

YOUR GMP/GDP Information Source

European Events - Live Online and on Site -



Quality Assurance Quality Control Sterile/Aseptic Manufacturing APIs/Excipients **Computer Validation** Data Integrity Production/Engineering Microbiology **Biopharmaceuticals** Validation GDP Others

www.gmp-compliance.org

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in co-operation with CONCEPT HEIDELBERG

ECA GMP/GDP Certification Programme

One reason for the ECA Academy's excellent reputation is its highquality Certification Programme. In the past years, thousands of GMP and GDP professionals already relied on the programme to advance their knowledge and to get an additional qualification - and completed the ECA Certification Level.

This comprehensive qualification curriculum comprises 15 programmes, allowing professionals to combine several seminars according to their fields of interest.

New – Attend Online Courses for Certification

Many of our training courses are offered live online. Also some training courses will be offered on demand (recording of live online training courses). These online courses will be recognized for the ECA GMP/ GDP Certification Programme as well!

Objectives

Highly qualified personnel is crucial within the field of GMP-compliant manufacturing of APIs and drugs. Although college and university education provide the scientific basis, a continuous advanced training is essential.

And this is where the ECA Academy GMP Certification Programme fills the gap. It offers modular training with an industry-known certification at the end. For most of the Certification Options you will need to attend 3 training courses of a comprehensive number of events. You can:

- select courses according to your individual professional demands
- suit the course registration to your company's necessities, i.e. usually there is a period of several months between the courses. If two dates are too close together, you can attend one course in the following year.

Recognition of the Certification Programme

The ECA Academy enjoys an excellent reputation within Europe's pharmaceutical industry. The Certification Programme represents a useful completion of your college and university education. The ECA Certification Programme is the largest programme of its kind in Europe.

Which Training Courses are Recognized for the Certification Programme?

To find out which training courses are recognized for the certification program, please click on the different certification options listed below. There you will find a link to the currently recognized training courses. Please note: On each program flyer for the Training Courses you will find an indication for which certification it is recognized.

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How to Obtain the Certificate?

To obtain the certificate, please send an e-mail prior or after the 3rd event you attended to info@gmp-compliance.org. This e-mail should also list the courses you attended in the past. You will then get your certificate during the 3rd course. The Certificate will not only include the title of the Certification Programme, but also lists all ECA courses and conferences you attended. Thus, it will serve as a valid documentation for your continuous GMP and GDP education.

Continuous GMP/GDP Certification – a service offered by the ECA Academy

In order to reflect the development of a continuous advanced education for GMP and GDP professionals from 2014 on the ECA Academy will issue the Certificates of the Certification Programme with a validity date. Every new Certificate (see list of the Certificates below) will be valid for two years. To renew it the applicant has to join one ECA Training Course or Conference within that period. Applicants are quite flexible in selecting training courses or conferences for the renewal. For example, a Validation Training Course or one on OOS Results will also be recognised for the renewal of the ECA Certified QA Manager Certificate, although these courses are not specifically recognized for the QA Manager Certificate (the same applies to all other certificates). This flexibility takes into account that applicants will broaden their knowledge in GMP Compliance.

The renewal process is easy and will be managed by the ECA Academy. If you have obtained one of the Certificates below in 2014 or later you will automatically receive a new version of your certificate which contains the new two years Certification statement every time you will participate in an ECA Training Course or Conference. Please contact us at info@gmp-compliance.org if you have any further question.

We offer the following modules:





European Conferences & Education Courses

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ECA Certified Computer Validation Manager

- (AI) Artificial Intelligence:
 In a GxP Environment
 Live Online Training on 29/30 October 2024
 In Visual Inspection
 Live Online Training on 31 October 2024
- Computerized System Validation: Introduction to Risk Management Live Online Training on 26 November 2024 06 May 2025, Vienna, Austria
 The GAMP 5 Approach Live Online Training on 27 - 29 November 2024 07 - 09 May 2025, Vienna, Austria
- Computerised System Validation: GMP Compliant Documentation
 Live Online Training from 11 - 13 December 2024
- Pharma meets IT Live Online Training on 11/12 February 2025
- Cloud Computing in a GxP Environment Live Online Training from 05 - 07 March 2025

ECA Certified Data Integrity Manager

- Data Integrity Requirements for a GMP-compliant Data Life Cycle
 Live Online Training on 20 - 22 November 2024
 14 - 16 May 2025, Copenhagen, Denmark
 With an optional full-day pre-course session "Audit Trail Review", 19 November 2024
 13 May 2025, Copenhagen, Denmark
- Laboratory Data Integrity and Data Quality Part 1: 12/13 November 2024, Barcelona, Spain Part 2: 13/14 November 2024, Barcelona, Spain
- HPLC Data Integrity Live Online Training on 22/23 January 2025
- Good Documentation Practice and Data Integrity 01 – 03 April 2025, Heidelberg, Germany
- Audit Trail Review for Computerised Systems in Analytical Laboratories Live Online Training on 06/07 May 2025

ECA Certified Technical Operations Manager

- Granulation & Tableting Live Online Training from 17 - 19 September 2024
- Spray Drying Solutions for the Pharmaceutical Industry 24 - 26 September 2024, Lisbon, Portugal
- Container/Closure Integrity Testing Live Online Training on 24 October 2024
- Product Transfer Organisation of a GMP-compliant Site Change Live Online Training on 29/30 October 2024
- Visual Inspection of Parenterals State-of-the-art Visual 100% Inspection 6/7 November 2024, Berlin, Germany
- Pharmaceutical Water Generation, Monitoring & Compliance Live Online Training on 28/29 January 2025

- Clean Rooms & HVAC Systems Live Online Training on 13/14 May 2025
- GMPs for Equipment, Utilities and Facilities 03 - 05 June 2025, Munich, Germany

ECA Certified Biotech Manager

- Pharmaceutical Biotechnology for Non-Biotechnologists 09/10 October 2024, Berlin, Germany
- Monoclonal Antibodies From Concept to Approval Live Online Training on 22/23 October 2024
- Blood, Plasma and Stem Cells Audits and Inspections Live Online Training on 05/06 November 2024
- Annex 2 & Co GMP Compliance for Biopharmaceuticals 27/28 May 2025, Vienna, Austria

ECA Certified Development Manager

- GMP meets Development 05 – 07 November 2024, Hamburg, Germany
- GMP meets GCP Live Online Training from 04 – 06 March 2025

ECA Certified GMP Auditor

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- GMP Auditor Practice An advanced Auditor Course with many interactive Sessions and practical Examples 08 – 10 October 2024, Barcelona, Spain
- The GMP Auditor Initial and Continuous Professional Training for GMP Auditors Live Online Training on 15 - 17 October 2024 21 - 23 May 2025, Barcelona, Spain
- Efficient Supplier Qualification With an optional Live Online pre-course Session on 25 June

2025: What you need to know about Suppliers in China and India

Live Online Training on 26/27 June 2025

ECA Certified Packaging Manager

- Design Controls for Drug-Device Combination Products Live Online Training on 15/16 October 2024
- Serialization/Aggregation Live Online Training Live Online Training on 23/24 October 2024
- GMP Pre-Sterilized Packaging Material Requirements and Challenges for RTU / RTS Products Live Online Training on 14 November 2024
- Pharmaceutical Packaging Systems Part 1: Pharmaceutical Packaging Systems - Development Live Online Training on 26/27 November 2024 Part 2: Pharmaceutical Packaging Systems - Quality Control Live Online Training on 27/28 November 2024

ECA Certified Microbiological Laboratory Manager

Bioburden - Regulatory Expectations and Practical Experiences

- Lessons and Panel Discussion -Live Online Training on 15/16 October 2024



European Conferences & Education Courses

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- Contamination Control Strategies Requirements, Measures and Strategies 05 - 07 November 2024, Berlin, Germany with an optional Post-Conference Workshop "Risk Assessment in Contamination Control" on 08 November 2024, Berlin, Germany
- Environmental Monitoring Trending, Analysis and Data Management Live Online Training on 12/13 November 2024
- Modern Microbiology Laboratory "Best Lab Practice" Live Online Training on 10 - 12 December 2024
- Microbiology for Non-Microbiologists Understand the "true" meaning of microbiological findings 11/12 March 2025, Berlin, Germany

ECA Certified GDP Compliance Manager

- Ambient Transport and Cold Chain Live Online Training on 06/07 November 2024
- The GDP Compliance Manager Live Online Training on 19/20 November 2024
- The GDP Audit Live Online Training on 03/04 December 2024
- GDP Audits How to Audit Logistics Service Providers Live Online Training on 30 April 2025
- The Responsible Person for Good Distribution Practices (GDP) 21/22 May 2025, Munich, Germany
- GDP for Beginners
 Storage Transportation Cold Chain
 With a guided Airport tour at Vienna Airport in cooperation with DHL
 14 – 16 May 2025, Vienna, Austria
- Pharma Supply Chain Live Online Training on 02 October 2025

ECA Certified API Production Manager

Handling of Foreign Particles in APIs and Excipients Live Online Training on 05/06 February 2025

ECA Certified Quality Assurance Manager

- Quality Risk Management 04/05 September 2024, Munich, Germany
- Quality Culture 17/18 September 2024, Berlin, Germany
- Ph. Eur., USP and other Pharmacopoeias Live Online Training on 17/18 September 2024
- GMP for Beginners Live Online Training on 15/16 October 2024 Live Online Training on 18/19 March 2025 Live Online Training on 14/15 October 2025
- The GMP Compliance Manager 19/20 November 2024, Hamburg, Germany
- GMP for Medical Devices
 Live Online Training on 19/20 November 2024

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Root Cause Analysis A CAPA Workshop on Successful Failure Investigation 04/05 December 2024, Berlin, Germany

- Combination Products 11/12 February 2025, Heidelberg, Germany
- Pharmaceutical Contracts: GMP and Legal Compliance 06/07 March 2025, Vienna, Austria
- Deviation Management and CAPA 11/12 March 2025, Barcelona, Spain
- Efficient Batch Record Design and Review 29/30 April 2025, Hamburg, Germany
- GMP and Quality Requirements for Radiopharmaceuticals Live Online Training on 29/30 April 2025
- KPIs and Quality Metrics How to foster Continual Quality Improvement 09/10 April 2025, Berlin, Germany
- Quality Oversight Supervision of the Pharmaceutical Quality System: Challenges and Opportunities Live Online Training on 27/28 May 2025
- Supply Chain Oversight 26/27 June 2025, Barcelona, Spain

ECA Certified Validation Manager

- Process Validation Live Online Training on 01/02 October 2024 Live Online Training on 20/21 May 2025
- Trending of Process Data for OPV/CPV Advanced Level Live Online Training on 08/09 October 2024
- Equipment Qualification Forum Release of ECA's Qualification and Validation Guide - Version 3.0 05/06 November 2024, Heidelberg, Germany
- Cleaning Validation
 Live Online Training on 13/14 November 2024
 Live Online Training on 06/07 May 2025

 Pre-Course: Impact of Annex 1 Revision on Cleaning Validation
 Live Online Training on 12 November 2024
 Live Online Training on 05 May 2025
- Process Understanding Statistical Process Control (SPC) as a tool to get there Live Online Training on 06/07 February 2025
- The Validation Manager in the Pharmaceutical Industry Live Online Training on 26/27 March 2025
- Ongoing/Continued Process Verification From the Control Strategy to Product Quality Review Live Online Training on 27/28 May 2025

ECA Certified Quality Control Manager

- Practical Statistical Tools for Analytical Laboratories 01/02 October 2024, Barcelona, Spain
- Validation of Analytical Test Procedures & Measurement Uncertainty 15 – 17 October 2024, Copenhagen, Denmark
- Setting Specifications and Acceptance Criteria 22/23 October 2024, Barcelona, Spain
- Stability Testing for Drug Substances and Drug Products 23/24 October 2024, Barcelona, Spain
- GMP/FDA Compliance in Analytical Laboratories 23 - 25 October 2024, Barcelona, Spain



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- Complaint Handling and Recall Management Live Online Training on 19/20 November 2024
- Quality Control of Starting Materials (APIs and Excipients)
 Live Online Training on 05/06 February 2025
- Reference Standards Live Online Training on 04 February 2025
- Analytical Instrument Qualification 13 – 15 May 2025, Vienna, Austria
- QC Compliance Manager Focus on Small-Molecule APIs and Drug Products Live Online Training on 27/28 May 2025
- Analytical Methods for CleaningValidation Development, Validation & Control Live Online Training from 03 - 05 June 2025
- EU GMP-/FDA-compliant Sampling Live Online Training on 16/17 September 2025

On behalf of APIC/CEFIC

27th APIC/CEFIC Global GMP & Regulatory API Conference

23/24 October 2024 in Vienna + Pre-Conference "From theory to practice: implementing API Process Knowledge" on 22 October 2024

 ICH Q7 Training Courses 2024

 22 November 2024
 ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
 20 Nov 2024
 ICH Q7 Compliance for APIs Manufactured by Cell Culture/ Fermentation, 18 – 20 Nov 2024

ICH Q7 Auditor Training Course, 20 – 22 Nov 2024

ECA Certified Regulatory Affairs Manager

- Drug Master File Procedures in the EU, the US and Japan Live Online Training on 17/18 September 2024
- Handling Changes and Variations 06/07 November 2024, Barcelona, Spain
- API Regulatory Starting Materials 18/19 February 2025, Munich, Germany
- GMP meets Regulatory Affairs 19/20 March 2025, Barcelona, Spain
- Global Registration and Life Cycle Management of APIs 08 – 10 April 2025, Vienna, Austria

ECA Certified Sterile Production Manager

- GMP for Beginners in Sterile Manufacturing Live Online Training on 24/25 September 2024
- Aseptic Process Simulation (APS) / Media Fills Live Online Training on 26/27 September 2024
- Isolator Technology Workshop 12/13 November 2024, Basel, Switzerland
- Environmental Monitoring 26/27 June 2025, Copenhagen, Denmark

On behalf of European Qualified Person Association

Qualified Person Education Course - Module A Understand the Implications of becoming a QP Live Online Training on 12/13 November 2024

QUALIFIED PERSON FORUM 2024

28/29 November 2024, Amsterdam, The Netherlands WITH SIX PARALLEL SESSIONS TO FOSTER INTERACTION Pre-conference sessions on 27 November 2024: Specific Requirements for IMPs (full day) QP Oversight for "Virtual Companies" (1/2 day) QP Liability and Indemnification (1/2 day)

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

The Impact of EU Legislation on the Supply Chain 10 - 12 February 2025 - Live Online -

- Qualified Person Education Course Module A 26/27 March 2025, Vienna, Austria With an optional Pre-Course Session "Investigational Medicinal Products (IMP) QP Education Course" on 25 March 2025
- Qualified Person Education Course Module B Mastering the QP Role in daily Practice 05/06 June 2025, Barcelona, Spain With an optional pre-course Session: "Interpersonal and Soft Skills for the QP" on 04 June 2025

Other Training Courses/Conferences

- Self Inspection Compliant and Successful Self-Inspections and Internal Audits Live Online Session on 12 September 2024
- Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals Live Online Training on 12/13 September 2024
- Cost of Quality Understand, Measure and Optimise Cost of Quality Live Online Session on 19 September 2024
- Focus on Tissue: A Multidisciplinary Approach Live Online Training on 19 September 2024
- Temperature-Sensitive Pharmaceuticals Transport and Vehicle Qualification Live Online Training on 10 October 2024, 09:00 – 12:30 h
- China GMP and Registration of APIs Live Online Training on 15 October 2024
- GMP meets Pharmacovigilance Live Online Training on 29 October 2024
- Quality Oversight in Sterile Manufacturing Live Online Training on 06 November 2024
- Japan Quality Live Online Training on 12 November 2024 09.00 – 17.00 h CET
- Efficient GMP Training Systems Live Online Training on 19/20 November 2024
- CAPAs in QC Laboratories Live Online Training on 14 January 2025 13.00 – 17.30 h CET
- How to register APIs in Brazil Focus on CADIFA and obtaining a Brazilian GMP Certificate Live Online Training on 13 February 2025



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- Fundamentals of Manual Visual Inspection 100 % Inspection of Parenterals Live Online Training on 15 May 2025
- Validation/Qualification for Beginners Live Online Training on 13 May 2025
- GMP for Excipients Live Online Training on 25 June 2025
- Transfer of Analytical Procedures Live Online Training on 01 October 2025

GMP Webinars

Statistical Simulations for Enhanced Understanding of Analytical Performance Live Webinar on Monday, 09 Sept. 2024, 14.00 – 16.00 CEST This webinar is included free of charge for all participants of the ECA course "Practical Statistical Tools for Analytical Laboratories" on 01/02 October 2024 in Barcelona, Spain. If you decide to book the course in

Barcelona after attending the webinar, the webinar fee will be credited.

GMP Update 2024/2025 Live Webinar on Tuesday, 10 December 2024, 14.00 – 16.00 CET