ECA Academy
Your GMP/GDP Information Source

European Events

2019/2020

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

- **D.I.C.T - Data Integrity in Clinical Trials**
  17-18 September 2019 , Copenhagen, Denmark
- **Emulsions & Gels**
  20-21 November 2019, Hamburg, Germany
- **GMP meets Development**
  5 – 7 May 2020, Barcelona, Spain

ECA Certified Computer Validation Manager

- **Computer Validation: Maintaining Control of Operation**
  29-31 October 2019, Copenhagen, Denmark
- **SAP – Validation and GMP Compliance**
  12-13 November 2019, Berlin, Germany
- **Virtual IT Systems in a GxP Environment**
  14-15 November 2019, Berlin, Germany
- **Computer Validation: Introduction to Risk Management & The GAMP®5 Approach**
  19 and 20 - 22 November 2019, Copenhagen, Denmark
  31 and 1–3 April 2020, Vienna, Austria
  17 and 18–20 November 2020, Copenhagen, Denmark
- **Computer Validation:**
  - Leveraging Suppliers
  - Computer Systems Validation Master Class
  12 & 13 - 15 May 2020, Barcelona, Spain

ECA Certified Data Integrity Manager

- **Data Integrity & optional pre-course session Audit Trail Review**
  10 - 13 December 2019, Copenhagen, Denmark
  17 - 20 March 2020, Prague, Czech Republic
  25 - 28 August 2020, Copenhagen, Denmark
  8 - 11 December 2020, Vienna, Austris
- **Lab Data Integrity - Meeting FDA and EU Concerns, Part 1 & 2**
  4-6 December 2019, Barcelona,Spain
  22-24 September 2020, Prague, Czech Republic
- **Audit Trail Review for Computerised Systems in Analytical Laboratories**
  28/29 January 2020, Barcelona, Spain
- **Data Integrity and Good Documentation Practice**
  31 March – 2 April 2020, Berlin, Germany
- **Lab Data Integrity Master Class**
  5 – 7 May 2020, Berlin, Germany
- **Data Integrity Quality Oversight in the QC Laboratory**
  16/17 June 2020, Hamburg, Germany

ECA Certified Technical Operations Manager

- **Granulation & Tableting**
  10-12 September 2019, Vienna, Austria
- **Reconstruction and Upgrading of GMP Facilities**
  10-11 September 2019, Vienna, Austria
- **CCI Testing of Parenterals**
  8 October 2019, Vienna, Austria
- **Visual Inspection Systems**
  9/10 October 2019, Vienna, Austria
- **Product Transfer**
  22-24 October 2019, Vienna, Austria
- **Continuous Manufacturing**
  4/5 December 2019, Berlin, Germany
- **Pharmaceutical Water**
  1-2 April 2020, Berlin, Germany
- **GMPs for Equipment, Utilities and Facilities**
  21-23 April 2020, Berlin, Germany
- **Spray Drying - with Hands-On Spray Drying Course at GEA Niro**
  12-14 May 2020, Copenhagen, Denmark

ECA Certified Regulatory Affairs Manager

- **Drug Master File Procedures in the EU, the US and Japan**
  17-18 September 2019, Copenhagen, Denmark
- **GMP meets GCP**
  15-17 October 2019, Hamburg, Germany
- **How to provide Process Validation Data in a Regulatory Submission**
  29/30 Oktober 2019, Hamburg, Germany
- **How to write the Quality Part of an IMPD**
  13/14 May 2020, Prague, Czech Republic
- **API Regulatory Starting Materials**
  26/27 May 2020, Hamburg, Germany
- **GMP meets Regulatory Affairs**
  28/29 May 2020, Hamburg, Germany

ECA Certified Biotech Manager

- **Pharmaceutical Biotechnology for Non-Biotechnologists**
  24/25 September 2019, Berlin, Germany
- **GMP for Vaccine Manufacturers**
  26/27 November 2019, Barcelona, Spain
- **Annex 2 & Co - GMP Compliance for Biopharmaceuticals**
  19/20 May 2020, Munich, Germany

ECA Certified Sterile Production Manager

- **GMP for Beginners in Sterile Manufacturing**
  8-9 October 2019, Berlin, Germany
- **Process Simulation/Media Fill**
  10-11 October 2019, Berlin, Germany
- **Environmental Monitoring**
  19/20 May 2020, Copenhagen, Denmark

ECA Certified Microbiological Laboratory Manager

- **Modern Microbiology Laboratory**
  17-19 September 2019, Munich, Germany
- **Contamination Control**
  20-22 November 2019, Barcelona, Spain
- **Environmental Monitoring Data Management**
  20/21 November 2019, Barcelona, Spain
- **Low Endotoxin Recovery/Masking**
  11/12 February 2020, Munich/Bernried, Germany

- **Monocyte Activation Test (MAT)**
  13/14 February 2020, Munich/Bernried, Germany
- **Microbiological Identification - Hands-on Laboratory Course**
  11 - 13 March 2020 | Berlin, Germany

ECA Certified GMP Auditor

- **GMP Auditor Workshop**
  5-6 September 2019, Berlin, Germany
- **The GMP Auditor**
  6 – 8 November 2019, Prague, Czech Republic

ECA Certified GDP Compliance Manager

- **The GDP Compliance Manager**
  24-26 September 2019, Barcelona, Spain
- **Ambient Transport and Cold Chain**
  09/10 October 2019, Berlin, Germany
- **GDP for Beginners**
  4-5 February 2020, Prague, Czech Republic

ECA Certified Quality Assurance Manager

- **Change Control – New Aspects and Best Practices**
  8-9 October 2019, Heidelberg, Germany
- **GMP for Medical Devices**
  01-02 October 2019, Berlin, Germany
- **The GMP Compliance Manager**
  16/17 October 2019, Vienna, Austria
- **Inspection Management**
  23 – 25 October 2019, Vienna, Austria
- **GMP for Beginners**
  29/30 October 2019, Berlin, Germany
  24/25 March 2020, Hamburg, Germany
  20/21 October 2020, Berlin, Germany
- **Pharmacopoeias for Beginners - How to work with the compendia**
  6-7 November 2019, Heidelberg, Germany
- **Complaint Handling and Recall Management**
  12-13 November 2019, Vienna, Austria
- **Quality Risk Management**
  20-21 November 2019, Barcelona,Spain
- **Combination Products**
  28/29 January 2020, Berlin, Germany
- **Pharmaceutical Contracts**
  11/12 February 2020, Barcelona,Spain
- **Improve your Quality Reviews**
  With an optional pre-course Session on 31 March:
  Statistical Process Evaluation and Reporting
  1/2 April 2020, Barcelona,Spain
- **Efficient Supplier Qualification -**
  With an optional pre-course Session on 06 May:
  What you need to know about Suppliers in China and India
  07/08 May 2020, Vienna, Austria
- **Deviation Management and CAPA**
  19/20 May 2020, Hamburg, Germany

ECA Certified Validation Manager

- **Process Validation in the light of the revised Annex 15 and FDA Requirements**
  16/17 October 2019, Berlin, Germany
  28/29 April 2020, Prague, Czech Republic
  6/7 October 2020, Berlin, Germany
- **Launch Conference - ECA's new Integrated Qualification and Validation Guide**
  8/9 October 2019, Berlin, Germany
- **The Validation Manager in the Pharmaceutical Industry, 19-21 February 2020, Barcelona, Spain**
- **Cleaning Validation**
  17-18 March 2020, Berlin, Germany
- **Statistical Process Control**
  25/25 March 2020, Heidelberg, Germany

ECA Certified Quality Control Manager

- **Analytical Methods for Cleaning Validation**
  10/11 September 2019, Heidelberg, Germany
- **Bioassays and Bioanalytics**
  17/18 September 2019, Copenhagen, Denmark
- **Stability Testing for Biological/Biotechnological Drug Substances and Drug Products**
  19 September 2019, Copenhagen, Denmark
- **Drug Substances and Drug Products**
  19 September 2019, Copenhagen, Denmark
- **Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals**
  24-25 September 2019, Berlin, Germany
- **Handling OOE and OOT Results**
  22/23 October 2019, Vienna, Austria
- **Post-Conference OOS Workshop**
  24 October 2019, Vienna, Austria
- **FDA Compliance in Analytical Laboratories**
  28 - 30 October 2019, Berlin, Germany
- **Setting Specifications and Acceptance Criteria**
  27/28 November 2019, Barcelona, Spain
- **Stability Testing for Drug Substances and Drug Products, 28/29 November 2019, Barcelona, Spain**
- **Quality Control of Starting Materials (APIs and Excipients)**
  6/7 February 2020, Munich, Germany
- **Dissolution Testing**
  Development / Quality Control and in vivo Relevance
  11/12 February 2020, Prague, Czech Republic
- **Analytical Instrument Qualification**
  3 – 5 March 2020, Prague, Czech Republic
- **QC Compliance Manager**
  10 – 12 March 2020, Barcelona, Spain
- **Validation of Analytical Test Procedures & Measurement Uncertainty**
  31 March – 2 April 2020, Prague, Czech Republic
- **GMP/FDA-Compliant Sampling**
  26-28 May 2020, Berlin, Germany

European Conferences & Education Courses

in co-operation with CONCEPT HEIDELBERG

ECA Certified Packaging Manager

- **Plastic/Elastomeric Materials for Pharmaceutical Packaging & Production**
  25/26 September 2019, Barcelona, Spain
- **Track & Trace Training Course**
  26/27 September 2019, Prague, Czech Republic
- **Pharmaceutical Packaging Systems**
  Part 1: Pharmaceutical Packaging Systems - Development
  18 /19 February 2020, Budapest, Hungary
  Part 2: Pharmaceutical Packaging Systems - Quality Control
  19 /20 February 2020,Budapest, Hungary

ECA Certified API Production Manager

- **Handling of Foreign Particles in APIs and Excipients**
  5-6 November 2019, Prague, Czech Republic

On behalf of European Qualified Person Association

- **Qualified Person Education Course – Understand the Implications of Working as a QP**
  29-30 October 2019, Barcelona, Spain
- **Qualified Person Forum 2019**
  Munich, Germany, 28-29 November 2019
  Pre-Conference Sessions on 27 November 2019:
  Specific Requirements for Investigational Medicinal Products (full day)
  New QPs meet experienced QPs (1/2 day)
  Serialisation revisited (1/2 day)

Miscellaneous

- **Procurement and Purchase meet GMP**
  23/24 October 2019, Vienna, Austria
- **GMP for Cannabis – what you need to know**
  29/30 October 2019, Heidelberg, Germany

On behalf of APIC/CEFIC

- **22nd European Conference on Active Pharmaceutical Ingredients**
  23-25 October 2019, Prague, Czech Republic
- **ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis**
  4 – 6 November 2019, Prague, Czech Republic
- **ICH Q7 Compliance for APIs Manufactured by Cell Culture/Fermentation,**
  4 – 6 November 2019, Prague, Czech Republic
- **ICH Q7 Auditor Training Course**
  6 - 8 November 2019, Prague, Czech Republic

PharmaLab Congress 2019

12-13 November 2019, Düsseldorf/Neuss, Germany

- Rapid Microbiological Methods
- Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14
- Endotoxin and Pyrogen Testing
- Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products
- Microbiological Real Time Counting and Testing
- Testing and Analytics of Cells, Tissues and ATMPs

GMP Webinar

- **Auditing of Data Integrity**
  5 September 2019, 14.00 - 15.30 h CEST
- **Endotoxin Update - the current hot topis**
  12 September 2019, 14.00 - 15.30 h CEST
- **From SAP ERP to SAP S/4HANA**
  Major changes from GMP perspective
  Tuesday, 17 September 2019, 14.00 – 15.30 h CEST
- **EMA´s Q & A regarding PDE**
  Thursday, 17 October 2019, 14.00 - 15.30 h (CEST)
- **ICH Q12 – New approach to support innovation**
  Tuesday, 5 November 2019, 14.00 - 15.30 h CET
- **Update IMPs: Impact of the new Regulation (EU) 536/2014 on clinical trials**
  Wednesday, 13 November 2019, 14.00 -15:30 h CET
- **GMP Update 2019/2020**
  Thursday, 05 December 2019, 15.00 – 16.30 h CET