ECA Academy
Your GMP/GDP Information Source

European Events

2020

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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ECA GMP/GDP Certification Programme

GMP/GDP Certification Programme

One reason for the European Compliance Academy's (ECA) excellent reputation is its high-quality Certification Programme. In the past years, hundreds of GMP professionals already relied on the programme to advance their knowledge and to get an additional qualification – and completed the ECA Certification Level.

Objectives

A highly qualified personnel is a crucial factor within the field of GMP/GDP-compliant manufacturing and distribution of APIs, drugs and medical devices. College and university education provide a scientific basis which needs to be completed. A continuous advanced training is therefore essential. This is where the ECA Academy's GMP/GDP Certification Programme fills the gap. This programme offers modular training with an industry-known certification at the end. Its structure respects companies' interests, i.e. professionals can

- select courses according to their individual professional demands
- suit the course registration to their and their companies' needs. Usually there are several months between the courses in the individual programmes. However, if there are two courses too close to each other, one course can be attended in the following year.
- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

Recognition

The courses of the ECA Academy enjoy an excellent reputation within Europe's pharmaceutical industry and regulatory authorities. This is proven by the large number of participants, the often booked-up courses and the fact that many speakers and participants come from European GMP Inspectorates. What is essential for the recognition of a qualified training programme is the speakers' reputation. ECA employs up to 8 speakers for an education course - preferably representatives from industry and authorities. Frequently, experienced consultants with an exceptional track record complete the trainings.

How to Obtain the Certificate

To obtain the certificate, please send an e-mail prior or after the 3rd event to info@concept-heidelberg.de. This e-mail should also list the courses you attended in the past. You will then get your certificate during the 3rd course or within the following two weeks by post.

Continuous GMP/GDP Certification

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 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 your Certificate 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:

- **ECA Certified Biotech Manager**
- **ECA Certified Pharmaceutical Development Manager**
- **ECA Certified Sterile Production Manager**
- **ECA Certified Computer Validation Manager**
- **ECA Certified Microbiological Laboratory Manager**
- **ECA Certified Technical Operations Manager**
- **ECA Certified Regulatory Affairs Manager**
- **ECA Certified API Production Manager**
- **ECA Certified QA Manager**
- **ECA Certified Validation Manager**
- **ECA Certified Quality Control Manager**
- **ECA Certified GMP Auditor**
- **ECA Certified GDP Compliance Manager**
- **ECA Certified Packaging Manager**
- **ECA Data Integrity Manager**

European Conferences & Education Courses

in co-operation with CONCEPT HEIDELBERG

ECA Certified Pharmaceutical Development Manager

- **ICH Q8 / ICH Q11 Training Course**
  8/9 October 2020, Vienna, Austria
- **GMP meets GCP - Management, Supply and Quality Assurance of Clinical Trials**
  3-5 November 2020, Barcelona, Spain
- **GMP meets Development**
  17-19 November 2020, Heidelberg, Germany
- **Stability by Design**
  28/29 April 2021, Vienna, Austria

ECA Certified Computer Validation Manager

- **Computer Validation: Maintaining Control of Operation**
  30 Sept - 2 Oct 2020, Copenhagen, Denmark
- **Computer Validation:**
  - Leveraging Suppliers
  - Computer Systems Validation Master Class
  27 & 28-30 October 2020, Barcelona, Spain
- **SAP – Validation and GMP Compliance**
  10/11 November 2020, Berlin, Germany
- **Computer Validation: Introduction to Risk Management & The GAMP®5 Approach**
  17 and 18-20 November 2020, Copenhagen, Denmark

ECA Certified Data Integrity Manager

- **Data Integrity & optional pre-course session Audit Trail Review**
  25 - 28 August 2020, Copenhagen, Denmark
  08 - 11 December 2020, Vienna, Austria
- **Lab Data Integrity - Meeting FDA and EU Concerns, Part 1 & 2**
  22-24 September 2020, Prague, Czech Republic
- **Lab Data Integrity Master Class**
  3-5 November 2020, Berlin, Germany
- **Data Integrity and Good Documentation Practice**
  24-26 November 2020, Berlin, Germany
- **Data Integrity Audits & Inspections**
  24/24 November 2020, Prague, Czech Republic
- **HPLC Data Integrity - Ensuring Control of Chromatographs, Integration and Results**
  02/03 February 2021, Prague, Czech Republic
- **Audit Trail Review for Computerised Systems in Analytical Laboratories**
  03/04 March 2021, Prague, Czech Republic
- **Data Integrity Quality Oversight in the QC Laboratory**
  13/14 April 2021, Hamburg, Germany
  with an optional post-conference Workshop „Audit Trail Review for CDS / Laboratory Systems", 15 April 2021, Hamburg, Germany

ECA Certified Technical Operations Manager

- **Product Transfer**
  20-22 October 2020, Berlin, Germany
- **Control of Parenterals**
  Container-/Closure-Integrity Testing
  Visual Inspection Systems
  6 - 8 October 2020, Barcelona, Spain
- **Lyophilization 2020 - with workshop at GEA**
  3 – 5 November 2020, Cologne, Germany
- **Clean Rooms & HVAC Systems**
  15/16 December 2020, Berlin, Germany
- **Spray Drying - with Hands-On Spray Drying Course at the GEA Niro Site**
  02 - 04 March 2021, Copenhagen, Denmark

ECA Certified Regulatory Affairs Manager

- **Drug Master File Procedures in the EU, the US and Japan**
  Tuesday, 29 September 2020, 09.00 - 16.45 h
  Wednesday, 30 September 2020, 08.30 - 16.30 h
- **API Regulatory Starting Materials**
  Tuesday, 13 October 2020, 9.00 – 17.30 h
  Wednesday, 14 October 2020, 9.00– 16.30 h
- **GMP meets Regulatory Affairs**
  Thursday, 15 October 2020, 09.00 – 17.15 h
  Friday, 16 October 2020, 09.00 – 16.45 h
- **How to provide Process Validation Data in a regulatory submission**
  04/05 November 2020, Hamburg, Germany
- **How to write the Quality Part of an IMPD**
  08/09 December 2020, Prague, Czech Republic

ECA Certified Biotech Manager

- **Quality, Safety and GMP for Advanced Therapy Medicinal Products (ATMPs)**
  10/11 November 2020, Neuss/Düsseldorf, Germany
- **GMP for Vaccine Manufacturers**
  24/25 November 2020, Barcelona, Spain
- **Pharmaceutical Biotechnology for Non-Biotechnologists**
  15/16 December 2020, Vienna, Austria
- **Annex 2 + Co - GMP Compliance for Biopharmaceuticals**
  16/17 March 2021, Munich, Germany

ECA Certified GMP Auditor

- **The GMP Auditor**
  10-12 November 2020, Vienna, Austria
  16-18 March 2021, Amsterdam, The Netherlands

ECA Certified Sterile Production Manager

- **Environmental Monitoring**
  22/23 September 2020, Copenhagen, Denmark
- **GMP for Beginners in Sterile Manufacturing**
  27/28 October 2020, Berlin, Germany
- **Process Simulation/Media Fills**
  29/30 October 2020, Berlin, Germany
- **Annex 1 Conference**
  10/11 November 2020, Neuss/Düsseldorf, Germany

- **Isolator Technology Workshop – Manufacturing Isolator**
  24/25 November 2020, Basel, Switzerland

ECA Certified Microbiological Laboratory Manager

- **Contamination Control Strategies**
  18-20 Novemer 2020, Barcelona, Spain
- **Environmental Monitoring - Trending, Analysis and Data Management**
  18-20 November 2020, Barcelona, Spain
- **Modern Microbiology Laboratory**
  Pharmacopoeial and GMP Compliance
  08-10 December 2020, Antwerp, Belgium
- **Microbiology for Non-Microbiologists**
  02/03 February 2021, Antwerp, Belgium
- **Bioburden Workshop**
  08/09 June 2021, Berlin, Germany

ECA Certified GDP Compliance Manager

- **The GDP Compliance Manager**
  06 – 08 October 2020, Vienna, Austria
- **The GDP Audit**
  28/29 October 2020, Vienna, Austria
- **Ambient Transport and Cold Chain**
  04/05 November 2020, Barcelona, Spain
- **The Responsible Person for Good Distribution Practices (GDP)**
  24/25 March 2021, Vienna, Austria

ECA Certified API Production Manager

- **ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis**
  30 November – 02 December 2020, Barcelona, Spain
- **ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation**
  30 November – 02 December 2020, Barcelona, Spain
- **ICH Q7 Auditor Training Course**
  02 – 04 December 2020, Barcelona, Spain

ECA Certified Quality Assurance Manager

- **Quality Culture - People Empowerment in GMP**
  10/11 September 2020, Prague, Czech Republic
- **Change Control**
  6/7 October 2020, Vienna, Austria
- **GMP for Medical Devices**
  13/14 October 2020, Heidelberg, Germany
- **Quality Risk Management - An ICH Q9 Training Course**
  14/15 October 2020, Berlin, Germany
- **GMP for Beginners**
  20/21 October 2020, Berlin, Germany
- **The GMP Compliance Manager**
  4/5 November 2020, Barcelona, Spain
- **Complaint Handling and Recall Management**
  17/18 November 2020, Heidelberg, Germany
- **Inspection Management**
  17-19 November 2020, Hamburg, Germany
- **Combination Products**
  23/24 February 2021, Heidelberg, Germany
- **Improve your Quality Reviews**
  25/26 March 2021, Prague, Czech Republic
  With an optional pre-course Session on 24 March:
  Statistical Process Evaluation and Reporting
- **Lean GMP Systems**
  06/07 May 2021, Vienna, Austria
- **Quality Oversight**
  19/20 May 2021, Berlin, Germany
- **Deviation Management and CAPA**
  01/02 June 2021, Prague, Czech Republic
- **Efficient Supplier Qualification**
  23/24 June 2021, Copenhagen, Denmark
  With an optional pre-course Session on 22 June:
  What you need to know about Suppliers in China and India

ECA Certified Validation Manager

- **Process Validation in the light of the revised Annex 15 and FDA Requirements**
  6/7 October 2020, Berlin, Germany
- **Launch Conference – Final version: ECA´s Integrated Qualification and Validation Guide – working with suppliers towards modern qualification and validation**
  27/28 October 2020, Berlin, Germany
- **Understanding Design of Experiments (DoE) in the Pharmaceutical Industry**
  03/04 November 2020, Heidelberg, Germany
- **The Validation Manager in the Pharmaceutical Industry**
  17-19 March 2021, Barcelona, Spain
- **Ongoing/Continued Process Verification**
  26/27 May 2021, Heidelberg, Germany
- **Analytical Methods for Cleaning Validation**
  29/30 June 2021, Heidelberg, Germany

ECA Certified Quality Control Manager

- **FDA Compliance in Analytical Laboratories**
  6-8 October 2020, Copenhagen, Denmark
- **Handling OOE and OOT Results**
  13/15 October 2020, Prague, Czech Republic
- **Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals**
  14/15 October 2020, Hamburg, Germany
- **Bioassays and Bioanalytics**
  20/21 October 2020, Hamburg, Germany
- **Stability Testing for Biological/Biotechnological Drug Substances and Drug Products**
  22 October 2020, Hamburg, Germany
- **Design Control for Drug – Device Combination Products**
  21–23 October 2020, Berlin, Germany
- **Validation of Analytical Test Procedures & Measuremnt Uncertainty**
  23-25 November 2020, Berlin, Germany

- **Reduced Sampling / Reduced Testing**
  26/27 November 2020, Berlin, Germany
- **The Impurities Workshop**
  01-03 Dezember 2020, Heidelberg, Germany
  Part I - General Strategies for Investigation & Control of Impurities
  Part II - Nitrosamine Impurities
  Part III - Elemental Impurities
- **Practical Statistical Tools for Analytical Laboratories**
  09/10 December 2020, Heidelberg, Germany
- **EU GMP/FDA-Compliant Sampling**
  19 – 21 May 2021, Berlin, Germany

- **Pharma Congress 2020 - Live Online Conferences**
  15/16 September 2020, Düsseldorf/Neuss, Germany
  - Barrier Systems
  - Data Integrity
  - Aseptic Processing

- **23rd APIC/CEFIC Global GMP & Regulatory API Conference**
  28-30 October 2020 in Amsterdam, The Netherlands or broadcasted live to your desk!

- **Launch Conference – Final version: ECA's Integrated Qualification and Validation Guide**
  27/28 October 2020 in Berlin, Germany
  or broadcasted live to your desk!

On behalf of European Qualified Person Association

- **Qualified Person Education Course**
  Understand the Implications of Working as a QP
  16/17 September 2020, Hamburg, Germany
  With an optional pre-course Session:
  "Investigational Medicinal Products (IMP) QP Education Course"
- **Qualified Person Education Course - Module A**
  Understand the Implications of becoming a QP
  03/04 March 2021, Munich, Germany
  With an optional pre-course Session:
  "Investigational Medicinal Products (IMP) QP Education Course"

Live Online Trainings/Conferences

- **Cleaning Validation**
  Tuesday, 7 July 2020, 09.00 - 16.30 h
  Wednesday, 8 July 2020, 09.00 - 13.45 h
- **Manufacture of Oral Solid Dosage Forms**
  Thursday, 9 July 2020, 09.00 to approx. 17.30 h CEST
- **Process Validation**
  Tuesday, 14 July 2020, 09.00 - 17.00 h
  Wednesday, 15 July 2020, 09.00 - 11.30 h
- **Efficient Supplier Qualification**
  Tuesday, 11 August 2020, 09.00 - 16.00 h
- **GDP in Switzerland**
  Specifics in the Distribution of Medicinal Products and APIs
  01 September 2020
- **Data Integrity Master Class with an optional full-day pre-course session on Raw Data – Understanding, Defining and Managing**
  Tuesday, 1 September 2020, 09.00 - 17.15 h
  Wednesday, 2 September 2020, 09.00 - 18.00 h
  Thursday, 3 September 2020, 09.00 - 18.00 h
  Friday, 4 September 2020, 09.00 - 15.45 h
- **Cleaning Validation**
  Thursday, 3 September 2020, 09.00 – 16.30 h
  Friday, 4 Septembery 2020, 09.00 – 13.45 h
- **Risk Assessment in Contamination Control**
  03 September 2020, 09.00 – 15.30 h CEST
- **Improve your Quality Reviews**
  03/04 September 2020
- **ICH Q2/Q14 - Analytical Procedure Life Cycle Management**
  Wednesday, 16 September 2020, 13.00 – 18.00 h
  Thursday, 17 September 2020, 08.30 – 17.00 h
- **ICH Q12 - Product Life Cycle Management**
  15/16 September 2020
- **EP - USP and other Pharmacopoeias: Dealing with different compendial methods**
  22/23 September 2020
- **Drug Master File Procedures in the EU, the US and Japan**
  Tuesday, 29 September 2020, 09.00 - 16.45 h
  Wednesday, 30 September 2020, 08.30 - 16.30 h
- **Process Validation**
  Tuesday 06 October 2020, 09.00 – 17.00 h
  Wednesday, 07 October 2020, 09.00 – 11.30 h
- **FDA Compliance in Analytical Laboratories**
  Tuesday, 06 October 2020, 09.00 h - approx. 16.35 h CEST
  Wednesday, 07 October 2020, 08.30 h - approx. 16.20 h CEST
- **GMPs for Equipment, Utilities and Facilities**
  Tuesday, 6 October 2020, 09.00 – 17.00 h
  Wednesday, 7 October 2020, 09.00 – 18.00 h
  Thursday, 8 October 2020, 09.00 – 15.15 h
- **API Regulatory Starting Materials**
  Tuesday, 13 October 2020, 9.00 – 17.30 h
  Wednesday, 14 October 2020, 9.00– 16.30 h
- **GMP meets Regulatory Affairs**
  Thursday, 15 October 2020, 09.00 – 17.15 h
  Friday, 16 October 2020, 09.00 – 16.45 h
- **Bioassays and Bioanalytics**
  Tuesday, 20 October 2020, 09.00 – 17.30 h CEST
  Wednesday, 21 October 2020, 09.00 – 17.30 h CEST
- **Stability Testing for Biological/Biotechnological Drug Substances and Drug Products**
  Thursday, 22 October 2020, 08.30 – 17.00 h CEST
- **GMP Auditor Practice**
  Wednesday, 21 October 2020, 9.00h – 17.00h
  Thursday, 22 October 2020, 8.30h – 17.00h
- **Ongoing/Continued Process Verification**
  Tuesday, 17 November 2020, 09.00 – 16.00 h

GMP Webinars

- **ICH Q10**
  Wednesday, 08 July 2020, 14.30 – 16.30 CEST
- **Self Inspection**
  Tuesday, 14 July 2020, 14.30 – 16.30 CEST
- **Early Analytical Life Cycle Management for Drug Substances and Drug Products**
  Thursday, 16 July 2020, 14.00 – 15.30 h CEST
- **ECA Guide for the Evaluation and Investigation of Microbiological Deviations - Chapter 2: Endotoxin Out of Specification (OOS) / Out of Trend (OOT) / Atypical Results**
  Tuesday, 21 July 2020, 14.00 – 15.30 h CEST
- **Switzerland and the EU - The Differences in GMP and GDP**
  Wednesday, 22 July 2020, 10.00h – 11.30h CEST
- **GDP Responsibilities for Financial Trading Organisations involved in the Procurement and Supply of Medicinal Products**
  Wednesday, 22 July 2020, 14.00h – 15.30h CEST
- **Audits / Inspections of computerised systems - Gaining Practical Insights**
  Wednesday, 22 July 2020 14.00 - 16.00 h CEST
- **To certify or not to certify: Batch Deviations and QP Certification**
  Thursday, 23 July 2020, 14.30h – 16.00h CEST
- **Quality KPIs**
  Tuesday, 28 July 2020, 14.30 – 16.00 h CEST
- **APIs & Excipients: Handling and Life Cycle Management in times of Covid-19**
  Tuesday, 28 July 2020, 14.00 – 15.30 h CEST
- **Human Error**
  Wednesday, 29 July 2020, 14.30h – 16.00h CEST
- **Knowledge Management**
  Thursday, 30 July 2020, 14.30h – 16.00h CEST
- **Continuous Verification in Pharmaceutical Analysis**
  Thursday, 30 July 2020, 14.00 – 15.30 h CEST
- **Medical Devices and Combination Products - Update on Risk Management**
  Thursday, 13 August 2020 14.00 - 15.30 h CEST
- **Cold Chain Management and its Validation**
  Wednesday, 19 August 2020, 14.00h – 15.30h CEST
- **Pharmacovigilance Inspections/Audits & the Role of the QPPV**
  Wednesday, 19 August 2020 14.00 - 15.30 h CEST
- **Medical Devices and Combination Products: Update on Post-Market Surveillance**
  Wednesday 02 September 2020 14.00 - 15.30 h CEST
- **Principles and Practices in Dissolution Testing**
  Thursday, 03 September 2020, 14.00 – 15.30 h CEST
- **The risk-based Approach and GDP**
  Monday, 28 September 2020, 14.00 – 15.30 h CEST
- **GDP for APIs**
  Thursday, 01 October 2020, 14.00 – 15.30 h CEST
- **Data Integrity in the Light of ICH Q7**
  Thursday, 15 October 2020, 14.00 – 15.30 h CEST
- **Webinar Series on „Validation in Pharmaceutical Analysis“**
  Calibration (Linearity), 29 July 2020, 14.00 – 15.30 h CEST
- **Webinar Series on „Annex 1“**
  Applications of Disinfectants and their Validation
  Thursday, 09 July 2020, 14.00 -15.30 h CEST
  Quality Risk Management using the example of the Contamination Control Strategy (CCS)
  Thursday, 23 July 2020, 14.00 – 16.00 h CEST
  Developments for RABS and Isolators
  Thursday, 06 August 2020, 14.00 -15.30 h CEST
  Container Closure Integrity Testing
  Thursday, 20 August 2020, 14.00 – 15.30 h CEST
  Cleaning and Disinfection Program from A to Z
  Wednesday, 02 September 2020, 14.00 -16.00 h CEST
  Requirements for personnel in the context of Contamination Control
  Thursday 17 September 2020, 14.00 – 15.30 h CEST
- **GMP Webinar Series on „Impurities“ – Highlights and Updates**
  Impurities coming from Supply Chains
  Tuesday, 14 July 2020, 14.00 – 15.30 h CEST
  Mutagenic Impurities with Focus on Nitrosamines – What do Regulatory Authorities Expect?“
  Wednesday, 02 September 2020, 14.00 – 15.30 h CEST
- **GMP Webinar Series “Covid-19: Audits and Inspections - Communication in a digital world”**
  Part 2: Tuesday, 07 July 2020, 14.00 – 15.30 h CEST
  Part 3: Monday, 20 July 2020, 14.00 – 15.30 h CEST
- **GxP Webinar Series on “Data Integrity”**
  Preparing a data integrity inspection
  Monday, 6 July 2020 14.00 - 16.00 h CEST
  Audit Trail Review from an inspector‘s point of view
  Friday, 17 July 2020 10.00 - 12.00 h CEST
  Data Integrity from the view of a GMDP inspector
  Monday, 5 October 2020 10.00 - 12.00 h