ECA Academy
Your GMP/GDP Information Source

European Events

2018/2019

Quality Assurance
Quality Control
Sterile/Aseptic Manufacturing
APIs/Excipients
Computer Validation
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 2 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 *2018/2019*

in co-operation with CONCEPT HEIDELBERG

- **8th European GMP Conference – Industry meets GMP Inspectorates**
  6-7 June 2019, Heidelberg, Germany

ECA Certified Pharmaceutical Development Manager

- **Stability by Design**
  2-3 April 2019, Vienna, Austria
- **ICH Q8 / ICH Q11 Training Course**
  10-11 April 2019, Hamburg, Germany
- **GMP meets Development**
  7-9 May 2019, Heidelberg, Germany
- **Lifecycle Management in Pharmaceutical Analysis**
  18-19 June 2019, Berlin, Germany

ECA Certified Computer Validation Manager

- **Cloud Computing in a GxP Environment**
  21-22 February 2019, Berlin, Germany
- **Computer Validation: Introduction to Risk Management & The GAMP®5 Approach**
  26 March & 27 – 29 March 2019, Vienna, Austria
  19 and 20 - 22 November 2019, Copenhagen, Denmark
- **Computer Validation: Leveraging Suppliers**
  21 May 2019, Vienna, Austria
- **Computer Systems Validation Master Class**
  22-24 May 2019, Vienna, Austria
- **Computer Validation: Maintaining Control of Operation**
  29-31 October 2019, Copenhagen, Denmark

ECA Certified Data Integrity Manager

- **Lab Data Integrity Meeting FDA and EU Concerns, Part 1 & 2**
  5-7 December 2018, Prague, Czech Republic
  26-28 June 2019, Vienna, Austria
- **Data Integrity & optional pre-course session Audit Trail Review**
  11-14 December 2018, Berlin, Germany
  12-15 March 2019, Barcelona, Spain
  27-30 August 2019, Copenhagen, Denmark
  10-13 December 2019, Copenhagen, Denmark
- **Audit Trail Review for Computerised Systems in Analytical Laboratories**
  13-14 February 2019, Barcelona, Spain
- **Data Integrity and Good Documentation Practice**
  9 – 11 April 2019, Barcelona, Spain
- **Data Integrity Quality Oversight in the QC Laboratory**
  20-21 May 2019, Berlin, Germany
- **Workshop Audit Trail Review for CDS / Laboratory Systems**
  22 May 2019, Berlin, Germany
- **Raw Data – Understanding, Defining and Managing**
  4 June 2019, Copenhagen, Denmark
- **Data Integrity Master Class**
  5-7 June 2019, Copenhagen, Denmark

ECA Certified Technical Operations Manager

- **Continuous Manufacturing**
  27-28 November 2018, Barcelona, Spain
- **Granulation & Tableting**
  10-12 September 2019, Vienna, Austria
- **Reconstruction and Upgrading of GMP Facilities**
  10-11 September 2019, Vienna, Austria
- **GMPs for Equipment, Utilities and Facilities**
  19-21 March 2019, Vienna, Austria
- **Clean Rooms & HVAC Systems**
  7-8 May 2019, Vienna, Austria
- **Single-Use Systems for Sterile & Biotech Applications**
  4-5 June 2019, Berlin, Germany
- **Product Transfer**
  22-24 October 2019, Vienna, Austria

ECA Certified Regulatory Affairs Manager

- **How to provide Process Validation Data in a Regulatory Submission**
  27-28 November 2018, Barcelona, Spain
- **Global Registration and Life Cycle Management of APIs**
  12-14 March 2019, Berlin, Germany
- **How to write the Quality Part of an IMPD**
  19-20 March 2019, Prague, Czech Republic
- **Handling Changes and Variations**
  26-27 March 2019, Copenhagen, Denmark
- **GMP meets Regulatory Affairs**
  21-22 May 2019, Barcelona, Spain
- **API Regulatory Starting Materials**
  23-24 May 2019, Berlin, Germany

ECA Certified Biotech Manager

- **Protein Analytics**
  28-29 May 2019, Munich, Germany

ECA Certified API Production Manager

- **Handling of Foreign Particles in APIs and Excipients**
  6-7 December 2018, Berlin, Germany
- **Raw Materials Used for Biological Medicinal Products An ECA, EBE and APIC Joint Conference**
  20-21 November 2018, Düsseldorf/Neuss, Germany

European Conferences & Education Courses *2018/2019*

in co-operation with CONCEPT HEIDELBERG

ECA Certified Sterile Production Manager

- **Isolator Technology Workshop**
  27-28 November 2018, Basel, Switzerland
- **Annex 1 – Changes, Challenges and Consequences**
  28-29 November 2018, Berlin, Germany
- **Lyophilization 2019**
  14 – 16 May 2019, Cologne, Germany
- **Environmental Monitoring**
  28-29 May 2019, Copenhagen, Denmark
- **GMP for Beginners in Sterile Manufacturing**
  8-9 October 2019, Berlin, Germany
- **Process Simulation/Media Fill**
  10-11 October 2019, Berlin, Germany

ECA Certified Microbiological Laboratory Manager

- **Contamination Control**
  28-30 November 2018, Berlin, Germany
- **Low Endotoxin Recovery/Masking**
  26-27 February 2019, Munich/Bernried, Germany
- **Monocyte Activation Test (MAT)**
  28 Feb - 1 March 2019, Bernried, Germany
- **Microbiology for Non-Microbiologists**
  12-13 June 2019, Berlin, Germany

ECA Certified GMP Auditor

- **Pre-course Session What you need to know about suppliers in China and India**
  27 March 2019, Hamburg, Germany
- **Efficient Supplier Qualification**
  28-29 March 2019, Hamburg, Germany
- **GMP Auditor Workshop**
  5-6 September 2019, Berlin, Germany

ECA Certified GDP Compliance Manager

- **GDP for APIs**
  4-5 December 2018, Berlin, Germany
- **GDP for Beginners**
  14-15 February 2019, Berlin, Germany
- **The Responsible Person for Good Distribution Practices (GDP)**
  15-16 May 2019, Vienna, Austria

ECA Certified Quality Assurance Manager

- **Combination Products**
  23-24 January 2019, Barcelona, Spain
- **Pharmaceutical Contracts: GMP and Legal Compliance,**
  13-14 February 2019, Berlin, Germany
- **GMP for Beginners**
  19-20 March 2019, Hamburg, Germany
  29-30 October 2019, Berlin, Germany
- **Improve your Quality Reviews**
  4-5 April 2019, Hamburg, Germany
- **Quality Oversight**
  10-11 April 2019, Berlin, Germany
- **Deviation Management and CAPA**
  8 -9 May 2019, Barcelona, Spain
- **Efficient Batch Record Design and Review**
  28-29 May 2019, Vienna, Austria
- **Lean GMP Systems**
  18-19 June 2019, Copenhagen, Denmark
- **Change Control – New Aspects and Best Practices**
  8-9 October 2019, Heidelberg, Germany
- **GMP for Medical Devices**
  01 - 02 October 2019, Berlin, Germany

ECA Certified Validation Manager

- **Cleaning Validation**
  6-7 February 2019, Prague, Czech Republic
- **Process Validation in the light of the revised Annex 15 and FDA Requirements**
  21-22 February 2019, Vienna, Austria
  16-17 October 2019, Berlin, Germany
- **Statistical Process Control**
  6-7 March 2019, Barcelona, Spain
- **Modern EU and FDA Validation: Ongoing/Continued Process Verification – from Control Strategy to Product Quality Review**
  14-15 May 2019, Frankfurt, Germany

ECA Certified Quality Control Manager

- **Setting Specifications and Acceptance Criteria**
  28-29 November 2018, Barcelona, Spain
- **Stability Testing for Drug Substances and Drug Products**
  29-30 November 2018, Barcelona, Spain
- **Pharmacopoeias for Beginners - How to work with the compendia (USP & Ph.Eur.)**
  11-12 December 2018, Barcelona, Spain
- **Quality Control of Starting Materials (APIs and Excipients)**
  7-8 February 2019, Copenhagen, Denmark
- **Dissolution Testing - Development/Quality Control and *in vivo* Relevance**
  19-20 February 2019, Prague, Czech Republic
- **Reduced Sampling / Reduced Testing**
  25-26 February 2019, Budapest, Hungary
- **Analytical Instrument Qualification**
  27 February - 1 March 2019, Budapest, Hungary
- **QC Compliance Manager**
  27-29 March 2019, Vienna, Austria
- **Validation of Analytical Test Procedures and Measurement Uncertainty**
  2 – 4 April 2019, Vienna, Austria

Please see the ECA website **www.gmp-compliance.org** for the detailed programmes. There you can register online!

- **Practical Statistical Tools for Analytical Laboratories**
  10-11 April 2019, Heidelberg, Germany
- **EP - USP and other Pharmacopoeias: Dealing with different compendial methods**
  14-15 May 2019, Barcelona, Spain
- **Data Integrity Quality Oversight in the QC Laboratory**
  20-21 May 2019, Berlin, Germany
  Post-conference Workshop Audit Trail Review
  22 May 2019, Berlin, Germany
- **HPLC Data Integrity**
  23 – 24 May 2019, Berlin, Germany
  Pre-Conference Workshop Audit Trail Review
  22 May 2019, Berlin, Germany
- **Sampling Strategies in the Pharma Industry**
  12-13 June 2019, Copenhagen, Denmark
- **Analytical Methods for Cleaning Validation**
  10/11 September 2019, Heidelberg, Germany

On behalf of European Qualified Person Association

- **Qualified Person Forum 2018**
  29-30 November 2018, Prague, Czech Republic
- **Qualified Person Education Course – Understand the Implications of Working as a QP**
  21-22 March 2019, Prague, Czech Republic

GMP Webinar

- **Stratified Sampling – What is state of the art regarding the validation of blend uniformity for solids?**
  Friday, 23 November 2018, 11.30 - 13.00 h (CET)
- **GMP Update 2018/2019**
  Wednesday, 5 December 2018, 15.00 - 16.30 h (CET)
- **Deviations and CAPA Managemet - What to do and how to do**
  Thursday, 13 December 2018, 15.00 - 16.30 h (CET)
- **Current Inspection Trends**
  Wednesday, 30 January 2019, 14.00 – 15.30 h CET