IPI Academy

MANAGEMENT forum



Presented by
Management Forum

In the Light of Annex 1: Use of Barrier Systems for Aseptic Pharmaceutical Manufacturing

Recorded on **6 March 24**

This free webinar will familiarise attendees with Restricted Access Barrier System (RABS) technologies. An excellent opportunity to receive detailed information about barrier systems with a main focus on isolator technology, particularly since the implementation of EU GMP Annex 1.

Format:
Recorded webcast

CPD:
1.5 hours for your records

Certificate of completion

Overview

The industry of aseptic pharmaceutical manufacturing, i.e. manufacturing companies as well as related equipment suppliers and engineering companies, have been pretty busy in evaluating the impact of the revised EU GMP guide Annex 1, which came into force on 25 August 2023.

Even before its release, Annex 1 has triggered many heated debates on how it will influence existing aseptic manufacturing processes. These debates have further intensified after publication in August 2022. On the one hand, some paragraphs leave a lot of room for interpretation. On the other hand, the industry fears over-regulation.

But what impact will the new EU GMP Annex 1 really have on sterile filling and processing operations? How will it change the way we work in the pharmaceutical industry? And which technologies are particularly suitable?

One topic, addressed at the very beginning of the Annex 1 guideline in "Chapter 2 Principle", is that *"The use of appropriate technologies (e.g. Restricted Access Barriers Systems (RABS), isolators, robotic systems, rapid/alternative methods and continuous monitoring systems) should be considered to increase the protection of the product from potential extraneous sources of endotoxin/pyrogen, particulate and microbial contamination such as personnel, materials and the surrounding environment, and assist in the rapid detection of potential contaminants in the environment and the product."*

This is a clear indication that Restricted Access Barrier Systems (RABS) or isolators should be used for new equipment to be installed in aseptic pharmaceutical manufacturing.

This webinar will familiarise attendees with barrier system technologies and discuss the complexities involved.

Beneftis of Attending

By participating in this webinar, you will receive detailed information about barrier systems with a main focus on isolator technology.

- **Gain** an overview of the justification for using barrier systems
- **Discover** the differences between RABS and Isolators
- **Understand** how an isolator is characterised
- **Learn** the difference between aseptic and high potent isolators
- **Hear** about isolator air management

Who Should Attend

Sterile Medicinal Product Manufacturers in the following departments:

- Quality Assurance
- Quality Control
- Manufacturing
- Aseptic Filling
- Regulatory Affairs
- Maintenance
- Engineering

This webinar will also be of interest to:

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

Presenter



Lukas Munzinger

Lukas Munzinger started his career with an apprenticeship in 2001 with Bosch Packaging Technology to become an industrial technician for fill/finish packaging machinery. From 2007 until 2011 he finished his bachelor's degree in industrial engineering and business administration at the University of Applied Sciences in Karlsruhe, Germany. Since 2011 he was working in international sales for fill/finish equipment machinery with Syntegon (formerly Bosch Packaging Technology). His market responsibilities were mainly in Latin American countries, but he was also handling complex isolator projects around the globe. From 2017 to 2018 he worked as a Business Developer in Panama City, Panamá. Since December 2022 he has been the global product manager for Barrier Systems and Isolator Technology as well as Depyrogenation Tunnels at the Syntegon site in Crailsheim, Germany. Overall, Lukas has more than 12 years of experience in the primary packaging industry for pharmaceutical fill/finish lines and contributed to many successful customer projects and installations all over the world.

Course date

6 March 24

Recorded webcast
14:00-15:30 **UK (London)** (UTC+00)
Course code 14278

How to book

Online:
ipi.academy/2712

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

★★★★★

Excellent

MD. M. MAHMUDUL ISLAM
Sr. Executive, Qualification & Validation
Healthcare Formulations Ltd
Mar 6 2024

★★★★★

Excellent.

Wondwossen Gebregergs
QC
Ethiopian FDA
Mar 6 2024

★★★★★

It is perfect with RABS and ISOLATOR model design for the clean room, Air handling units and classification of surrounded area as per Annex I.

Mahmood Tolba
TQM Manager
Allmed
Mar 6 2024

★★★★★

Excellent

Mahmoud Sedeek
Validation manager
Allmed
Mar 6 2024

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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