La Roche he established the IT quality assurance department and was accountable in Technical Operations as Vice Director for the GMP/CSV compliance of all global computer systems and the setup of the Data Integrity program.

DR PAUL STOCKBRIDGE
Dr Stockbridge spent 23 years with Eli Lilly, initially in fermentation development and then in quality assurance. He then moved to Aventis Pharma before being appointed Corporate Quality Director for Cobra Biomanufacturing Plc. He is now providing independent consulting and training services for the steriles, aseptic and biotechnology industries.

DR INGRID WALTHER
Dr Walther has more than 25 years professional experience in the pharmaceutical industry and in GMP consulting.

Basic GMP Training

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

We can also offer a two day training course which includes Workshops

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 for validation
- How to write a validation plan
- Methodology and performance

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

15.15 - 15.30 Break

15.30 - 16.30
Sampling
- Sampling plan
- Performance of sampling
- Pitfalls and failures of sampling
- SOP for sampling

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

We also offer further training courses for QC personnel, e.g. on
- Stability Testing
- Out-of-Specification (OOS) Handling

Deviation, Failure Investigation, Annual Product Review and Change Management

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

Auditing / Self Inspection

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
- 483s / 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

We also offer 2 and 3 days auditing courses with practical case studies!

Regulatory Compliance for IT Professionals

08.40 - 09.00 Welcome and Introduction

09.00 - 10.00
The Regulators Requirements: What you Need to Know

10.00 - 11.00
Computer Validation - What is Required?

11.00 11.15 Break

11.15 - 12.15
How do the Regulations Impact on an IT Department?

12.15 - 13.15 Lunch

13.15 - 14.15
Qualifying a Network and IT infrastructure

14.15 - 15.15
Regulatory Compliance Issues that must be Considered when Outsourcing your IT Operations

15.15 - 15.30 Break

15.30 - 16.30
Auditing IT Operations

16.30 - 17.00 Discussion

Are you looking for an individual training course on computer validation? Please contact us we will be glad to develop a training course that will meet your demands.

Requirements for Data Integrity in GMP Laboratories

09.00 - 09.15 h Introduction to Course and Instructor

09.15 - 10.15 h
Why is Data Integrity Important?

10.15 - 10.45 h
Role of Management in Data Integrity

10.45 - 11.00 h Break

11.00 - 11.45 h
Principles of Data Integrity

11.45 - 12.30 h
US 21 CFR 211 and EU GMP Chapter 4: Complete data versus raw data

12.30 - 13.30 h Lunch

13.30 - 14.15 h
Ten Compliance Commandments for Laboratory Systems

14.15 - 15.30 h
Facilitated Discussion / Workshop on Key Data Integrity Topics

15.30 - 15.45 h Break

15.45 - 16.45 h
Workshop: Developing a Data Integrity Plan

16.45 h
Key Learning Points and Final Discussion

More on Data Integrity?
We also can offer:

- 2-days training courses
- Data Integrity in Production
- Audit Trail Review

Good Distribution Practice

Day 1

08.00 h
Introduction

08.15 h
International Regulations/Requirements related to Storage and Transportation

09.30 h
European Regulatory Requirements and Guidance

10.30 h Coffee Break

11.00 h
Best Practices in Storage

12.15 h Lunch

13.15 h
Workshop Session 1:
Deviations in the Supply Chain
(What are the data telling us | How to assess deviations | What CAPAs are effective)

15.00 h Coffee Break

15.30 h
Q & A – Responses to the pre submitted questions.

Day 2

08.00 h
Cold Chain Management and its Validation

09.00 h
Best practices in Transport and Logistics

10.00 h Time for Discussion

10.15 h Coffee Break

10.45 h
Workshop Session 2:
The Selection of the best Supply Route

12.45 h Lunch

13.45 h
Security in the Supply Chain

14.30 h
Track and Trace and anti-counterfeiting Devices

15.15 h Coffee Break

15.45 h Final Discussion - Q & A

Good Storage Practice

09.00 - 09.30 h
Welcome, Introduction, Presentation of the Speaker

08.30 - 09.30 h
Regulatory Requirements of Good Storage Practice
- Europe
- USA
- Other regulations and guidelines

09.30 - 10.30 h
Good Storage Practice
- Facilities and equipment
- Environmental monitoring
- Product handling
- Maintenance
- GSP

10.30 - 10.45 h Break

10.45 - 11.45 h
Documentation
- SOPs
- Electronic and paper records
- Monitoring of the storage conditions
- Computerised systems

11.45 - 12.45 h
Operations
- Maintenance
- Control of incoming material
- Release

12.45 - 13.45 h Lunch

13.45 - 14.45 h
Management of Returned Goods
- Different storage areas
- Labelling
- Measures necessary
- Links to other department

14.45 - 15.00 h Break

15.00 - 16.00 h
Frequently found Failures / Warning Letters

16.00 - 16.30 h Discussion

ICH Q 7 Compliance for APIs

Day 1

9.00 - 9.15
Introduction and expectations for the two days

9.15 – 10.15
GMP Requirements
- General overview of Regulations (EU, US and others)
- Introduction of ICH
- ICH Q7 in general
- ICH Q7 for chemical APIs / for biotech APIs

10.00 – 10.15 Break

10.45 – 11.30
GMPs for APIs through Product Lifecycle
- Process knowledge and cGMP
- Key compliance issues

11.30 – 12.15
Change Control through the Product Lifecycle
- Changes: Good or bad? Forced or voluntary?
- The Importance of Change Control
- Scope and Responsibilities
- General requirements
- Detailed requirements for Specific Changes
- Implementation of Changes

12.15 – 13.15 Lunch

13.15 – 14.00
Supplier Qualification and Procurement
- ICH Q7 requirements
- Supplier qualification covering the full supply chain
- One strategy for supplier qualification from non-critical raw material to API
- Requirements and strategy for reduced testing (CoA release) of materials

14.00 – 15.00
Deviation and Failure Investigation
- Definitions and basic requirements
- Scope and responsibilities
- Detailed requirements
- Principles of justification for deviations
- A quick look on Root Cause Analysis
- The role of the quality unit for handling deviations and justification

15.00 – 15.30 Coffee break

15.30 – 16.45
GMP Scenarios, an interactive Workshop

16.45 – 17.00 Discussion and Q&A

Day 2

9.00 - 10.30
API Workshop „What to do if.....“
An interactive workshop on a scenario dealing with batch dispositions

10.30 – 11.00 Coffee break

11.00 – 12.00
Process Validation
- Purpose of process validation
- Prospective, concurrent and retrospective validation approaches
- Process validation protocol design
- Dos and don'ts in process validation
- Revalidation of processes
- Change control and process validation

12.00 – 13.00
Cleaning Verification or Validation
- Cleaning requirements and cleaning methods
- Cleaning verification versus validation
- Acceptance levels
- Cleaning validation approaches in mono vs multipurpose environments
- Monitoring of cleaning effectiveness after validation

13.00 - 13.15 Discussion and Q&A

GMP/GDP In-house Training Programme

Basic GMP
- Basic GMP

Quality Control
- FDA Compliance in analytical Quality Control
- Stability Testing in the Pharmaceutical Industry
- Out-of-Specification Results

Quality Assurance
NEW
- Data Integrity
- 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
- GMP and FDA Compliance in Quality Assurance Units
- Pharmaceutical Quality Systems
- Hygiene Training Course

Good Distribution Practice (GDP)
NEW
- Good Distribution Practice (Storage, Transportation, Cold Chain)
- Good Storage 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

Solid Dosage Form Manufacture
- Tablet Manufacturing and Validation

Good Clinical Practice
- Basic Course in Good Clinical Practice

Medical Devices
- Regulatory Requirements for Medical Devices

APIs
- ICH Q7 Compliance

Regulatory Affairs
- Marketing Authorisations and Post-Approval Obligations in the EU
- Quality Data in the Marketing Authorisation Application
- Quality by Design

You will find a time schedule for each training course at www.gmp-compliance.com, button 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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Title, first name, surname

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