ECA FOUNDATION

ASSOCIATIONS, INTEREST & WORKING GROUPS

DRIVING HARMONISATION

ECA Foundation

Fostering harmonisation of GMP/GDP regulations

About the ECA Foundation

The ECA Foundation was established in 1999 as an independent, non-profit organisation. It was set up to 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 Foundation comprises an educational organisation (the ECA Academy) and various non-profit Associations, Interest Groups and Working Groups, providing comprehensive information and training services. The ECA Academy offers basic and advanced training courses, conferences, and various well-recognised certification programmes. The Associations, Interest and Working Groups, such as the European QP Association, develop guideline documents and white papers to support the exchange of information between the industry and regulatory authorities. Additionally, task forces comprising experts from various industries are formed on demand to provide feedback on new draft guidelines, for example. For the organisation of its ECA Academy training programmes as well for all organisational and management issues of the Foundation's Associations and Groups, the ECA Foundation relies on its exclusive partner, Concept Heidelberg, Europe's leading GMP/GDP information and training services provider.

The modern structure of the ECA Foundation allows to develop and include the activities of these groups, and to build new groups with greater flexibility to support the needs of ECA members. The ECA and its groups have **more than 20,000 members** from all over Europe and abroad, representing more than 60 countries – and are on the road to reaching 30,000 members.

Further information on the various ECA Foundation Associations, Interest and Working Groups can be found on the following pages.

For more information please scan the QR code or see the
European QP Association website

Membership is open to
- QPs in Europe
- Professionals in similar functions

EUROPEAN QP ASSOCIATION

ECA | QP ASSOCIATION
An ECA Foundation Interest Group

Due to their unique function and responsibility, Qualified Persons (QP) need to be highly qualified and always need to have the latest information on current developments in the area of GMP/GDP and regulatory compliance. The European QP Association has thus been the voice of Qualified Persons and similar functions in the European pharmaceutical industry since its foundation in 2006. It provides QPs and IMP QPs in Europe and professionals in similar functions with a platform for sharing and exchanging experience as well as for discussing latest regulatory requirements. This way, the Association supports members in identifying and addressing difficulties and challenges – and in turn supports the Association in its goal to aim for a harmonised European approach. Today, the Association unites members from more than 40 countries across Europe and beyond.

For more information please scan the QR code or see the
European GDP Association website

EUROPEAN GDP ASSOCIATION

ECA | GDP ASSOCIATION
An ECA Foundation Interest Group

The supply chain of medicinal products is exposed to various threats: counterfeit medicines coming into the legal supply chain, adulteration, cross contamination and any other negative impact on the quality and integrity. For that reason, the GDP Guidelines were developed to ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products. However, as many requirements in the GDP Guidelines are not clear and require interpretation, it is the objective of the European GDP Association to support all stakeholders in Good Distribution Practices – like Responsible Persons for GDP, Logistic Managers and other individuals involved in a secure pharma supply chain. For that purpose the Association provides its members with guidance documents on GDP interpretation, a discussion forum and a GDP Supplier Database.

For more information please scan the QR code or see the
Pharmaceutical Microbiology Group website

PHARMACEUTICAL MICROBIOLOGY WORKING GROUP

ECA | Pharmaceutical Microbiology Group
An ECA Foundation Working Group

The different subjects in pharmaceutical microbiology are in the Pharmaceutical Microbiology Working Group's centre of attention. It concentrates and provides its members with information and advice on all relevant microbiological questions in the context of the development and manufacturing of pharmaceutical, biopharmaceutical and combination products.

Membership in any ECA Foundation Association, Interest and Working Group is free of charge. Please see the respective website for your membership application.

For more information please scan the QR code or see the
GMP Auditor Association website

GMP AUDITOR ASSOCIATION

ECA | GMP Auditor Association
An ECA Foundation Interest Group

The GMP Auditor has a central function within the pharmaceutical quality assurance system. By working together, GMP Auditors can contribute to continuously improve pharmaceutical quality assurance and to ensure the safety and efficacy of pharmaceutical products. The latest ECA Interest Group, established in January 2024, therefore intends to promote the dialogue between GMP Auditors in the industry, to provide them with a platform to connect, share experiences, and learn from each other and to enhance their skills and knowledge through conferences and training courses. Other goals of the group are to serve as a hub for the exchange of information and best practices and to represent their interests by developing guidelines and recommendations that can help harmonize auditing processes across different organisations, to advocate for the interests and concerns at various levels – including with regulatory bodies and industry associations – as well as to represent a unified voice to attain a stronger impact in discussions related to regulatory policies and industry standards.

For more information please scan the QR code or see the
Analytical Quality Control Group website

ANALYTICAL QUALITY CONTROL GROUP

ECA | Analytical Quality Control Group
An ECA Foundation Interest Group

The group aims at providing a networking platform for analytical chemists in development and manufacturing, quality control, regulatory affairs and quality assurance professionals in order to facilitate an active discussion of the impact of the latest regulatory changes as well as identifying and addressing technical issues and challenges. In addition, it actively supports a harmonised approach by providing guidance documents on topics of specific interest to Quality Control, developing discussion/position papers and generic procedures via expert working groups, facilitating an effective and efficient communication between industry, competent authorities and the pharmacopoeias regarding analytical quality control.

For more information please scan the QR code or see the
Visual Inspection Group website

VISUAL INSPECTION GROUP

ECA | Visual Inspection Group
An ECA Foundation Interest Group

The Visual Inspection Group's Objective is to assemble knowledge on visual inspection of parenterals, for example by continuously developing the Best Practice Guidance on visual inspection. This guidance paper is available for all members of the group. It contains practical solutions on how to organise and carry out the visual inspection of parenterals. Moreover, the group started working on the topic of Container-/Closure-Integrity testing (CCIT).

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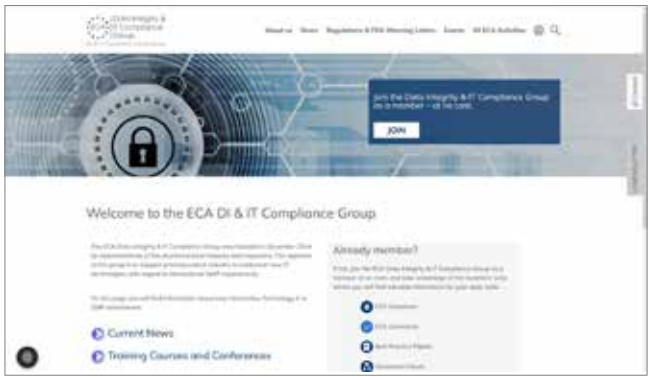
For more information please scan the QR code or see the
Validation Group website

VALIDATION GROUP

ECA Validation Group

An ECA Foundation Interest Group

Although Validation has been one of the most important topics in the GMP environment, there are still different approaches in the US and the EU. The FDA favours a Life Cycle Approach with a 3-stage model focused on process knowledge and process understanding – including explicitly mentioned statistics. The EU's Annex 15 goes in the same direction. It emphasizes a life cycle approach, however with some differences remaining. Thus, how do these differences need to be handled? How can a Process Validation Life Cycle be implemented to show process knowledge and process understanding? The Validation Group therefore assembles knowledge on Validation – also to continuously develop their Good Practice Guide.



For more information please scan the QR code or see the
Data Integrity and IT Compliance Group website

DATA INTEGRITY & IT COMPLIANCE GROUP

ECA Data Integrity & IT Compliance Group

An ECA Foundation Interest Group

The Data Integrity & IT Compliance Group's goal is to support the pharmaceutical industry in implementing new IT technologies – like Cloud Computing, use of Mobile Devices, Data Integrity, Audit Trail Review and SLAs – with regard to international GMP requirements. For that purpose the group develops best practice guides, taking advantage of its members' experience and knowledge as well as their learnings from the past.

For more information please scan the QR code or see the
ATMP Group website

ATMP GROUP

ECA ATMP Group

An ECA Foundation Interest Group

To facilitate an effective and efficient communication between sciences, industry, competent authorities and the pharmacopoeias with regard to relevant topics around Advanced Therapy Medicinal Products (ATMP) is one of the ATMP Group's objectives. It also encourages active discussions on latest regulatory requirements within the EU, US and worldwide. In addition it aims at identifying and addressing regulatory, scientific and technical issues and challenges, including training needs. To accomplish this, the group provides a networking platform for all professionals involved in the development, manufacturing, quality management and marketing authorisation of ATMPs.

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