IPI Academy

MANAGEMENT forum

Presented by
Management Forum

New EU GMP Annex 1 and its Impact on Pharmaceutical Manufacturers

Recorded on **8 June 2023**

This free webinar will explain the reasons for the revision of Annex 1 and will address the changes and implications for pharmaceutical manufacturers. Topics to be covered will include how to prepare your Contamination Control Strategy (CCS) document, and how to adapt to the principles of Quality Risk Management. The expectations of the regulatory authorities and the questions that may be encountered in audits/inspections will also be discussed.

Format:
Recorded webcast

CPD:
1.5 hours for your records

Certificate of completion

Overview

The requirements of Annex 1, (which came into effect in August 2022), are applicable to the production of sterile pharmaceutical products. Manufacturers were given one year to adapt to the new guidelines, except for a part related to Lyophilization, where an additional year has been allowed to meet the Lyophilization criteria.

Since Annex 1 was first published, there have been numerous changes in technology, authority and patient expectations in GMP regulations.

A key element of Annex 1 is Contamination Control Strategy (CCS). Although this was presented as a new requirement, in fact contamination and cross-contamination were already mandatory requirements in facilities producing sterile medicinal products. The objective here is to include the measures taken by the manufacturing facility in a master document, which can be used periodically by senior management to ensure their facility meets the safety requirements.

Annex 1 refers to the importance of fulfilling the requirements set forth in ICH Q9 regarding Quality Risk Management. Interestingly, ICH completed the revision of Q9 in January 2023 and finally released it after 18 years of discussions.

Both sterile medical product manufacturers and the regulatory authorities emphasize the importance of evaluating the new Annex 1 according to the ICH Q9 guideline.

This webinar will explain the reasons for the revision of Annex 1 and will address the changes and implications for pharmaceutical manufacturers. Topics to be discussed will include how to prepare your CCS document, and how to adapt to the principles of Quality Risk Management. The expectations of the regulatory authorities and the questions that may be encountered in audits/inspections will also be discussed.

Benefits of Attending

By participating in this webinar, you will receive detailed information about the new Annex 1, be brought up-to-date regarding the requirements, and the webinar documents will be a useful reference source for the future.

This is a 90-minute free event, book your place now!

Who should attend?

- Sterile Medicinal Product Manufacturers in the following departments:
- Quality Assurance
- Quality Control
- Manufacturing
- Aseptic Filling
- Regulatory Affairs
- IT

This webinar will also be of interest to:

- Regulatory Authority Inspectors / Auditors
- Pharmacy, chemistry, engineering students and new graduates

Presenter

Mustafa Edik

Mustafa Edik is an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and he is preparing his latest book on ‘GMP Audits’ which will be published by Taylor & Francis in 2023.

Course date

8 June 2023

Recorded webcast
13:30-15:00 **UK (London)** (UTC+01)
Course code 12982

How to book

Online:
ipi.academy/2654

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Well presented and Well structured

Leeann Naicker
Researcher
Private
Jun 8 2023

★★★★★

Really enjoyed it - Thank you.

Michael Rieder
Quality Assurance - Validation
Janssen
Jun 8 2023

★★★★☆

I achieved what I hoped to accomplish. [I particularly liked] the speaker and the presentation content. I would recommend to my colleagues.

Hyginus Chijioke Owoh
Graduate
Graduate/jobseeker
Jun 8 2023

★★★★☆

The presentation was very informative

Lethukuthula Manyaka
Locum Pharmacist
LocumSA
Jun 8 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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