ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Fatima Bicane
Pharma Deutschland e.V.
Pharmaceutical Technology/ GMP Officer

Dr Fatima Bicane is a pharmacist and worked in the pharmaceutical industry for several years. Since 2020, she has been working within the Medicines Association (Pharma Deutschland e.V.), where she focuses on GMP and pharmaceutical development issues.

Dr Ulrich Kissel
KisselPharmaConsulting GmbH

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.

Drug Shortage Policy in the EU: How to deal with Regulatory Requirements?

Live Online Training on 30 June 2025

The EMA Guidance on Medicine Shortages and Availability Issues and the European Shortages Monitoring Platform (ESMP)

Highlights

- Challenges with the European regulatory strategy for managing and monitoring drug shortages
- New Requirements like Reporting, SMP, SPP, i-SPOC
- Collaborative Solutions for Drug Shortage Management and Preventive Measures

Programme

Objectives

This Live Online Training aims to provide a comprehensive understanding of the regulatory framework governing drug shortages in the European Union (EU) and explore strategies for compliance with EU regulatory requirements. It will discuss solutions for managing and mitigating drug shortages effectively and offer insights from experts on navigating current and future challenges.

Background

Drug shortages have become a critical issue in the European healthcare sector, with a significant impact on patient care, treatment continuity and pharmaceutical supply chains. The causes of drug shortages are diverse and can be due to manufacturing disruptions, raw material supply constraints, increased demand and regulatory compliance issues. These shortages can lead to treatment delays, increased costs and potential risks to patient safety.

To address this challenge, regulatory authorities such as the European Medicines Agency (EMA) and national competent authorities have implemented a number of guidelines and requirements to ensure the continuity of medicines supply. The European Shortage Monitoring Platform (ESMP) became fully operational on 29th January 2025. All marketing authorization holders are now required to use only this platform to report data on shortages and availability of medicines. Measures include notification of shortages, preparation of a Shortage Prevention Plan (SPP) and Shortage Mitigation Plan (SMP), registration of an industry single point of contact (i-SPOC) and increased transparency in the pharmaceutical supply chain. However, despite these efforts, ensuring compliance remains a major challenge for pharmaceutical manufacturers, wholesalers and healthcare providers who must navigate complex regulations while maintaining business sustainability.

This course will cover key regulatory requirements, recent legislative developments and practical approaches to compliance. It will also examine how industry stakeholders can effectively manage and prevent shortages while minimizing the impact on healthcare systems and patient welfare.

Target Audience

This course it intended for all person from EU with the following background:

- Regulatory Affairs Professionals
- Quality Assurance Managers
- Supply Chain and Procurement Specialists
- Pharmaceutical Manufacturers and Wholesalers
- Healthcare Providers and Hospital Pharmacists
- Legal and Compliance Experts in the Pharmaceutical Industry

Programme

Understanding the EU Regulatory Framework on Drug Shortages

- The European regulatory strategy to manage and monitor drug shortages: current challenges and recommendations.
- Legal obligations for Marketing Authorization Holders (MAHs) and manufacturers
- Notification requirements and reporting obligations

Solutions for Managing Drug Shortages and Ensuring Compliance

- Collaboration with regulatory authorities, healthcare providers and stakeholders
- Implementation of a drug shortage prevention plan
- Causes of drug shortages and solutions

Date of the Live Online Training

Thursday, 30th June 2025, 13.00 h - 16.00 h
All times mentioned are CEST.

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 345
The fee is payable in advance after receipt of invoice.

Registration

Please register online at **www.gmp-compliance.org under the number 22291.**

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files.
After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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