Your Certified GMP/GDP Excellence!

ECA Academy
Your GMP/GDP Information Source

Early-bird discount*: 10% off with the code **SAVE10**

GMP/GDP Training & Conferences

OVERVIEW OF ALL EVENTS ON-SITE AND LIVE ONLINE

www.gmp-compliance.org

02/2026

* Please see the reverse side for the full terms and conditions.

Welcome

Dear readers,

The ECA Foundation's ECA Academy is Europe's leading training and information services provider in pharmaceutical quality assurance. This catalogue presents a wide variety of GMP and GDP conferences, courses, webinars and recordings supporting you to meet current regulatory expectations and best practices. Our events bring together experts from industry, academia and authorities sharing up-to-date knowledge and practical solutions for your daily work.

We look forward to welcoming you to one of our events in the near future.

Wolfgang Heimes
Administration Manager, ECA Foundation

Book by 31 July 2026 and get a 10% early-bird discount on all events* starting on or after 25 August 2026.

Here's how it works:

- Select the event of interest on www.gmp-compliance.org
- Book by 31 July 2026
- Enter the code "**SAVE10**" during the booking process

The discount will be automatically deducted from the event price.

Secure a 10% early-bird discount

*This offer does not apply to recordings and conferences with their own early bird discount (PharmaLab, QP Forum, 29th APIC/CEFIC Conference)

On-Site

Our on-site events are held in sustainable hotels throughout Europe. These events provide valuable opportunities to engage not only with the speakers but also with fellow participants.

Live Online

Live online seminars have become an integral part of our event repertoire in recent years. Thanks to modern software and location independence, professional development has never been so easy!

Recordings

Our seminar recordings offer maximum flexibility. You decide when and where you want to conduct your training and set the pace yourself. No additional software is required—the videos run directly in your browser.

GMP/GDP Training Certificate – Proof of your Qualification

Each participant of ECA Training Courses or Conferences (onsite, online training or recording/on demand) will receive a certificate from the ECA Academy.

The international GMP and GDP Guides like the EU GMP Guide and the US FDA cGMP Guide state that qualified personnel are a key prerequisite for manufacturing in compliance with the pharmaceutical legislation. Manufacturers thus need to make sure their personnel is sufficiently trained – and must document the training.

On the other side it is essential that the organisation conducting the training is qualified and recognized. The ECA Academy as the ECA Foundation's educational organisation is Europe´s largest training and information services provider – which is actually also why several thousand training and conference participants rely year by year on our training expertise.

Content

We have organised our events for you by topic – information about our certification programmes can be found at the beginning of each topic area and on our website.

ECA Academy
Your GMP/GDP Information Source

The ECA Academy

The ECA Academy is the ECA Foundation's educational organisation. It has been developing and conducting comprehensive training courses and a certification programme (education courses, conferences and webinars) in the GMP/GDP and regulatory compliance environment since the organisation was established in 1999. Together with the ECA Foundation and its ten Interest Groups, it has become the leading European provider of information and training services in the areas of pharmaceutical Quality Assurance and GMP/GDP compliance.

To learn more about the ECA Academy, please visit **www.gmp-compliance.org.**

Training Fees

The standard fees for ECA training courses and conferences (on-site and live online), webinars, and recordings are as follows:

1-day course	EUR 1,290
2-day course/conference	EUR 2,090
3-day course/conference	EUR 2,490
webinars	EUR 399

Discounts apply to ECA Members, EU/GMP Inspectorates, and APIC Members. Rebates are also available for the combination of specific training courses. Please see the website for applicable registration fees.

The ECA Certification Programme

One reason for the ECA Academy's excellent reputation is its high-quality Certification Programme – which builds on your college or university education. In the past years, thousands of GMP and GDP professionals already have relied on the programme to advance their knowledge, gain an additional qualification, and achieve the ECA Certification Level.
The comprehensive qualification curriculum comprises 15 programmes, allowing you to combine several seminars according to your fields of interest.

For more information and the individual programmes, please see **www.gmp-certification.org**

Pharmaceutical Technology

All courses marked with this symbol are recognised for the „ECA Certified Technical Operations Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Product Transfer

Organisation of a GMP-compliant site change

22-23 September 2026, Live Online Training — Course No. 22437

Highlights:

- Development of a regulatory Transfer Strategy
- Critical Quality Attributes to consider in Transfers of sterile and solid Dosage Forms
- Project Management & GMP-compliant Documentation of a Transfer

Speakers:

Dr Eva Keller, Ferring | Dr Felix Kern, Merck | Christof Langer, OSConsulting | Dr Jean-Denis Mallet, Former Head of the Pharmaceutical Inspection Dpt. AFSSAPS | Dr Lisa Matzen, Boehringer Ingelheim | Dr Harald Stahl, Romaco

Image: Spray Drying Facilities at Hovione

Spray Drying

Solutions for the pharmaceutical industry

29-30 September 2026, Live Online — Course No. 22520

Highlights:

- Fundamentals of Spray Drying
- Development of a Spray Drying Process
- Advanced Characterisation of Spray Dried Particles

Speakers:

Dr Sune Klint Andersen, Janssen Pharmaceutica | Dr Inês Matos, Hovione | Simon Phillips, Nova Laboratories Dr Thomas Quinten, Janssen Pharmaceutica | Dr Inês Ramos, Hovione | Dr Harald Stahl, Romaco | Dr João Vicente, Hovione | Dr Ann-Cathrin Willmann, Boehringer Ingelheim Pharma

15th Visual Inspection Conference

State-of-the-art 100% Visual Inspection of Parenterals

7-8 October 2026, Live Online — Course No. 22676

With an Optional Pre-Conference Course:
Fundamentals of Visual Inspection on 6 October — Course No. 22674

Highlights:

- Compliance with EU & US GMPs and Pharmacopoeias
- Manual and Automated Visual Inspection – including Usage of AI
- Organisation, Implementation and Qualification of Visual Inspection

Speakers:

Martin Dearden, M&F Pharma Quality Solutions | Haluk Dönmez, B. Braun | Dr Steven Langille, Formerly FDA Dr Helmut Gaus, ECA Visual Inspection Group & former Director Quality Control at Boehringer Ingelheim Felix Krumbein, Head ECA Visual Inspection Group, STIC consulting | Christof Langer, OSConsulting Sebastian Mayer, Heuft Systemtechnik | Dr Daniel Müller, GMP Inspector | Dr Max Scheible, Vetter Pharma Fertigung

Granulation & Tableting

13-15 October 2026, Live Online — Course No. 22472

Highlights:

- Fundamentals & Scale-Up of granulation processes: Fluidbed-Granulation, High-Shear Granulation, Roller Compaction
- Fundamentals of commercial compression processes
- Global GMP requirements for the manufacture of oral solid dosage forms

Speakers:

Dr Michael Braun, Boehringer Ingelheim Pharma | Dr Jean-Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS | Dr Harald Stahl, Romaco | Prof Dr Karl G. Wagner, University of Bonn Dr Lars Reinders, Romaco | Dr Kristina Steffens, University of Bonn

Lyophilization 2026
Includes Workshop at GEA

13-15 October 2026, Cologne, Germany — Course No. 22589

Highlights:

- Fundamentals of freeze drying
- Formulation & Process development
- Lyo-cycle development and improvement
- Scale-up and validation of freeze drying processes
- Freeze drying of highly potent and sensitive biological material

Speakers:

Anthony Cannon, MSD | Maik Guttzeit, Freelance Consultant | Dr Andrea Hawe, Coriolis Pharma Research Kristien Janssen, Pfizer | Dr Benjamin Ledermann, GEA | Mathias Montfort, Refolution Industriekälte Heide Nagel, Novartis Pharma Stein | Dr Frank Sielaff, Hessian State Office of Health and Care, Germany Dr Andrea Weiland-Waibel, ExplicatPharma

Container-/Closure-Integrity Testing

26 November 2026, Live Online — Course No. 22712

Highlights:

- Pharmacopeial & GMP Requirements for CCI testing
- Overview CCI Testing Technologies
- Case Studies Boehringer Ingelheim

Speakers:

Christof Langer, OSConsulting | Roland Koch , Gasporox | Jens Höllein, be integral | Luigi Scaffidi, Boehringer Ingelheim Pharma

Cleanrooms & HVAC Systems

9-10 March 2027, Live Online — Course No. 22850

Highlights:

- Zone Concepts for Sterile, Non-sterile and Highly Potent Products
- HVAC Components & Concepts
- GMP-compliant Clean Room Walls, Ceilings and Floors
- Implementation of Barrier Systems (Isolator/RABS)
- Classification, Qualification & Monitoring of Clean Rooms

Speakers:

Nikolaus Ferstl, Facility Engineering Services, Germany | Dr Lars Kreye, Boehringer Ingelheim, Germany | André Lourenco, Novo Nordisk, Denmark | Dr Jean Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS, France | Andreas Nuhn, D&B Pharmadesign, Germany

Pharmaceutical Water - Generation, Monitoring & Compliance

11-12 March 2027, Live Online — Course No. 22884

Highlights:

- Current GMP and Pharmacopoeial Requirements
- Engineering, Commissioning & Qualification of Pharmaceutical Water Systems
- Microbiological Control of GMP Water Systems: Monitoring & Sanitisation

Speakers:

Dr Anthony Bevilacqua, Mettler-Toledo-Thornton | Stephan Löw, CSL Behring
Markus Multhauf, Senior Consultant GMP-Engineering

Cross Contamination Control

Implementation of a cross-contamination control strategy

4-5 May 2027, Live Online — Course No. 22893

Highlights:

- Regulatory Requirements: Contamination Control Strategy & Cross Contamination
- Containment: Avoiding Exposure - Minimizing Cross Contamination
- Cross Contamination through Poor Organisation, Poor HVAC & Equipment Design
- GMP Inspector's View on Cross Contamination
- Cleaning & Cleaning Validation

Speakers:

Nikolaus Ferstl, Facility Engineering Services | Dr Andreas Flückiger, formerly F. Hoffmann La-Roche
Dr Rainer Gnibl, Government of Upper Bavaria, Germany | Dr Markus Keller, Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) | Robert G. Schwarz, GXP TrainCon, Austria

Data Integrity

All courses marked with this symbol are recognised for the „ECA Certified Data Integrity Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Data Integrity Master Class

26-28 August 2026, Copenhagen, Denmark — Course No. 22290

Highlights:

- Data Integrity in the PQS / Data Governance
- Metrics for Data Integrity
- Data Integrity Inspection / Preparing your Company for a Data Integrity Inspection

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland | Dr Franz Schönfeld, GMP Inspector, Germany | Dr Wolfgang Schumacher, SPC, Switzerland

With an optional full-day pre-course session on Raw Data - Understanding, Defining, and Managing

25 August 2026, Copenhagen, Denmark — Course No. 22288

Highlights:

- What are Raw Data? Understanding GMP Definitions and Regulations
- Interpretation of Raw Data
- True Copy vs. Raw Data

Speakers:

Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland

A discount of €600 applies when booking both courses together.

Audit Trail Review for Computerised Systems in Analytical Laboratories

22-23 September 2026, Live Online — Course No. 22411

Highlights:

- Regulations and Guidance for Audit Trails and their Review
- Audit Trail Review as Part of a Data Integrity Strategy
- Validation of Audit Trail Functionality

Speakers:

Dr Markus Dathe, F. Hoffmann-La Roche, Switzerland | Dr Bob McDowall, Member of the ECA IT Compliance Interest Group | Dr Frank Sielaff, Regional Authority, Darmstadt, Germany

Data Integrity

Requirements for a GMP-compliant data life cycle

28-30 October 2026, Live Online — Course No. 21649
12-14 May 2027, Live online — Course No. 23015

Highlights:

- Understand the Regulatory Requirements for an Audit Trail (review)
- Identifying GMP-relevant Data
- Review of Audit Trail Entries

Speakers:
Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland | Dr Franz Schönfeld, GMP Inspector, Germany

Optional full-day pre-course session: Audit Trail Review

27 October 2026, Live Online — Course No. 21647
11 May 2027, Live Online — Course No. 23013

Highlights:

- FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'
- WHO, MHRA and GAMP Data Integrity Guidances - Key Points
- Data Integrity – EU Requirements

Speakers:
Bob McDowall, R.D.McDowall, UK | Yves Samson, Kereon, Switzerland

A discount of €600 applies when booking both courses together.

HPLC Data Integrity

Ensuring Data Integrity of Chromatography Data Systems

20-21 January 2027, Live Online — Course No. 22113

Highlights:

- Regulatory Requirements for Analytical Labs (EU and U.S.)
- Data Process Mapping to Identify Risks and Vulnerabilities
- The draft update of USP <1058> - A Critical Review
- The Role of Log Books for Ensuring Data Integrity / The Role of Suppliers in Data Integrity
- Understanding Complete Data and Raw Data
- Controlling Chromatographic Integration and Data Processing

Speakers:
Dr Markus Dathe, F. Hoffmann-La Roche AG, Switzerland | Dr Bob McDowall, R D McDowall Ltd, UK
Dr Christine Mladek, Boehringer Ingelheim, Germany

Good Documentation Practice and Data Integrity

GMP-compliant instructions and records

20-22 April 2027, Heidelberg, Germany Course No. 22975

Highlights:

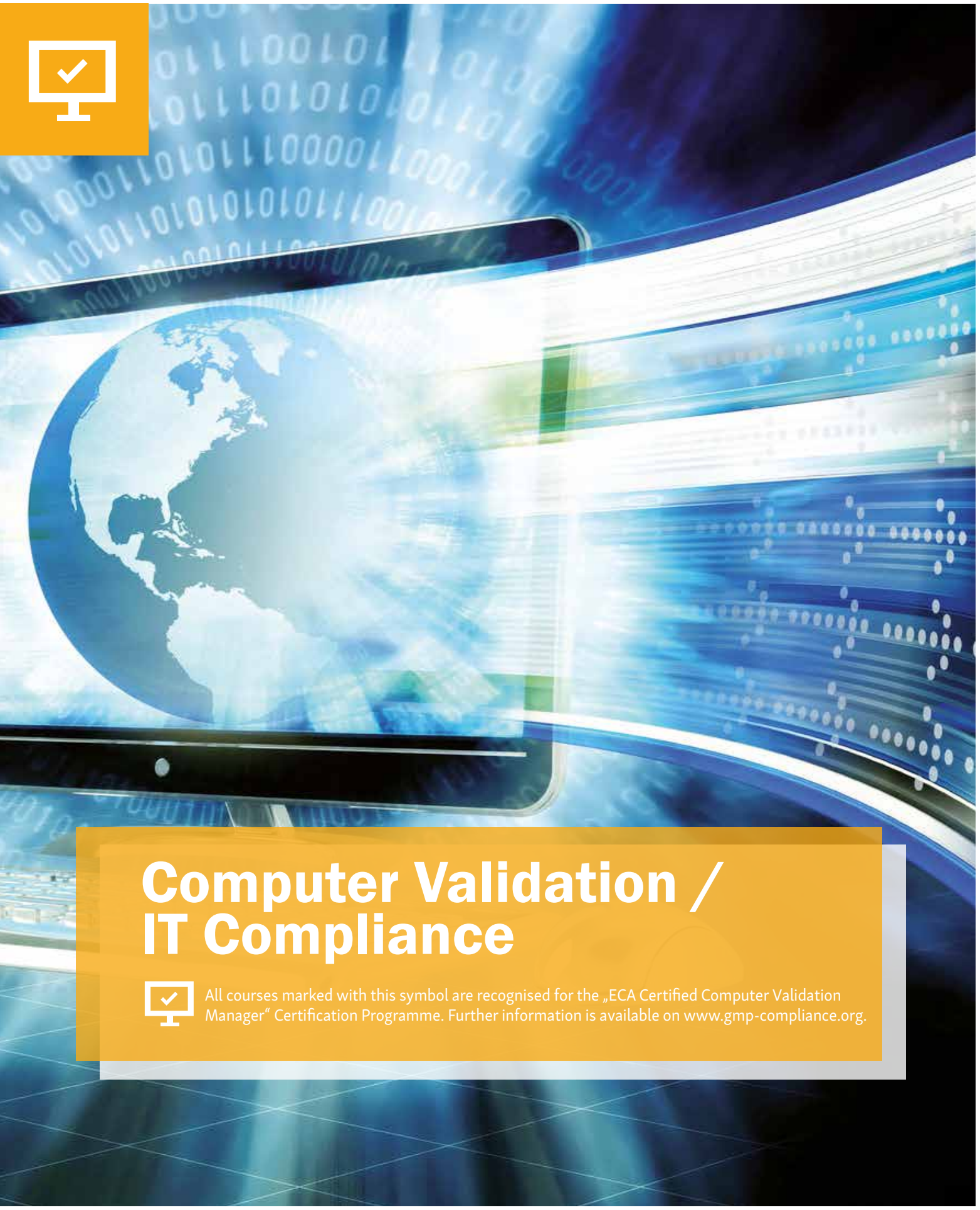
- Updates to EU GMP Chapter 4 (Documentation), Annex 11 (CSV) and USP<1029> Good Documentation Practice
- Instructions, blank forms and records – Life cycle and Data Integrity considerations
- How to perform Second Person Review of Batch Records in different formats and how to train staff in Good Documentation Practice and Data Integrity
- AI / LLM tools with regard to Data Integrity

Speakers:
Bob McDowall, McDowall Ltd. | Dr Stephan Dresen, D|Consulting | Dr Wolfgang Schumacher, SPC

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The latest recordings on the topic of Data Integrity that are currently available:

Course No.	Title
22085	ECA - Data Integrity - Online Training Recording
22084	ECA - Audit Trail Review - Online Training Recording
22426	Audit Trail Review for Computerised Systems in Analytical Laboratories - Online Training Recording
22130	ECA - HPLC Data Integrity - Online Training Recording
21418	ECA - Lab Data Integrity Master Class - Online Training Recording
20548A	ECA - Lab Data Integrity - A Practical Approach for Generating and Auditing Laboratory Records - Part 1+2 - Online Training Recording



Computer Validation / IT Compliance

All courses marked with this symbol are recognised for the „ECA Certified Computer Validation Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Computerised System Validation: GMP-Compliant Documentation

15-17 September 2026, Copenhagen, Denmark — Course No. 22398

Highlights:

- Which Documents for the Validation of Computer-based Systems are Required by Regulation?
- Which Documents are Checked in the Course of an Inspection?
- What Level of Detail must Documents Have?

Speakers:

Dr Rainer Gnibl, District Government of Upper Bavaria, Germany | Uwe Mai, Bayer, Germany | Yves Samson, Kereon, Switzerland

Computerised System Validation: How to Handle Legacy Systems?

29 September 2026, Live Online — Course No. 22402

Highlights:

- Regulatory requirements for the qualification / validation of legacy systems
- Considerations in the context of legacy system audits
- Legacy systems compliance from a QA perspective

Speakers:

Yves Samson, Kereon, Switzerland | Uwe Mai, Bayer, Germany | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

Maintaining Compliance During Operation

30 September - 02 October 2026, Live Online — Course No. 22404

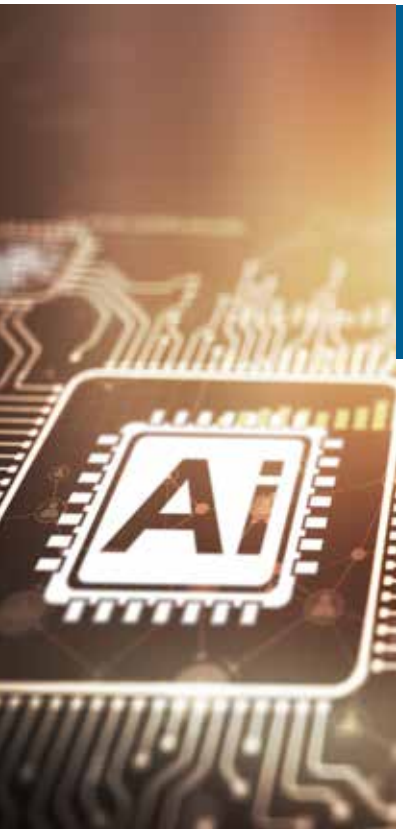
Highlights:

- Requirements from the EU GMP Guide Annex 11 and GAMP®5 2nd Edition
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems Good Practice Guide
- Handover and Establishing Support Services

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.



2nd Annex 22 / AI Conference

7-8 October 2026, Copenhagen Denmark — Course No. 22696

With a Pre-Conference Course on Basics of AI

06 October 2026, Copenhagen Denmark — Course No. 22694

Highlights:

- News about EU GMP Guide Annex 22 'Artificial Intelligence'
- What Questions about AI can be expected during an Inspection?
- Case Studies from CSL Behring / NNIT / Takeda

Speakers:

Ib Alstrup, Danish Medicines Agency, DMA, Denmark | Martin Heitmann, MH Consulting & Advisory, Germany Martin Kisselbach, CSL Behring, Germany | Volkan Kocak, Novo Nordisk, Denmark | Matthias Markus Bayer, Germany | Stefan Münch, Körber Pharma Consulting, Germany | Yves Samson, Kereon, Switzerland Julia Tomasch, Takeda, Austria | Jesper Madsen Wagner, Niras, Denmark | Michael Wegmann, Formerly F. Hoffmann-La Roche, Switzerland | Daniel Santak Wolf, Ulm University Hospital

Save EUR 400 and book both courses together (Course No. 22695)

IT for Non-IT Professionals

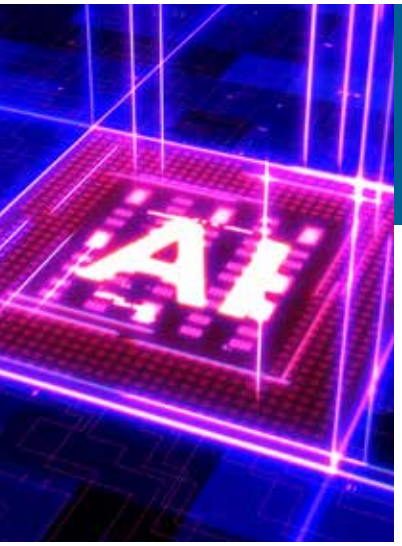
22-23 October 2026, Live Online — Course No. 22693

Highlights:

- The Technology behind your IT
- Requirements for Data Handling, Data Life Cycle and Data Management
- IT System Landscapes

Speakers:

Stefan Münch, Körber Pharma Consulting, Germany | Yves Samson, Kereon, Switzerland



GMP meets AI

How to use Artificial Intelligence in Quality Assurance and Quality Control

17-18 November 2026, Live Online — Course No. 22906

Highlights:

- AI in the GxP Environment
- How to train a GPT; Prompt Engineering
- How to Use GPT and digital Tools to Support Daily Work in QA; Application Examples

Speakers:

Peter Hackel, Takeda, Austria | Frank Hanakam, QuaSyCon | Manfred Karner, Takeda, Austria Torsten Kneuß, Bayer, Germany | Philip Lienbacher, Takeda, Austria | Arno Terhechte, District Government Münster (GMP Inspectorate)

Computerised System Validation: Introduction to Risk Management

24 November 2026, Live Online — Course No. 22405

The GAMP® 5 Approach

25-27 November 2026, Live Online — Course No. 22407

Highlights:

- The use of GAMP® 5 Second Edition
- The EU GMP Guide Annex 11 including Draft 2025
- 21 CFR Part 11
- Case studies

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland
Dr Robert Stephenson, Rob Stephenson Consultancy, UK

Computerised System Validation: Introduction to Risk Management

27 April 2027, Vienna, Austria — Course No. 22792

The GAMP® 5 Approach

28-30 April 2027, Vienna, Austria — Course No. 22794

Highlights:

- The Use of GAMP®5 Second Edition
- The EU GMP Guide Annex 11 Including Draft 2025
- Up to 10 Workshops / Interactive Sessions

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Yves Samson, Kereon, Switzerland
Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.

IT / OT Infrastructure Qualification and Operation in a GxP Environment

19-21 May 2027, Copenhagen, Denmark — Course No. 22801

Highlights:

- Information Technology (IT) / Operational Technology (OT) Infrastructure Enterprise Model
- Regulatory Requirements
- IT Compliance for the IT Infrastructure

Speakers:

Frank Behnisch, formerly of CSL Behring, Germany | Bob McDowall, R.D.McDowall, UK
Yves Samson, Kereon, Switzerland

Computerised System Validation: Auditing and Leveraging IT / OT Suppliers and Service Providers

8 June 2027, Copenhagen, Denmark — Course No. 22798

Highlights:

- Overview of IT/OT Suppliers and Service Providers
- Supplier Selection Process, Auditing IT/OT Suppliers, Leveraging Audit Findings
- Two Workshops: Selecting A Supplier and Quality Planning Exercise

Speakers:
Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

Computerised System Validation Master Class

9-11 June 2027, Copenhagen, Denmark — Course No. 22800

Highlights:
This event will provide you with

- Suggestions on how current regulatory guidance on computerised systems relating to data integrity, critical thinking and CSA (Computer Software Assurance) can be put into practice
- Real-life examples of how validation effort can be scaled according to risk-based approaches
- Answers to specific questions, e.g. on source code review or on creating specification documents
- Learning by doing: 9 Workshops

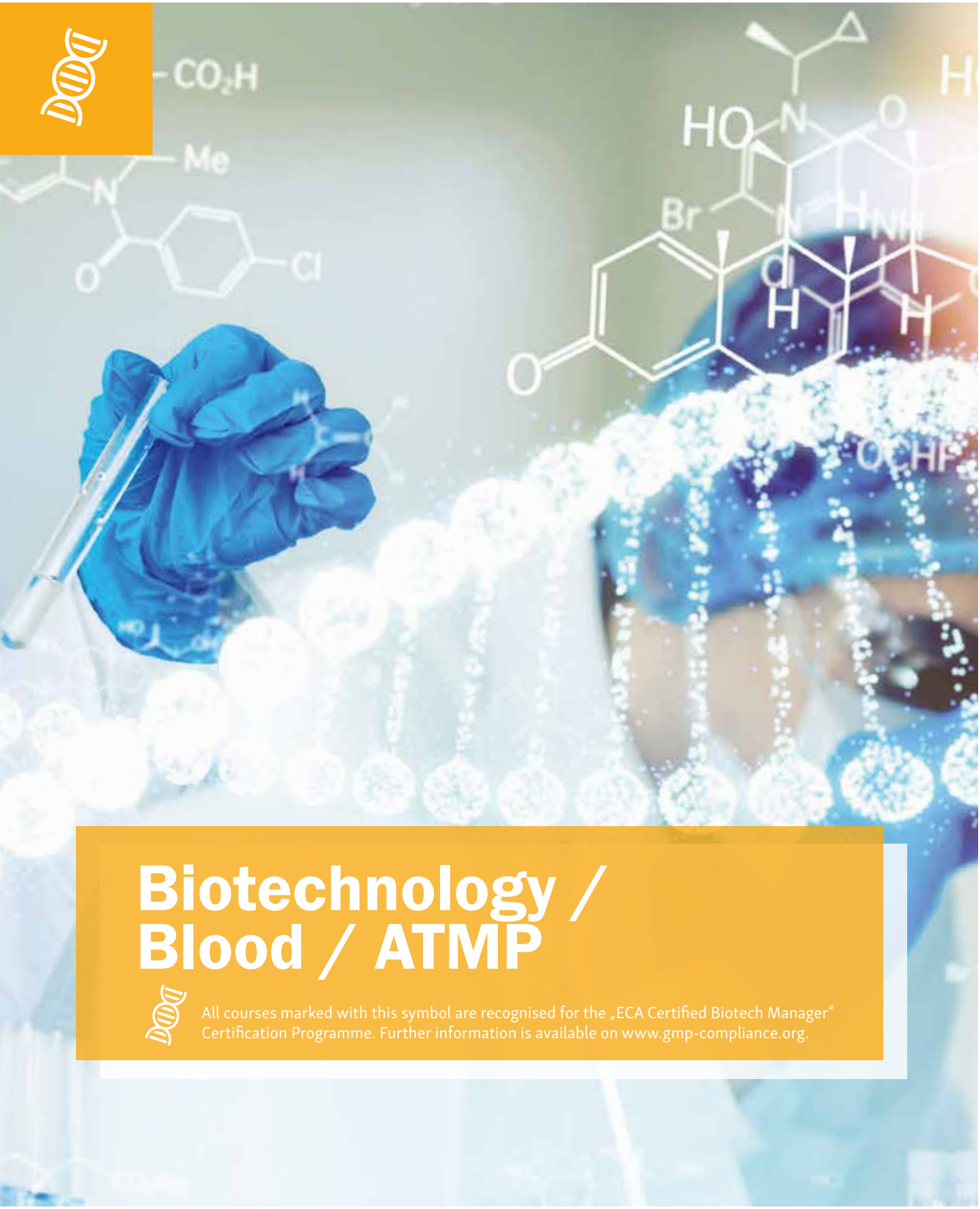
Speakers:
Frank Behnisch, formerly CSL Behring, Germany | Yves Samson, Kereon, Switzerland | Dr Robert Stephenson, Rob Stephenson Consultancy, UK

A discount of €600 applies when booking both courses together.

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The latest recordings on the topics of Computer Validation / IT Compliance that are currently available:

Course No.	Title
22890	ECA - Cloud Computing in a GxP Environment - Online Training Recording
22727	ECA - Computerised System Validation: The GAMP 5 Approach - Online Training Recording
22713	ECA - Computerised System Validation: Introduction to Risk Management - Online Training Recording
22639	ECA - IT for Non-IT Professionals - Online Training Recording
22606	ECA - Annex 11: the new draft and its consequences - Online Training Recording
22304	ECA - Computerised System Validation: Maintaining Compliance during Operation - Online Training Recording
22305	ECA - Computerised System Validation: How to handle Legacy Systems? - Online Training Recording
22079	ECA - Computerised System Validation: GMP Compliant Documentation - Online Training Recording



Biotechnology / Blood / ATMP

All courses marked with this symbol are recognised for the „ECA Certified Biotech Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

GMP for ATMPs

Basic training for beginners & newcomers

30 September/01 October 2026, Live Online Training — Course No. 22587

Highlights:

- Definitions and Key Regulations of ATMP and GMP
- Risk-based Approach
- Environmental Monitoring and (Cross) Contamination

Speakers:

Dr Rüdiger Alt, Novartis | Dr Rainer Gnibl, Local Government of Upper Bavaria | Dr Sabine Hauck, Chair of ECA ATMP Interest Group | Dr Ulrich Kissel, Chair of ECA ATMP Interest Group

Pharmaceutical Biotechnology for Non-Biotechnologists

20-21 October 2026, Heidelberg, Germany — Course No. 22588

Highlights:

- Basics & Regulatory Requirements
- Overview and Step in into the field of Biotechnology
- Process Overview: From Manufacturing of API to Fill&Finish
- Regulations & Challenges for ATMPs

Speakers:

Dr. Ulf Gurok, Roche Diagnostics | Dr Sabine Hauck, dequra pharma consult hauck | Stephan Löw, CSL Behring

GMP for Vaccine Manufacturers

27-28 October 2026, Heidelberg, Germany — Course No. 22590

Highlights:

- 3 Case Studies: Vaccine Facility Design, Design, Construction and Qualification of a new production line , GMP development and manufacturing of recombinant viral Vaccines for Clinical Trials
- Regulatory Requirements of conventional and modern vaccines
- GMP issues for upstream and downstream processing
- Staff Safety

Speakers:

Mag. Petra Falb, AGES - Austrian Agency for Health and Food Safety | Faye Litherland, FPC Life Sciences
Robert G. Schwarz, GXP-TrainCon | Dr Frank Sielaff, GMP Inspector, Regional Authority, Darmstadt, Germany
Dr Jörg Weyermann, GlaxoSmithKline

Development

All courses marked with this symbol are recognised for the „ECA Certified Pharmaceutical Development Manager“ Certification Programme. Further information is available on www.gmp-compliance.org

AI in Development

AI/ML-based Methods for Optimizing Pharmaceutical Research Processes

29 October 2026 Live Online — Course No. 22217

Highlights:

- How to use Machine Learning (ML) for Molecular Discovery
- Innovative Methods to decode Pathways
- Risk-based Validation of Computer-Aided and AI-Based Systems

Speakers:

Nils Strohmenger, Merck Life Science | Dr Marcel Franke, Merck Life Science | Dr Irina Tihaa, d-fine
Prof Dr Pascal Friederich, Karlsruhe Institute of Technology | Emily Butterworth, AstraZeneca UK
Dr Torsten Stemmler, BfArM (invited)

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

18-20 November 2026, Heidelberg, Germany — Course No. 22518

Highlights:

- Legal Requirements and Authority Inspections
- GMP Issues and best Practices
- Case Studies and practical Examples

Speakers:

Dr. Joachim Ermer, Ermer Quality Consulting, Germany | Dr. Sue Mann, Sue Mann Consultancy, UK
Dr. Ulrich Kissel, European QP Association (EQPA), KisselPharmaConsulting, Germany | Ian Pardo, Spires Quality / RareGenix, UK | Dr Ralf Schreiner QProgress, Germany

Auditing / Inspections

All courses marked with this symbol are recognised for the „ECA Certified GMP Auditor „ Certification Programme. Further information is available on www.gmp-compliance.org.

The GMP Auditor

Initial and continuous professional training for GMP Auditors

20-22 October 2026, Live Online — Course No. 22519
13-15 April 2027, Barcelona, Spain — Course No. 22822

Highlights:

- Expectations of the Authorities
- Risk-based Audit Planning
- Categorisation of Audit Findings

Speakers:
Dr Christian Hösch, GMP Inspector | Stefan Reintgen, Team Connex | Charis Schmidt, Ferring
Thomas Højsholm Schmidt, CSL Behring

GMP Auditor Practice

An advanced auditor course with many interactive sessions and practical examples

10-12 November 2026, Hamburg, Germany — Course No. 22489

Highlights:

- Understand and discuss: Root Causes in poor personal Behaviour, Challenging Personalities in the Audit
- How to audit: Quality Systems, Solid Dosage Forms, Parenteral Dosage Forms, ...

Speakers:
Energy Kristina Hansen, Novo Nordisk, Denmark | Ágnes Kis, form. GMP-Inspector at OGYÉI, Hungary | Christof Langer, OSConsulting, Austria | Thomas Højsholm Schmidt, CSL Behring, Switzerland

Please see www.gmp-compliance.org for updates

Efficient Supplier Qualification

17-18 March 2027, Live Online — Course No. 22826

Speakers:
Melanie Distl, Roche | Mukesh Patel, CommQP | Philipp Reusch, Reuschlaw Wolfgang Schmitt, Concept Heidelberg | Dr Franz Schönfeld, GMP Inspector | Dr Reto Theiß, Merck Healthcare

With an optional pre-course Session on

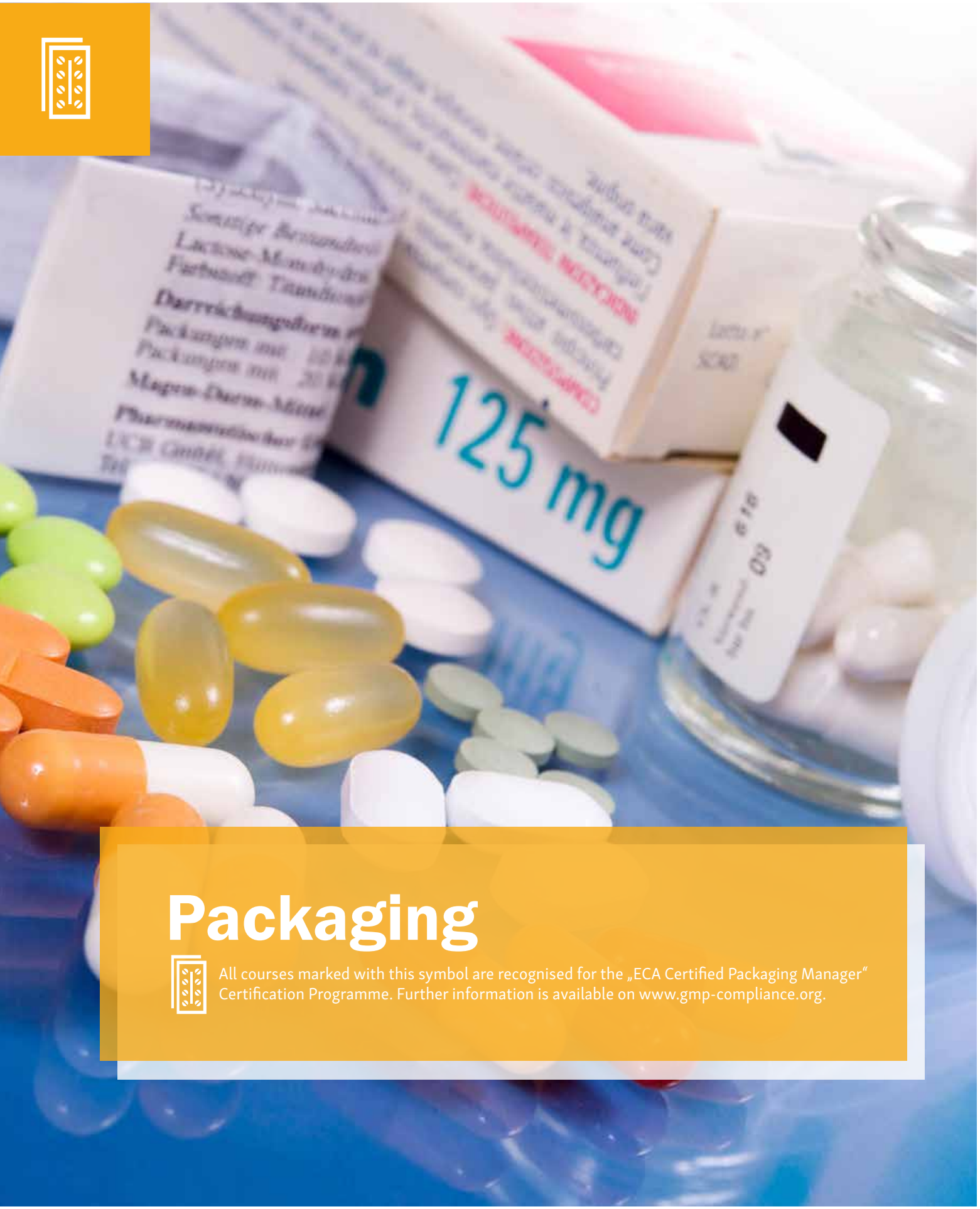
Please see www.gmp-compliance.org for updates

What You Need to Know about Suppliers in China and India

14 March 2027, Live Online — Course No. 22824

Speakers:
York Moeller, J.A.Moeller Chongqing | Mukesh Patel, CommQP

A discount of €400 applies when booking both courses together.



Packaging

All courses marked with this symbol are recognised for the „ECA Certified Packaging Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Avoiding Non-Compliance in Packaging Operations

4-5 November 2026, Live Online — Course No. 20643

Highlights:

- GMP Requirements & Guidelines for Packaging Operations
- Requirements for Packaging Facilities
- Cleaning and Hygienic Concepts for Packaging Areas

Speakers:

Alexandra Wengerter , Merz, Germany | Daniel Guirao Navarro | Reig Jofre, Spain | Dr Rainer Kahlich, GMP Inspector, Germany | Sergio Cuevas Luján, Teva | Dr Stephan Schwarze, StepS Consulting, Germany | Ana Cláudia Pinho Bial, Portugal | Alexander Gutbrod, Vetter, Germany

Pharmaceutical Packaging Systems - Development & Quality Control

Part 1: Pharmaceutical Packaging Systems - Development
24-25 November 2026, Live Online — Course No. 22468

Part 2: Pharmaceutical Packaging Systems - Quality Control
25-26 November 2026, Live Online — Course No. 22467

Highlights:

- With Case Study on Reduced Testing / Reduced Sampling!
- Regulatory Requirements & Compendial Standards:
- Sterile Packaging Material & Container Closure Integrity (CCI)
- Packaging and the Common Technical Document (CTD)

Speakers:

Dr Katrin Buss, Quality Assessor (Invited) | Katharina Golly, Novartis | Peter Huonker, Lonza
Dr Deolinda Izumida Martins, West Pharmaceutical Services | Vincent Jeanguyot, Novartis
Dr Gerald Kindermann, GxP Consulting | Torsten Kneuss, Bayer | Sergio Cuevas Luján, Teva
Dieter Mößner, Packaging Expert | Dr Haakon Wiedemann, SCHOTT

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The latest recordings on the topic of Packaging that are currently available:

Course No.	Title
22479	ECA - GMP Pre-sterilized Packaging Material - Online Training Recording
21425	ECA - Fundamentals of AQL Testing in Packaging Control - Online Training Recording

14th PharmaLab Congress

Analytics ▪ Bioanalytics ▪ Microbiology

Developments in Modern Pharmaceutical and Biopharmaceutical Laboratories

Darmstadt, Germany

(near Frankfurt Airport)

23 - 25 November 2026

Register until 31 August 2026 and save 100 EUR per congress day

Pre-Conferences Events on 23 Nov 2026

- 7th International Mycoplasma qPCR Testing User Day
- **NEW!** Data Quality Management of Aberrant Results
- Quality Control of mRNA/LNP Products

Conferences on 24/25 Nov 2026

- Alternative and Rapid Microbiological Methods
- Endotoxin and Pyrogen Testing
- Analytical Procedure Lifecycle Management (APLM)
- Artificial Intelligence in Laboratories
- GMP Compliance Trends in Analytical Laboratories
- Laboratory Optimization, Automation and Digitalization/Outsourcing in Pharmaceutical Laboratories
- Bioanalytical Control of Biological Drug Substances and Products
- Bioassays/Potency Assays – Regulatory Requirements, Development and Routine Use
- Cell and Gene Therapies/ ATMPs - Quality and Safety

Please see
www.pharmalab-congress.com
for details

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CONCEPT HEIDELBERG

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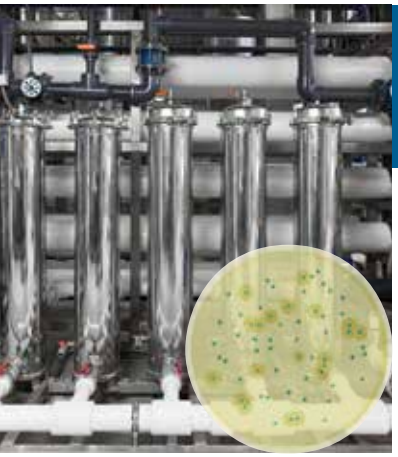
Microbiology / Hygiene

All courses marked with this symbol are recognised for the „ECA Certified Microbiological Laboratory Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.



Rapid Microbial Methods for Pharmaceutical Water Systems

29-30 September 2026, Live Online — Course No. 22297

Highlights:

- Rapid Water Monitoring Systems – Case Studies
- Validation of alternative methods for microbiological examination of water
- Case studies of contamination in pharmaceutical water systems without microbial online monitoring

Speakers:

Markus Multhauf | Michael Miller | Hans-Joachim Anders | Jürgen Illerhaus | Harmen Hawer | Liew Feng Jin Isabel Mabrito

Contamination Control – Requirements, Measures and Strategy

3-5 November 2026, Vienna, Austria — Course No. 22721

and Post-Conference Workshop „Risk Assessment in Contamination Control“

6 November 2026, Vienna, Austria — Course No. 22817

Highlights:

- Regulatory Requirements, incl. Annex 1
- Principles of Hygiene and Microbiology
- Disinfectants: Characteristics, Selection and Qualification
- Sources of Contamination and Preventive Measures
- Microbiological Monitoring and Trending
- Risk Management
- Handling of OOS Results
- Cleanroom Garment and Single Use Consumables
- Hygiene of Personnel and Training of Operators
- Contamination Control Strategy – a Dynamic System

Speakers:

Walid El Azab, QP Pro Services, Belgium | Werner Hofstetter, Octapharma, Austria | Arjan Langen, MSD, The Netherlands | Carsten Moschner, CMC3, Germany | Inga Marie Schlägl, Bayer, Germany | Axel Schroeder, Concept Heidelberg, Germany | Robert G. Schwarz, GxP TrainCon, Austria | Wolf-Dieter Wanner, Germany

A discount of EUR 500 applies when booking both courses together.

Environmental Monitoring Data - Trending, Analysis and AI

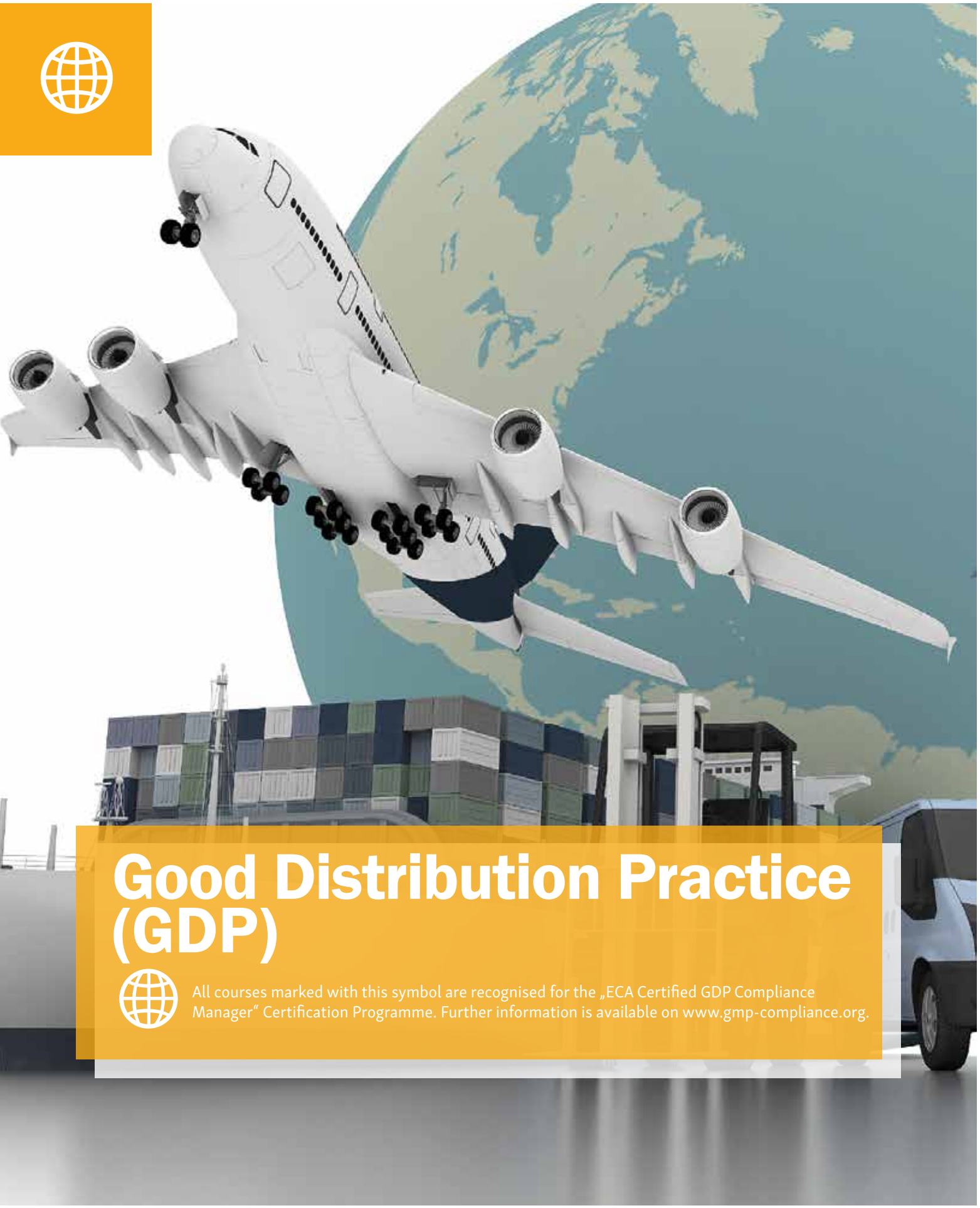
17-19 November 2026, Live Online — Course No. 22730

Highlights:

- Regulations and Infra Structure
- Dos and Don’ts for setting up an efficient monitoring program for trending and analysis
- Tools like Novatek Environmental Monitoring System, MODA and Minitab
- Charting, Trending and approaches for Interpretation
- Data Variability and Control Charts

Speakers:

Dr Raphael Bar, BR Consulting | Susan Cleary, Novatek International | Josh Magnus, Magnus Solutions Michael Schiffer, CSL Behring | Staci Williams, Lonza



Good Distribution Practice (GDP)

All courses marked with this symbol are recognised for the „ECA Certified GDP Compliance Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

8 September 2026, Basel, Switzerland — Course No. 22238

Highlights:

- Legal Bases for the Distribution of Medicinal Products
- Tasks, Responsibilities and Liability
- Practical Implementation in Switzerland

Speakers:

Dr Ina Bach, Dr Bach | Dr Johannes Fröhlich, Akroswiss | Dr Felix Kesselring, Bratschi | Dr Matthias Schwebe, Roche Pharma

Transport Validation / Transport Verification

29 September 2026, Live Online Webinar — Course No. 23001

Highlights:

- Regulatory requirements and expectations
- Planning and risk-based implementation of transport validation/verification
- Examples

Speaker:

Tim Ohlrich, gempex

Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors

6 October 2026, Live Online — Course No. 22567

Highlights:

- Mastering Supply Chain Risks
- Quality and Risk Management Systems
- Standards and Guidance in Supply Chain (GDP meets ISO; Certification and Selection of Logistics Suppliers)

Speakers:

David Abraham, Quality Resource Solutions | Dr Zvonimir Majic, IATA Senior consultant for Healthcare, Croatia

Introduction to Good Distribution Practice (GDP)

GDP in Practice – Core Requirements for Beginners)

6-7 October 2026, Live Online — Course No. 22764

Highlights:

- Regulatory Framework
- Best Practices in Storage, Transport and Cold Chain
- Data Integrity, Supply Chain Security, Import and Export, GDP Inspections

Speakers:

Kane Edgeworth, Biomap, UK | Dr Zvonimir Majic, IATA Senior consultant for Healthcare, Croatia
Sue Mann, Sue Mann Consultancy, UK

GDP for APIs

22 October 2026, Live Online — Course No. 22242

Highlights:

- Regulatory requirements
- GDP-compliant transport of active substances (human and veterinary), GDP-compliant storage
- Monitoring of suppliers and the supply chain from the perspective of the Qualified Person

Speakers:

Dr Marcel Günther, Regierungspräsidium Tübingen, Germany | Dr Martin Melzer, gempex, Germany
Dr Ulrich Kissel, KisselPharmaConsulting, Germany

The GDP Compliance Manager

1-2 December 2026, Live Online — Course No. 22244

Highlights:

- Key Areas of the EU GDP Guidelines
- GDP Expectations of the Authorities
- Gap Analysis and Risk Assessment

Speakers:

David Abraham, Quality Resource Solutions Associates, UK | Heike Gottschalg, Boehringer Ingelheim, Germany
Alfred Hunt, Hunt Pharma Solutions, Ireland | Savvas Koulouridas, Fagron BV, Netherlands
Dr Daniel Müller, GMP/GDP Inspector, Germany | Robert Müller, Boehringer Ingelheim, Germany

GDP Audits

How to audit logistics service providers

16 February 2027, Live Online — Course No. 22864

Highlights:

- Audit methodology for road transport, air freight and ocean freight
- How to prepare for and successfully host a Quality and Risk Management & GDP audit
- Practical self-study scenarios with guided feedback

All participants will exclusively receive an audit checklist for air, road, and ocean transport.

Speaker:

Dr Zvonimir Majic, IATA Senior Consultant for Healthcare, Croatia

GDP Update 2027

18 March 2027, 14:00-16:30h, Live Online Webinar — Course No. 22931

Highlights:

- Current regulatory developments: updates from the past 12 months (authorities/associations)
- Typical GDP findings in 2026: root causes, CAPA, and prevention
- GDP compliance at a glance: overview of requirements, responsibilities, and necessary documents/SOPs

Speaker:
Dr Christian Grote-Westrick, B. Braun Avitum AG

The Responsible Person for Good Distribution Practices (GDP)

28-29 April 2027, Live Online — Course No. 23030

Highlights:

- Inspector view: what authorities expect from the RP and the quality system
- RP in practice: self-inspections, validation, deviation management, and export/import
- From cold chain to security: managing different distribution scenarios

Speakers:
Alfred Hunt, Hunt Pharma Solutions, Ireland | Dr Daniel Müller, GMP/GDP Inspector, Germany
Jonathan Riley, Takeda UK | Dr Torsten Schmidt-Bader, moveproTec, Germany

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The following recordings on the topic of Good Distribution Practice that are currently available:

22868	ECA - GDP Audits - Online Training Recording
22733	ECA - The GDP Compliance Manager - Online Training Recording
22678	ECA - Webinar Recording - Commercial GDP Certificates
22624	ECA - Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors - Online Training Recording
22063	ECA - The GDP Audit - Online Training Recording
21604	ECA - GDP for Beginners - Online Training Recording
21986	ECA - Temperature-Sensitive Pharmaceuticals – Transport and Vehicle Qualification - Online Training Recording
22613	ECA - Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals - Online Training Recording

APIs / Excipients

All courses marked with this symbol are recognised for the „ECA Certified API Production Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Synthetic Peptides
Practical approaches for identification and control

19 November 2026, Live Online — Course No. 22821

Highlights:

- EMA Guideline for Development and Manufacture of Synthetic Peptides
- Peptide Related Impurities: Root Causes and Case Studies
- Peptide Synthesis: Process Understanding and Case Studies

Speaker:
Osama Chahrour, Astra Zeneca, United Kingdom

Lifecycle Management of Impurities - From Development to Market

20 November 2026, Copenhagen, Denmark — Course No. 22578

Highlights:

- How to set starting material specifications with limited data available
- How to make the link between impurities and the process
- How to evaluate potential impurities not present in your product
- **Plant tour at NCK A/S, Denmark**

This ECA course ideally complements the following 29th APIC/CEFIC Global GMP & Regulatory API Conference.

Speakers:
Marieke van Dalen, MARA Consultancy, The Netherlands | Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM, France | Anders Lohse, NCK, Denmark

ICH Q7 Training Courses 2026

ICH Q7 in modern API manufacturing - what to do and how to do

23 - 27 November 2026, Live Online

ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation
23-25 November (Course No. 22351)

ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
23-25 November (Course No. 22352)

ICH Q7 Auditor Training Course
25-27 November (Course No. 22353)

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE a sector group of cefic

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www.ichq7-week.org

29th APIC/CEFIC

GLOBAL GMP & REGULATORY API CONFERENCE

21 - 22 October 2026

in Copenhagen, Denmark

api-conference.org

Europe's largest API Conference

Speakers from Authorities and Industry

Highlights

- AI in the API industry
- Reshoring - quality & regulatory hurdles or opportunities?
- Update from EDQM, ICH, ANVISA and the Danish Medicines Agency
- 8 interactive Parallel Sessions with hot topics of the API Industry

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE a sector group of cefic

In cooperation with ECA Academy Your GMP/GDP Information Source

How to register APIs in Brazil and obtain the Brazilian GMP certificate

19 January 2027, Live Online — Course No. 22882

Highlights:

- How to handle Brazilian registrations
- Content of the registration file
- Handling changes in Brazil
- Obtaining the Brazilian GMP certificate

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Susan Swiggers, Aspen Oss, The Netherlands

GMP for Excipients

16 February 2027, Live Online — Course No. 22783

Highlights:

- EU GMP Requirements for Excipients – View of an Inspector
- Formalized Risk Assessment for Excipients

Speakers:

Emerich Grassinger, Takeda, Austria | Dr Franz Schönfeld, German GMP and GDP Inspector at the District Government of Upper Franconia

Handling of Foreign Particles in APIs and Excipients

16-17 February 2027, Live Online — Course No. 22771

Highlights:

- How to deal with technically unavoidable particles in excipients
- How to identify the source of insoluble matter
- Analytical control methods for particle detection
- How to minimise the presence of particles – strategies for cleaning and detection

Speakers:

Karl Heinz Freitag, Takeda Manufacturing Austria | Rajnish Kumar, QAR Solutions, The Netherlands
Martin Melzer, gempex, Germany | Robert G. Schwarz, GXP-TrainCon, Austria

Quality Assurance / Qualified Person

All courses marked with this symbol are recognised for the „ECA Certified Quality Assurance Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

GMP

Root Cause Analysis

A CAPA workshop on successful failure investigation

2-3 September 2026, Copenhagen, Denmark — Course No. 22618

Highlights:

- Regulations and Background
- Human Error
- Tools presented: 5 Whys, Ishikawa (Fishbone), Comparative Analyses, Bow-Tie Risk Management, ...

Speakers:

Energy Kristina Hansen, MilCor Consulting | Cecilie Hejlskov, Syntese | Tim Ohlrich, Gempex | Wolfgang Schmitt, Concept Heidelberg

GMP

Quality Risk Management

An ICH Q9 training course

16-17 September 2026, Barcelona, Spain — Course No. 22509

Highlights:

- ICH Q9 Implementation
- Expectations of the Inspector
- QRM Tools

Speakers:

Alexandra Bauloye, Johnson & Johnson Innovative, Medicine, Belgium | Christof Langer, OSConsulting, Austria
Aidan Madden, FivePharma, Ireland | Dr Franz Schönfeld, GMP Inspector, Germany

ECA | QP ASSOCIATION
An ECA Foundation Interest Group

Qualified Person Education Course: Module A

Understand the implications of becoming a QP

8-9 October 2026, Live Online — Course No. 22515

Highlights:

- The Legal and Professional Duties of the Qualified Person
- Update on European Requirements
- Delegation of Duties and Responsibilities

Speakers:

Julia Gudd, GMP and GDP Inspector, Hamburg, Germany | Dr Ulrich Kissel, European QP Association | Savvas Koulouridas, Fagron BV, The Netherlands | Aidan Madden, FivePharma, Ireland | Sue Mann, Sue Mann Consultancy, UK | Lance Smallshaw, UCB Biopharma, Belgium

CMO Oversight

Quality oversight of pharmaceutical contract manufacturing organisations

14-15 October 2026, Vienna, Austria — Course No. 22558

Highlights:

- Requirements and Responsibilities
- Challenges and possible Solutions
- Quality System Aspects

Speakers:

Energy Kristina Hansen, MilCor Consulting, Denmark | Canice Kearney, Takeda, Ireland | Sue Mann, Sue Mann Consultancy, UK | Jette Scheck, Roche, Switzerland

GMP for Beginners

Understanding the importance of GMP

20-21 October 2026, Live Online — Course No. 22462

Highlights:

- GMP History & Trends
- Basic Principles of GMP
- Elements of a QA System

Speakers:

Dr Christoph Prinz, BioNTech, Germany | Dr Heinrich Prinz, PDM Consulting, Germany | Dr Wolfgang Schumacher, SPC, Switzerland

The GMP Compliance Manager

27-28 October 2026, Berlin, Germany — Course No. 22530

Highlights:

- Current Regulatory Requirements and Expectations
- Deviations and CAPA
- Documentation Systems, Review and Approval

Speakers:

Ingo Ebeling, Abbott | Melanie Kinzner, Sandoz | Katja Kotter, Vetter Pharma-Fertigung | Sue Mann, Sue Mann Consultancy | Sebastian Rögner, Croma Pharma

Human Error: Cause or Consequence?

People empowerment in GMP

29 October 2026, Live Online — Course No. 22732

Highlights:

- Background and Regulatory Expectations
- Rethinking "Human Error" – From Blame to System Thinking
- Practical Case Examples

Speaker:
Sue Mann, Sue Mann Consultancy, U.K.

Quality Culture - People empowerment in GMP

3-4 November 2026, Hamburg, Germany — Course No. 22555

Highlights:

- How to implement Quality Culture in Business
- Knowledge Management
- Error Culture and Human Behaviour

Speakers:
Bothaina Attia, Ferring, Germany | Thaleia Aikaterini Darmi, Boehringer Ingelheim Hellas, Greece
Arnoud Herremans, Y47 Consultancy, The Netherlands | Aidan Madden, FivePharma, Ireland
Edel Ryan, Bristol Myers Squibb, Ireland

Efficient GMP Training Systems

How to implement EU-GMP Chapter 8

18-19 November 2026, Live online — Course No. 22699

Highlights:

- Optimising Quality of Training with a Focus on Virtual Reality Training and AI
- Views and Expectations of an Inspector
- Practical Examples

Speakers:
Dr Sabine Hauck, dequra pharma consult hauck | Michael Hopper, GxPpro | Dr Katrin Prospero, Vetter Pharma-Fertigung | Linda Reijinga, Ferring | Luigi Scaffidi, Boehringer Ingelheim Pharma | Dr Franz Schönfeld, GMP Inspector

Complaint Handling and Recall Management

How to implement EU-GMP Chapter 8

1-2 December 2026, Live online — Course No. 22516

Highlights:

- Regulatory requirements
- Failure Investigation
- Decision Making Process

Speakers:
Dr Rainer Gnibl, GMP Inspector for EMA and Local Government | Dr Gerald Kindermann, GxP Consulting
Dr Ágnes Kis, Compliance Consultant, formerly F. Hoffmann La-Roche | Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting | Aidan Madden, FivePharma

Please see www.gmp-compliance.org for updates

European GMPs and the Role of the Qualified Person (QP)

1-3 February 2027, Live Online — Course No. 22835

Speakers:
David Cockburn, form. European Medicines Agency (EMA) | Dr Susanne Ding, Boehringer Ingelheim
Dr Rainer Gnibl, EU-GMP Inspectorate | Dr Ulrich Kissel, European QP Association

Qualified Person Education Course Module A: Understand the Implications of becoming a QP

10-11 March 2027, Barcelona, Spain — Course No. 22776

Highlights:
- Legal Background
- Tasks and responsibilities
- Liability and indemnification

Speakers:
Julia Gudd, GMP and GDP Inspector, Ministry of Justice and Consumer Protection, Hamburg, Germany
Dr Ulrich Kissel, European QP Association | Savvas Koulouridas, Fagron BV, The Netherlands
Aidan Madden FivePharma, Ireland | Sue Mann, Sue Mann Consultancy, U.K. | Lance Smallshaw UCB, Belgium

With an optional pre-course Session: Investigational Medicinal Products (IMP) QP Education Course

9 March 2027, Barcelona, Spain — Course No. 22774

Highlights:
This pre-course session provides a detailed overview of the specific characteristics in IMP manufacturing a QP must know to certify IMP batches for the release for clinical trials.

Speakers:
Dr Susanne Ding, Boehringer Ingelheim, Germany | Patryk Jegorow, Takeda, Ireland
Sue Mann, Sue Mann Consultancy, U.K

A discount of €400 applies when booking both courses together.

Pharmaceutical Contracts: GMP and Legal Compliance

4-5 May 2027, Berlin, Germany — Course No. 22818

Highlights:

- GMP requirements
- Legal knowledge
- Practical perspective
- Every participant will get contract examples

Speakers:
Dr Carsten Coors, Vetter Development Services, Austria | Dr Rainer Gnibl, EU-GMP Inspector, Government of Upper Bavaria, Germany | Dr Monika Hupfauf, Koch/Hupfauf Lawyers, Austria

Please see www.gmp-compliance.org for updates

Qualified Person Education Course Module B

Mastering the QP role in daily practice

16-17 June 2027, Vienna, Austria — Course No. 22859

Speakers:
Georg Göstl, Qualified Person, Takeda, Austria | Dr Ulrich Kissel, European QP Association | Sue Mann, Sue Mann Consultancy, UK | Jens-Uwe Rengers, JeRo Consulting, Switzerland | Ewa Rybak, JJP Biologics, Poland

With an optional pre-course session on

Please see www.gmp-compliance.org for updates

Soft Skills for the QP

15 June 2027, Vienna, Austria — Course No. 22857

Speakers:
Arnoud Herremans, Y47 Consultancy, The Netherlands | Sue Mann, Sue Mann Consultancy, UK

A discount of €400 applies when booking both courses together.

Please see www.gmp-compliance.org for updates

Efficient Batch Record Design and Review

23-24 June 2027, Berlin, Germany — Course No. 22860

Please see www.gmp-compliance.org for updates

Quality Oversight

20-21 June 2027, Live Online — Course No. 22912

EUROPE'S BIGGEST QUALIFIED PERSON CONFERENCE

21st QP FORUM

Barcelona, Spain, 26-27 November 2026

Six parallel sessions to foster interaction

ECA | QP ASSOCIATION

An ECA Foundation Interest Group

Pre-Conference Sessions on 25 November 2026

- Specific Requirements for IMPs
- Data Quality and Data Management
- New QPs meet experienced QPs

Speakers from Authorities and Inspectorates:

Dr Björn Cohrs, GMP Inspector, Germany
Brendan Cuddy, European Medicines Agency (EMA)
Dr Rainer Gnibl, GMP Inspector, Head of Inspectorate, Germany
Mag.pharm. Andreas Kraßnigg,
Austrian Agency for Health and Food Safety (AGES)

Speakers from Industry:

Cheryl Chia, BeOne Medicines
Dr Susanne Ding, Boehringer Ingelheim
Rebecca Haywood, Pfizer
Katrien Himpens, J&J Innovative Medicine
Dr Monika Hupfauf, Koch/Hupfauf Lawyers
Patryk Jegorow, Takeda
Dr Ulrich Kissel, EQPA
Dr Nina Langoth-Fehringer, Langoth Pharma Consulting
Hanneke Later-Nijland, Genome Lawyers
Dr Elke A. Loris, Merck Healthcare
Dr Aidan Madden, FivePharma
Sue Mann, Sue Mann Consultancy
Heike Meichsner, Dr. Falk Pharma
Carme Espadamala Morató, Boehringer Ingelheim España
Susanne Müller, Reddy Holding/ betapharm
Gillian Renouf, Royal Pharmaceutical Society QP Assessment Panel, U.K.
Markus Roemer, comes compliance services
Ewa Rybak, JJP Biologics
Prof Dr Stefanie A. Schubert, SRH University Heidelberg

(other speakers invited)

www.qp-forum.org

Validation / Qualification

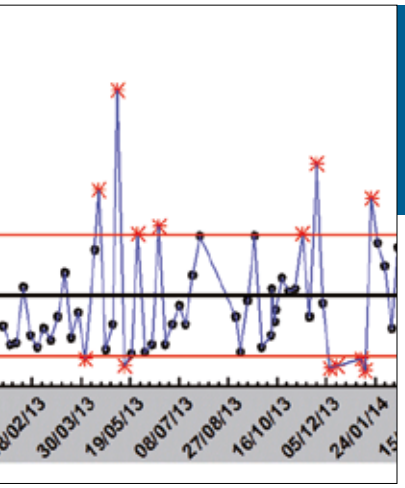
All courses marked with this symbol are recognised for the „ECA Certified Validation Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Process Validation

29-30 September 2026, Live Online — Course No. 22627

Highlights:
- EU Inspector's and FDA's Point of View
- The link between Quality by Design and Process Validation
- Establishing the Control Strategy

Speakers:
Madeleine Fritzsche, EU Inspector, Germany | Dr Line Lundsberg-Nielsen | Dr Thomas Schneppe Sarah Zimmet, Boehringer Ingelheim Pharma, Germany



Trending of Process Data for OPV/CPV

14-16 October 2026, Advanced Level Live Online Training — Course No. 22641

Highlights:
- Overview of control charts
- Process Stability & Capability
- Why fundamental requirements for control charts are not met in real-life process data

Speaker:
Dr Raphael Bar, BR Consulting

Cleaning Validation - With 2 interactive live workhops

24-25 November 2026, Live Online — Course No. 22688
27-28 April 2027, Live Online — Course No. 22994

Highlights:
- Hygienic Equipment Design / Cleaning Process Development / Sampling / Cleaning Validation, incl. practical approaches / Handling Deviations and OOS

Speaker:
Robert G. Schwarz, FH Campus Vienna, Austria

Optional post-course session on „Impact of Annex 1 Revision on Cleaning Validation"

26 November 2026, Live Online — Course No. 22690
29 April 2027, Live Online — Course No. 22996

Highlights:
- Regulatory requirements of Annex 1 regarding Cleaning Validation & Cleaning
- Annex 1, Annex 15 and EMA "Shared facilities Guideline"
- Annex 1 & Cleaning Validation – practical approaches

Speaker:
Robert G. Schwarz, FH Campus Vienna, Austria

A discount of €200 applies when booking both courses together.

Combination Products

Medicinal Products /Drugs meet Medical Devices

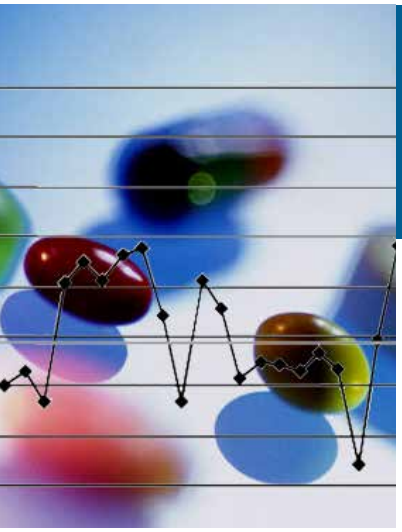
9-10 February 2027, Live Online — Course No. 22861

Highlights:

- Regulatory Requirements Medicinal Products/Drugs
- Regulatory Requirements Medical Devices
- Classification of Medical Devices in the USA
- How to get a Combination Product on the market?
- Case Study: Registration of a Combination Product

Speakers:

Dr Peer Schmidt, AbbVie | Harald Rentschler, mdc, medical devices certification
Dr Andrea Weiland-Waibel, Explicat



Statistical Process Control in the Pharmaceutical Industry

4-5 March 2027, Live Online — Course No. 22845

Highlights:

- Six Sigma, Basic Statistic, Process Improvement, Process Capability
- Case Study SPC and Trending of Microbiological Data
- Case Study Sanofi-Aventis SPC as tool for Continued Process Verification

Speakers:

Dr Ingolf Stückrath, Sanofi-Aventis, Germany | Dr Sven Wedemeyer, Merck, Germany
Dr Björn Wiese, Johnson & Johnson, Switzerland

Validation / Qualification for Beginners

4 May 2027 Live Online — Course No. 23004

Highlights:

- Change Control
- Risk Assessment
- Qualification
- Process Management

Speaker:

Dr Wolfgang Schumacher, SPC, Switzerland

The Validation Manager in the Pharmaceutical Industry

7-9 April 2027 Barcelona, Spain Course No. 22953

Highlights:

- Cleaning Validation, Computer Validation
- Risk Assessment
- Case Studies Qualification/Validation
- Four parallel workshops

Speakers:

Lynn Bryan, Ballygan Consulting, UK | Dr Line Lundsberg-Nielsen, Lundsberg Consulting, Denmark | Dr Wolfgang Schumacher, formerly of F. Hoffmann-La Roche, Switzerland | Dr Norbert Skuballa, Biologische Arzneimittel Heel, Germany

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The following recordings on the topics of Validation / Qualification are currently available:

Course No.	Title
23021	ECA -Validation/Qualification for Beginners - Online Training Recording
23009	ECA - Post-Course: Impact of Annex 1 on Cleaning Validation- Online Training Recording
23008	ECA - Cleaning Validation- Online Training Recording
22704	Equipment Qualification Forum - Online Training Recording
22655	Advanced Level: Trending of Process Data for OPV/CPV - Online Training Recording
22632	ECA - Process Validation - Online Training Recording
22481	ECA - Analytical Methods for Cleaning Validation - Online Training Recording
20706A	ECA - Lean Equipment Qualification - Online Training Recording

Quality Control / Analytics

All courses marked with this symbol are recognised for the „ECA Certified Quality Control Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Reference Standards

3 September 2026, Live Online — Course No. 22127

Highlights:

- Reference Substances of the European Pharmacopoeia – Establishment and Use
- Compendial and Regulatory Requirements
- Qualification, Management and Use of Reference Standards
- Reference Standards – GMP Inspectors' Expectations
- Uncertainty in Content Assignment of Reference Standards
- Reference Standards – a Laboratory View

Speakers:

Dr Heiko Brunner, Hamburg, Germany | Dr Joachim Ermer, Ermer Quality Consulting, Germany
Dr Rainer Gnibl, GMP Inspector for EMA and local Government, Germany | Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

EU GMP-/FDA-Compliant Sampling

22-23 September 2026, Live Online — Course No. 22565

Highlights:

- Regulatory and Compendial Requirements
- Acceptance Sampling and Sampling by Variables
- Classification of Nonconformities and allocating AQL to Classes

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Dr Gerald Kindermann, GxP Consulting, Switzerland | Philip Lienbacher, Takeda, Austria

Ph. Eur., USP and Other Pharmacopoeias

Dealing with different compendial methods

6-7 October 2026, Live Online — Course No. 22463

Highlights:

- Structure of Ph. Eur. and USP and their enforcement
- Additional Pharmacopoeias around the world – Japan, China, India, Int. Ph. (WHO)
- Harmonisation of Ph. Eur., USP, JP

Speakers:

Dr Raphael Bar, BR Consulting, Israel | Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM | Dr Lance Smallshaw, UCB, Belgium

Validation of Analytical Test Procedures & Measurement Uncertainty

13-15 October 2026, Barcelona, Spain — Course No. 22245

Highlights:

- Analytical Instrument Qualification
- Measurement Uncertainty and its Impact on Analytical Methods Validation
- Practical Determination of Validation Characteristics

Speakers:

Dr Christopher Burgess, Burgess Analytical Consultancy, UK | Trevor J. Coomber, Pharmaceutical Development, Consultant, UK | Dr Xaver Schratt, GBA Pharma, Germany

Analytical Instrument and System Qualification – An Overview

14 October 2026, Live Online — Course No. 22737

Highlights:

- Practical Exercises and Examples on how to qualify Analytical Instruments and Systems
- Updates of the revision of the USP monograph <1058> Analytical Instrument Qualification (AIQ)
- Provides an overview of instrument groups (Group A, B and C – USP <1058>) and software categories (Category 1, 3, 4 and 5 – GAMP Categories)
-

Speakers:

Dr Karl-Heinz Bauer, Trainer - Consultant – Coach (formerly with Boehringer Ingelheim)

Practical Statistical Tools for Analytical Laboratories

20-21 October 2026, Live Online — Course No. 22246

Highlights:

- Participants should gain an understanding of: basic statistical fundamentals, distribution of data and its Parameters, accuracy and precision
- Participants will be shown how to: apply statistical principles scientifically and pragmatically in their day-to-day Business, use statistical simulations

Speakers:

Dr Christopher Burgess, Burgess Analytical Consultancy, UK | Dr Joachim Ermer, Ermer Quality Consulting, Germany

The Impurities Workshop

Practical approaches for assessing the risks of Impurities

General Strategies for investigation and control of Impurities
27 October 2026, Live Online — Course No. 22757

Nitrosamine Impurities
28 October2026, Live Online — Course No. 22759

Elemental Impurities
29 October 2026, Live Online — Course No. 22761

Speakers:
Carolien Buvé (PhD), Nelson Labs, Belgium | Osama Chahrour, Astra Zeneca, UK | Dr Gerd Jilge, Formerly Boehringer Ingelheim, Germany | Dr Cornelia Nopitsch-Mai, Bonn, Germany | Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM, France | Dr Xaver Schratt, GBA Pharma, Germany

Setting Specifications and Acceptance Criteria

3-4 November 2026, Barcelona, Spain — Course No. 22573

Highlights:
- Principles for Setting of Release and Shelf-life Specifications throughout Development
- Regulatory Requirements for Specifications (ICH Q6A)
- Specifications of Biopharmaceuticals

Speakers:
Dr Ulli Backofen, Boehringer Ingelheim, Germany | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Dr Josef Hofer, EXDRA, Germany | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Dr Bettina Pahlen, Quality x Pharma Consulting, Germany | Dr Thomas Uhlich, Bayer, Germany

Stability Testing for Drug Substances and Drug Products

4-5 November 2026, Barcelona, Spain — Course No. 22574

Highlights:
- Stability Testing from Early Development to Product Launch
- Guidelines for Stability Testing
- Stability Testing for: Biologicals, Drug Substances

Speakers:
Dr Ulli Backofen, Boehringer Ingelheim, Germany | Dr Heiko Brunner, Hamburg, Germany | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Dr Josef Hofer, EXDRA, Germany | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Dr Thomas Uhlich, Bayer, Germany

A discount of €400 applies when booking both courses together.

System Suitability Tests (SST) and Troubleshooting for HPLC Methods

10 November 2026, Live Online — Course No. 22685

Highlights:

- Importance of the system suitability test (SST) and regulatory requirements of chromatographic analytical methods
- Current changes in the pharmacopoeial SST chapters
- SST parameters and their acceptance criteria with a focus on chromatographic methods

Speakers:

Dr Heiko Brunner, Hamburg, Germany | Dr Gerd Jilge, Retired Head of a Method Development Laboratory at Boehringer Ingelheim Pharma, Germany

The Analytical Procedure Lifecycle

From Analytical Target Profile to Ongoing Performance Monitoring

17-18 November 2026, Heidelberg, Germany — Course No. 22717

Highlights:

- The Analytical Procedure Lifecycle (APLC) according to USP <1220>, ICH Q14, ICH Q2(R2), USP <1221> (draft) and USP <1225> (revision draft)
- Analytical Quality by Design (AQbD) framework; Analytical Target Profile (ATP) concept; Role of measurement uncertainty (MU) throughout the APLC; Design of Experiments (DoE) and modelling tools, including available software
- Workshops in parallel sessions (small molecules & biologics)

Speakers:

Dr Joachim Ermer, Ermer Quality Consulting, Germany | Dr Amanda Guiraldelli Mahr, RIC Group, Belgium
Patrick Jackson, GSK, UK

LeanLab 2.0

Working Structures Redefined: How to Keep Your Office, Laboratory and PC Under Control

3 December 2026, Live Online — Course No. 22722

Highlights:

- Analogue and digital order in harmony: Methods for efficient workplace design – physical and digital – in the laboratories and offices
- LEAN meets AI: Fast-acting tools and smart technologies for structured work and self-effective process optimization
- Practical focus with immediate effect: Interactive exercises, tools and personal action plan to implement results on the next working day

Speakers:

Dr. Karl-Heinz Bauer, Training - Beratung - Coaching

CAPAs in QC Laboratories

11 February 2027 , Live Online — Course No. 22854

Highlights:

With practical examples and exercises to define effective CAPA measures

- Regulatory requirements for CAPA systems in quality control laboratories
- Understanding and preventing human error in the laboratory
- Effective measures to prevent OOS results

Speaker:

Dr Karl-Heinz Bauer, Trainer - Consultant - Coach (previously of Boehringer Ingelheim)

Quality Control of Starting Materials (APIs and Excipients)

Testing and Sampling of Incoming Active Pharmaceutical Ingredients (APIs) and Excipients

2-3 March 2027, Live Online — Course No. 22939

Highlights:

- Participate in 2 Workshops: Sampling and Reduced Testing
- Current regulatory/GMP and pharmacopoeial requirements for APIs, excipients and drug products
- Sampling of incoming APIs and excipients
- Reduced testing of supplied APIs and excipients

Speakers:

Emerich Grassinger Takeda, Austria | Veronika Käser, Merck Healthcare, Germany
Dr Reto Theiß, Merck Healthcare, , Germany

GMP/FDA Compliance in Analytical Laboratories

How to implement cGMP requirements in the everyday practice of quality control laboratories

9-11 March 2027, Barcelona, Spain — Course No. 22576

Highlights:

- cGMP compliance and regulatory inspection readiness in quality control laboratories
- Validation, qualification and lifecycle management of analytical methods, instruments and computerised systems
- Data integrity, GMP documentation practices and risk-based quality control
- Including 4 Interactive Workshops

Speakers:

Dr Joachim Ermer, Ermer Quality Consulting, Germany | Dr Manfred Fischer, Manfred Fischer Consulting, Germany | Joerg Kastenschmidt, Merck, Germany | Dr Bob McDowall, R D McDowall Ltd, UK

QC Compliance Manager

Key GMP Requirements and Best Practices for Analytical Quality Control Laboratories

8-9 June 2027, Live Online — Course No. 22907

Highlights:

- Regulatory Requirements for Analytical Labs (EU and U.S.)
- Sampling, Reference Standards, Stability Data, OOS/OOT Results
- Data Integrity, Lifecycle Approach, Analytical Instrument Qualification, Method Transfer

Speakers:

Dr Thomas Backensfeld, Berlin, Germany | Dr Raphael Bar, BR Consulting, Israel | Dr Thomas Fürst, Boehringer Ingelheim, Germany | Sue Mann, Sue Mann Consultancy, UK | Dr Ralph Nussbaum, betapharm Arzneimittel, Germany

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The following recordings on the topics of Quality Control / Analytics are currently available:

Course No.	Title
22914	ECA - QC Compliance Manager - Online Training Recording
22862	ECA - CAPAs in QC Laboratories - Online Training Recording
22743	ECA - GMP/FDA Compliance in Analytical Laboratories - Online Training Recording
22741	ECA - Continuous/Ongoing Verification in Pharmaceutical Analysis - Online Training Recording
22692	ECA - Stability Testing for Drug Substances and Drug Products - Online Training Recording
22739	ECA - System Suitability Tests (SST) and Troubleshooting for HPLC Methods - Online Training Recording
22640	ECA - Stability Testing Update: The New ICH Q1 Draft Guideline - Online Training Recording
22635	ECA - Practical Statistical Tools for Analytical Laboratories - Online Training Recording
22631	ECA - Transfer of Analytical Procedures - Online Training Recording
22626	ECA - EU GMP-/FDA-compliant Sampling - Online Training Recording
22473	ECA - 5s-Optimization in Offices & QC Laboratories - Online Training Recording
22447	ECA - CEP 2.0 - Online Training Recording
22414	ECA - Excel in the GxP-regulated Environment - Online Training Recording
21707	ECA - Validation in Pharmaceutical Analysis: Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit - Online Training Recording
21706	ECA - Validation in Pharmaceutical Analysis: ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy - Online Training Recording

Regulatory Affairs

§ All courses marked with this symbol are recognised for the „ECA Certified Regulatory Affairs Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Drug Master File Procedures in the EU, the US, and Japan

6-7 October 2026, Live Online — Course No. 22344

Highlights:

- Requirements of the European ASMF procedure
- Different types of Drug Master Files in the US
- How to document drug substance stability

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | Dr Cornelia Nopitsch-Mai, former Quality Assessor, Germany | Wilhelm Schlumbohm, Berlin, Germany

Handling Changes and Variations

10-11 November 2026, Vienna, Austria — Course No. 22356

Highlights:

- Also covering: Updated Variations Regulation and Veterinary Medicinal Products Variations
- The European Variations Procedure
- The CMDh Best Practice Guides and Explanatory Notes

Speakers:

Dr Peter Bachmann, BfArM, Germany | Dr Josef Hofer, exdra, Germany | Dr Wilhelm Schlumbohm, Berlin, Germany | Cristina Jimenez Sala, Centrient Pharmaceuticals

Japan Quality

1 December 2026, Live Online — Course No. 22736

Highlights:

- Regulatory Requirements in Japan
- Regulatory Management for Japan
- Specific Japan Requirements Regarding Analytical Testing, Oral Solid Dosage Forms, Liquid/Sterile Dosage Forms, Secondary Packaging Materials

Speakers:

Dr Helmut Gaus, WinSol, previously Boehringer Ingelheim | Kunihiko Furuzawa, GXP Consulting, Japan
Dr Josef Hofer, EXDRA | Dieter Mößner, Packaging Expert | Dr Jochen Scher, Boehringer Ingelheim Pharma

Global Registration and Life Cycle Management of APIs

Regulatory API information and changes thereto

11-13 May 2027, Barcelona, Spain — Course No. 22881

Highlights:

- Dossier Requirements for the Drug Substance and Requirements for the Certificate of Suitability
- ASMF Procedure
- Synthesis derived impurities, genotoxic impurities, elemental impurities and residual solvents
- Choice and justification of the API starting material in a submission
- Variations/Changes and life cycle management and Stability Data
- Registration procedures in the US, Brazil, China and Japan

Speakers:

Marieke van Dalen, MARA Consultancy, The Netherlands | EDQM speaker to be named
Dr Wilhelm Schlumbohm, Germany | Cristina Jimenez Sala, Centrient Pharmaceuticals, Spain

GMP Meets Regulatory Affairs

2-3 June 2027, Copenhagen, Denmark — Course No. 22952

Highlights:

- Structure of the CTD: Module 1-5
- Relevant GMP documents for a marketing authorisation application
- Certificate of Suitability (CEP) and Drug Master Files/Active Substance Master Files
- Regulatory Compliance and Authority Inspections

Speakers:

Marieke van Dalen, MARA consultancy, The Netherlands | Dr Rainer Gnibl, EU-GMP Inspector, Bavarian Government, Germany | Dr Josef Hofer, EXDRA, Germany | Dr Cornelia Nopitsch-Mai, Bonn, Germany

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The following recordings on the topic of Regulatory Affairs are currently available:

Course No.	Title
22894	ECA - How to register APIs in Brazil - Online Training Recording
22855	ECA - Handling of Foreign Particles in APIs and Excipients - Online Training Recording
22645	ECA - Drug Master File Procedures in the EU, the US and Japan - Online Training Recording
22622	ECA - China GMP and Registration of APIs - Online Training Recording
23036	ECA - How to write the Quality Part of an IMPD - Online Training Recording

Sterile Manufacturing

All courses marked with this symbol are recognised for the „ECA Certified Sterile Production Manager“ Certification Programme. Further information is available on www.gmp-compliance.org.

Isolator Technology Workshop

Engineering – Validation – Operation

10-11 November 2026, Basel, Switzerland — Course No. 22114

Highlights:

- You get an update on isolators for aseptic manufacture and for sterility testing
- You get to know the results of recent studies on the validation of isolators
- You have the opportunity to discuss your individual questions personally with experts
- You can translate the theory directly into practice **during 4 workshops at the manufacturing site of Skan in Allschwil**

Speakers:

Theresa Ladwig, SKAN | Ruben Rizzo, SKAN | Jordi Ruano, Hipra | Katharina Schlereth, Labor LS
Yves Scholler, SKAN | Alexandra Stärk, Novartis Pharma Stein | Dr Tarik Cheema, F. Hoffmann-La Roche

PUPSIT in Practice

Regulatory Expectations & Implementation

12 November 2026, Live Online — Course No. 22734

Highlights:

- Practical solution proposals
- Experience reports from inspections to implement regulatory requirements
- Application of risk-based approaches for integrating PUPSIT into existing cleanrooms

Speakers:

Dr Philip Hörsch, Vetter Pharma, Germany | Matthias Schaar, Novartis, Switzerland
Dr Frank Sielaff, Regional Authority Darmstadt, Germany

Quality Oversight in Sterile Manufacturing

3 December 2026, Live Online — Course No. 22591

Highlights:

- Quality Oversight; Only an FDA Requirement? Quality Oversight from a European Perspective
- Typical Challenges in Practice & Expectations of an Inspector
- Case Studies on Quality Oversight from different Companies: Boehringer Ingelheim Pharma, F. Hoffmann-La Roche, Lonza, Vetter Pharma Manufacturing

Speakers:

Michael Grosser, Lonza Biologics, Switzerland | Dr. Svenja Lacher, F. Hoffmann-La Roche, Switzerland
Dr Bettina Rietz-Wolf, GMP Inspector, Local Authority of Baden Württemberg, Germany | Hans Steier, Vetter Pharma-Fertigung, Germany | Dr Florian Witte, Boehringer Ingelheim Pharma, Germany

GMP for Beginners in Sterile Manufacturing

17-18 November 2026, Live Online — Course No. 22594

Highlights:

- Contamination Control in Aseptic Manufacturing
- Validation, Monitoring and Process Control
- Quality Oversight and Regulatory Compliance

Incl. Case Studies: "Entering the Clean Area" and "Establishing an Environmental Monitoring Program and Handling of Failures in Microbiology"

Speakers:

Michael Grosser, Lonza Biologics | Dr Björn Wiese, Johnson & Johnson | Dr Florian Witte, Boehringer Ingelheim Pharma | Margarete Witt-Mäckel, Witt-Hygienemanagement

Aseptic Process Simulation (APS) / Media Fills

GMP Requirements on Validation of Aseptic Processes

19-20 November 2026, Live Online — Course No. 22597

Highlights:

- Details from the Revised EU GMP Annex 1
- Expectations from an Inspector
- Design of a Media Fill
- Risk Management During Media Fills
- QA-Overview

Speakers:

Dr Bettina Rietz-Wolf, GMP Inspector for EMA and local Government, Germany | Luigi Scaffidi, Boehringer Ingelheim Pharma, Germany | Dr Florian Witte, Boehringer Ingelheim Pharma, Germany

A discount of EUR 500 applies when booking both courses together.

Recordings (on Demand)

The course number makes it quick and easy to find your seminar: simply enter the number into the search field at www.gmp-compliance.org to find and book the course straight away! The following recordings on the topic of Sterile Manufacturing are currently available:

Course No.	Title
22496	ECA - Annex 1 Intensive Course - Online Training Recording
22715	ECA - GMP for Beginners in Sterile Manufacturing - Online Training Recording
22029	ECA - Quality Oversight in Sterile Manufacturing - Online Training Recording

Other Topics

Emulsions & Gels

Development, Manufacture & Control of Dermatopharmaceutics and Cosmetics

30 June – 1 July 2026, Live Online — Course No. 22754

Highlights:

- GMP aspects relevant to semisolids
- Manufacturing & filling of semisolids
- Microbiological requirements

Speakers:

Dr Michael Czieborowski, BAV Institut | Dr Michael Drechsler, Bayer Consumer Care, Switzerland
Dr Claude Oelschlaeger, Karlsruhe Institute of Technology (KIT), Germany | Prof Dr Miriam Pein-Hackelbusch, University of Applied Sciences and Arts Ostwestfalen Lippe, Germany

Excel in the GxP-Regulated Environment

16 September 2026, Live Online — Course No. 22236

Highlights

- Regulatory, technical, and data integrity requirements
- Life cycle approach according to GAMP 5
- Classification (criticality and complexity)

Speaker:

Roland Miksche, MiRo Consulting, Vienna, Austria

Pharmaceutical Knowledge for Non-Pharmacists

23-24 September 2026, Live Online — Course No. 22580

Highlights:

- Pharmaceutical Knowledge Explained for Non-Pharmacists
- Comprehensive Overview from Drug Development to Release
- Understanding Interdependencies, Processes, Responsibilities

Speakers:

Sue Mann, Sue Mann Consultancy | Dr Josef Hofer, exdra | Dr Georg Böck, Boehringer Ingelheim Pharma
Dr Harald Stahl, Romaco Holding | Dr Janine Fischer, Roche Diagnostics | Dr Sabine Hauck, dequra pharma consult hauck

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