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About the ECA Foundation

The ECA was founded on the 1st of January 1999 as an independent not-for-profit organisation. It is chaired by a Scientific Advisory Board with 11 members of the pharmaceutical industry and regulatory authorities.

With the beginning of 2010 the organisation was transferred to a Foundation that manages the activities of the ECA Academy as well as of the interest groups European QP Association and Rapid Microbiological Methods (RMM) Group.

With **close to 4,000 members**, ECA has become the leading European association with regard to pharmaceutical Quality Assurance and GMP compliance. The members from all over Europe and abroad represent almost 60 countries.



Richard Bonner
Vice Chairman & Regulatory Affairs Director
ECA Foundation Advisory Board
*Independent Consultant, UK
Quality Assurance*

Our Mission

„The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances“.

The Advisory Board

The ECA Advisory Board represents European regulatory authorities as well as the pharmaceutical and biopharmaceutical industry. By their voluntary work, the board members support ECA in fulfilling its mission to impart most relevant knowledge on the interpretation and implementation of GMP and regulatory requirements.



Chairman
*Vacancy due to the untimely death of
Daniel Scheidegger in September 2011*



Matt Moran
*PharmaChemical, Ireland
Active Pharmaceutical Ingredients*



Dr Wolfgang Schumacher
*F. Hoffmann-La Roche, Switzerland
Computer Validation (incl. Part 11)*



Rudolf Völler
*Regierungspräsidium Darmstadt, Germany
GMP Supervision*



Ian Thrussel
*MHRA, UK
GMP Supervision*



Dr Bernd Renger
*Bernd Renger Consulting
Analytical Quality Control
Chair European Qualified Person Association*



Colin Booth
*Oxoid Limited, UK
Development Microbiology*



Dr Boris Pimentel
*DNP (DSM-Nutritional Products),
Switzerland
Regulatory Affairs*



Dr Jean-Denis Mallet
*SNC Lavalin
France*

The team focuses on the development of new courses and conferences on emerging GMP challenges. The evaluation of all events by the Advisory Board ensures best quality and participant satisfaction.

Membership Benefits

There are many reasons to join the European Compliance Academy. In the following, the 4 most important benefits are listed.

1. Discount:

You can join any future ECA event with the reduced members' fee:

- For more than 60 conferences and education courses a discount of 10% will be granted.
- For over 20 GMP Webinars the discount is 25% off the regular fee.

In addition, publications and the ECA Good Practice Guides are available for a 35% discount.

2. Members' Area:

Individual Members will have access to the members' area at www.gmp-compliance.org. The members' area includes among others:

- Free access to the Guideline Database of ECA. This Database with more than 400 GMP guidelines is the basis for the CD Rom GMP Navigator. The online database will be updated every month.
- Special discount offers that have been negotiated e.g. with publishing companies (e.g. Books, Journals).
- Additional free ECA Documents like Compliance Checklists, SOPs etc.

3. GMP Guideline Manager Software - free

Members will receive the latest version of the GMP Guideline Manager Software (more than 10.000 pages of guidelines including Warning Letters and presentations – the most comprehensive summary of global guidances).



4. GMP Certification:

By completing the GMP Certification Programme participants receive an internationally acknowledged certificate.

How do you become a Member of ECA?

Currently, we offer 3 opportunities to join the European Compliance Academy:

You automatically become a member for 2 years – free of charge – by participating in one of the European Compliance Academy courses or conferences marked with ECA (exception: Webinars).

Individual Membership

Membership is also possible without attending an ECA event. The annual membership fee is 190,- € plus VAT.

Company Membership

In addition to individual memberships, the European Compliance Academy also offers a company membership. With this membership you will automatically be able to take advantage of all ECA membership benefits, if your company is a registered member.

The annual membership fee for companies is:

- 990.- € for companies with less than 100 employees.
- 1,490.- € for companies with more than 100 but less than 500 employees.
- 1,990.- € for companies with more than 500 employees.

Company membership is for one country only, but includes all sites located in that country. Company Members receive a multi-user version of the GMP Guideline Manager Software which allows company-wide access to this unique GMP database.

You will find the membership application form at www.gmp-compliance.org.

For a Global Company Membership please contact info@gmp-compliance.org.

European GMP Certification Programme

Highly qualified personnel is a crucial factor within the field of GMP-compliant manufacturing of APIs and drugs. Here, college and university education provide a scientific basis which needs to be completed. Continuous further education is therefore of considerable importance.

This is where the GMP Certification Programme of the European Compliance Academy fills the gap. **The GMP Certification Programme offers modular further education with a certification at the end.** Its structure takes the company's interests into account, i.e. in the further education the employees can select courses according to their individual professional demands, suit the course registration to the company's necessities, i.e. usually there is a time span of several months between the courses. Should the situation arise that two dates are too close together, one course can be attended in the following year.

By taking part in an education course, the applicants become ECA members.



Certification Opportunities

The European Compliance Academy currently offers 11 Certification Modules:

- Certified Validation Manager
- Certified Quality Assurance Manager
- Certified API Production Manager
- Certified Quality Control Manager
- Certified Technical Operations Manager
- Certified Computer Validation Manager
- Certified Regulatory Affairs Manager
- Certified Microbiological Laboratory Manager
- Certified Sterile Production Manager
- Certified Pharmaceutical Development Manager
- Certified Biotech Manager

For more information please visit www.gmp-certification.org

The Activities of the European Compliance Academy

In order to achieve the goals defined in ECA's mission, the activities focus on:

- The development of the Guideline Manager Software with annual update of all GMP-relevant regulations issued by the most important medicines authorities and organisations worldwide
- Providing an Internet platform (www.gmp-compliance.org) for research on and interpretation of the regulations regarding pharmaceutical quality assurance and regulatory compliance



- The development of GMP tools aiming at the fulfilment of GMP requirements defined by various regulatory authorities (e.g. GMP Matrix)
- The organisation of education courses and conferences on topical subjects concerning GMP and regulatory compliance.
- To organise on-site in-house trainings and Webinars with selected instructors



Get involved in ECA's Interest Groups

The European Compliance Academy established 2 Interest Groups for an active involvement in current GMP compliance topics.

European Qualified Person Association

The Qualified Person Association was founded on 7 July 2006 with the objective to represent the Qualified Persons in Europe.

The responsibilities and the tasks of a Qualified Person in Europe are unique. This is why Qualified Persons in Europe need a forum. This Association offers to its members:

- Regular exchange with other Qualified Persons
- Opportunity to discuss current regulatory questions with representatives from European Authorities

For more Information please visit the Website of the QP Association www.qp-association.eu.

Rapid Microbiology Methods (RMM) Working Group

The ECA RMM Working Group was founded on 7 June 2006 at the German Federal Agency for Sera and Vaccines by 11 representatives from the European Pharmaceutical Industry and the German Federal Agency for Sera and Vaccines, the Paul-Ehrlich-Institute (PEI).

One of the current issues the group identified is the lack of standardisation for the submission of RMMs. To help both authorities and industry get a better understanding of the requirements for the introduction of RMMs and to provide them with guidance based on case studies and available experience, the group will establish a Best Practice Guide.

To learn more about this group and how you can get involved please visit www.gmp-compliance.org

Sponsorship Opportunities

Do you want to support the activities of the European Compliance Academy and at the same time win new customers? The European Compliance Academy offers you the opportunity to present your company, your products and services - by means of a Conference Exhibition at selected GMP Conferences.

- You can rent exhibition spaces at many events.
- No standardised trade fair structures - just bring along your own folding booth!

For more information about further sponsorship opportunities, e.g. lunch and coffee break sponsorship, please visit www.gmp-compliance.org