GMP-related Amendments in the new Regulation and Directive

GMP Update: Consequences from the New EU Commission Proposal

The Commission Proposal to revise EU Medicines Legislation

Live Online Session on 13 June 2023

ECA Academy
Your GMP/GDP Information Source

Objectives and Background

The European Commission on 26 April 2023 published the proposal for the envisaged revision of the EU pharmaceutical legislation. The changes are to be regulated in a directive and a regulation.
Specifically, Directive 2001/83 (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use) and Directive 2009/35/EC are to be replaced. The proposal for a new Regulation 726/2004 (authorisation of medicinal products and establishment of the European Medicines Agency) is intended to replace Regulation 141/2000 for orphan drugs and Regulation 1901/2006 for paediatric medicinal products, but also brings a number of new and adapted regulations.

The reform aims to improve the availability, accessibility and affordability of medicines, while promoting higher environmental standards and increasing the competitiveness and attractiveness of the pharmaceutical industry in the EU. Key elements of the proposal include reducing administrative burdens, promoting innovation and competitiveness, addressing pharmaceutical shortages, ensuring environmental sustainability and tackling antimicrobial resistance.

There are also GMP-relevant changes, which will be discussed in this Live Online Session.

Target Audience

This Live Online Session has been developed for all who are dealing with GMP-relevant aspects in the pharmaceutical industry and would like to get an overview about the envisaged GMP-relevant changes coming with the proposal to revise EU Medicines Legislation.

Programme

Status and overview of the planned revision of the general pharmaceutical legislation in the EU

- Background
- What is currently planned?
- Possible general effects

Possible GMP-relevant Consequences from Directive and Regulation

- What MAHs, CMOs, suppliers and the QP need to know
  - Qualification of the Qualified Person (QP)
  - Written Confirmation
  - Remote inspections
  - Security of supply of medicinal products
  - Serialisation
  - Colours and functional excipients
  - Traceability of substances
  - Decentralised manufacturing sites
- How associations see this

Other possible consequences, QA, QC, Manufacturing and the QP need to know

- New definitions
- Regulatory Data Protection (RDP)
- Paediatric medicines
- Adjustments to risk management plans for the authorisation of generic medicines and biosimilars
- Electronic product information (ePI) (as opposed to paper leaflets)
- Regulations for products combining a medicinal product and a medical device
- Evaluation of certain excipients (colours as authorised food additives)
- Etc.

Speakers

Dr Fatima Bicane

German Medicines Manufacturers' Association (BAH)

Dr Fatima Bicane is a Pharmaceutical Technology/ GMP Officer in the Special Therapeutics and Pharmaceutical Technology/GMP Department at the German Medicines Manufacturers' Association (Bundesverband der Arzneimittel-Hersteller - BAH)

Dr Ulrich Kissel

European QP Association

Dr Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Details

Date of the Live Online Training
Tuesday 13 June 2023, 13.00 – 17.45 h CEST

Technical Requirements
We use Webex for our live online training courses and webinars.

Fees (per delegate plus VAT)
ECA Members EUR 590
APIC Members EUR 640
Non-ECA Members EUR 690
EU GMP Inspectorates EUR 590
The conference fee is payable in advance after receipt of invoice. The Registration does not include ECA Membership.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64 | 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content, contact:
Wolfgang Schmitt (Director Operations) at
+49(0)62 21/84 44 39, or at
w.schmitt@concept-heidelberg.de

For questions regarding organisation, contact:
Sonja Nemec (Organisation Manager) at
+49(0)62 21/84 44 24 or at
nemec@concept-heidelberg.de

All details and registration online at:
www.gmp-compliance.org

CF/10052023