IMA LIFE
invites you to

ISOLATION TECHNOLOGY DAY

September 22nd 2026
Bologna

IMA
Sustain Ability

ISOLATION TECHNOLOGY DAY

Program

SEPTEMBER 22nd 2026

08:45 **Registration.**

09:15 **Welcome.**
Speaker: Michele Arduini – Managing Director at IMA Life.

09:30 **From small-batch to high-speed filling lines: designing flexible isolator systems through real production line case studies.**
Speaker: Giacomo Guidi – Strategic marketing and aseptic processing specialist at IMA Life.

10:00 **High-potent isolators - part 1: containment solutions for formulation and compounding, with a case study on bulk ADC API production integrated with freeze dryers.**
Speaker: Specialist from ProSys Technology.

10:30 **Modularity in HVAC design and VPHP system to improve efficiency, optimise complexity and layout impact in modern isolators.**
Speaker: Marco De Bellis – Process engineer team leader at IMA Life.

11:00 **Coffee break.**

11:20 **Rogue BIs: myth or reality? Ensuring biological indicator reliability and defining an effective cycle development and PQ strategy for decontamination cycles.**
Speaker: Alessandra Benassi - Microbiology and sterility assurance team leader at IMA Life.

11:50 **High-potent isolators – part 2: containment strategies for high-potent drugs as ADCs in aseptic fill-finish systems.**
Speaker: Giacomo Guidi - Strategic marketing and aseptic processing specialist at IMA Life.

12:20 **Introducing RTU vials and PFS into aseptic areas through continuous decontamination: how NEBULA meets the challenge, with experimental residue-control case studies.**
Speaker: Sergio Manera - R&D technology scouting and validation manager at IMA Life.

12:50 **Lunch buffet.**

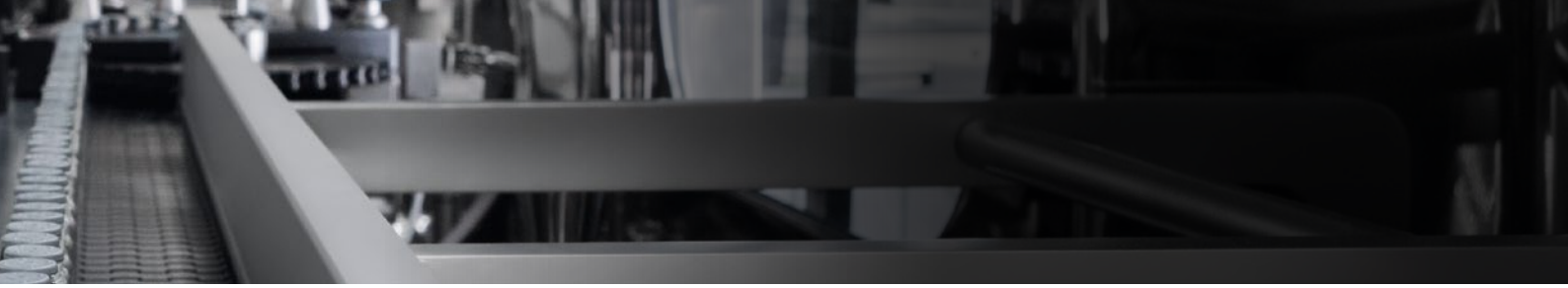
14:00 **Key Annex 1 considerations: a review of the regulatory aspects with the greatest impact on isolators and aseptic filling line projects with IMA Life customers.**
Speaker: Alessandra Benassi - Microbiology and sterility assurance team leader at IMA Life.

14:30 **GMP panel with regulatory professionals: a cross-industry discussion among equipment manufacturers, pharmaceutical companies and inspectors.**
Panel participants: Filippo Trionfera - Quality Operation Manager at BSP Pharmaceuticals and President of PDA Italy chapter; Marisa Delbò – Former AIFA inspector and current member of the PIC/S group of experts, Aseptic drug manufacturers and IMA Life specialists.
Moderator: Giacomo Guidi - Strategic marketing and aseptic processing specialist at IMA Life.

15:45 **Facility tour and IsoTech Lab.**

17:15 **Q&A session and feedback questionnaire.**

17:30 **Aperitif and entertainment.**



Presentation overviews

From small-batch to high-speed filling lines: designing flexible isolator systems through real production line case studies.

Abstract: This presentation will explore how flexible isolator systems can be designed to support different aseptic production scenarios, from small-batch applications to medium- and high-speed filling lines. Through real production line case studies, the session will compare solutions ranging from isolators with integrated ventilation to larger-scale RTU platforms for syringes and vials. The focus will include both liquid and lyophilized products, highlighting how barrier technology, process architecture, and line configuration can be adapted to meet diverse production needs while supporting sterility assurance and Annex 1 requirements.

Modularity in HVAC design and VPHP system to improve efficiency, optimise complexity and layout impact in modern isolators.

Abstract: This presentation will explore how modular HVAC design and VPHP system can help improve efficiency while optimising complexity and layout impact in modern isolators. The session will different ventilation strategies and how they can be adapted to diverse production scenarios while maintaining flexibility in pressure cascade management, filtration architecture, washing requirements, and VPHP-based decontamination or deactivation cycles. Real case studies will compare isolator installations using air inlet from the room or from the external environment, highlighting pros and cons of the different approaches.

High-potent isolators - part 2: containment strategies for high-potent drugs such as ADCs in aseptic fill-finish.

Abstract: This presentation will explore how containment strategies for ADCs and other high-potent compounds are applied to drug product fill-finish operations. The session will focus on the balance between aseptic processing requirements and high-containment needs, showing how isolator and line design can protect both product and operators. Liquid and lyophilized product configurations will be discussed, highlighting key design choices for filling, stoppering, transfer, freeze dryer integration, and contained handling throughout the process.

Key Annex 1 considerations: a review of the regulatory aspects with the greatest impact on isolators and aseptic filling line projects with IMA Life customers.

Abstract: This presentation will review the key Annex 1 considerations that have the greatest impact on modern isolator and aseptic filling line projects. Drawing on discussions and project experiences with IMA Life customers, the session will address the main challenges related to the integration of isolators and filling machines, where process design choices are often critical to contamination control. Different technological solutions will be analysed in terms of their ability to mitigate risks, strengthen sterility assurance, and support full compliance with Annex 1 expectations.

High-potent isolators - part 1: containment solutions for formulation and compounding, with a case study on bulk ADC API production integrated with freeze dryers.

Abstract: This presentation will focus on containment strategies for the formulation and handling of ADCs and equivalent high-potent compounds in high-containment isolator systems, with less than 1 ug/m3 OEL. Starting from small-scale solutions for limited quantities, the session will show how isolator architectures can scale toward larger drug substance production platforms, including kilo-lab applications. Particular attention will be given to the integration of isolators with freeze dryers for bulk API production, with approaches based on Lyoguard systems or more traditional tray-based solutions.

Rogue BIs: myth or reality? ensuring biological indicator reliability and defining an effective cycle development and PQ strategy for decontamination cycles.

Abstract: This presentation will examine cycle development and performance qualification strategies for VPHP decontamination cycles, with a specific focus on the impact of rogue or "late-positive" biological indicators. These atypical BIs can compromise validation and requalification activities by generating unexpected results that are difficult to interpret and may lead to unnecessary cycle redesign or investigation. The session will highlight why BI pre-qualification is essential to ensure reliable cycle development, robust PQ execution, and consistent requalification outcomes. It will also introduce BI reliability as a key design principle behind the new biological indicators produced under the IMA brand.

Introducing RTU vials and PFS into aseptic areas through continuous decontamination: how NEBULA meets the challenge, with experimental residue-control case studies.

Abstract: This presentation will introduce NEBULA as a continuous decontamination approach for transferring RTU vials and prefilled syringes into aseptic areas across both low- and high-speed production scenarios. The session will show how continuous VPHP-based decontamination can provide operational advantages versus traditional no-touch debagging strategies or e-beam solutions. Particular focus will be given to system validation, with experimental case studies on H_2O_2 penetration and residue control inside primary containers, including strategies to achieve very low residual levels for oxidation-sensitive products.

GMP panel with regulatory professionals a cross-industry discussion among equipment manufacturers, pharmaceutical companies and inspectors.

Abstract: This GMP panel will open a cross-industry discussion among consultants, pharmaceutical companies, equipment manufacturers, and scientific organisations such as PDA Italy. Building on the key Annex 1 challenges presented during the previous session, the debate will explore how regulatory expectations are reshaping the injectable and ophthalmic pharmaceutical markets. The discussion will focus on how different stakeholders can address these challenges in a balanced and effective way, aligning compliance, manufacturing feasibility and technological innovation.

Venues

IMA LIFE
Via Maestri del Lavoro 203
40024 Castel San Pietro Terme, Bologna – Italy

REGISTRATION
The number of participants is limited.
We would require you to register by **August 21st, 2026** by completing the following registration form:

Registration form

After we receive your application, your registration will be confirmed by email.

FEES
Participation in the event is free of charge and covers seminar documents, coffee break, lunch and aperitif. Only travel, individual transport and accommodation expenses are not accounted for.

CONTACT INFORMATION
For any request or additional information about the event, do not hesitate to contact us at *symposium.life@ima.it*

IMA S.p.A. - LIFE Division
marketing.life.it@ima.it • imagroup.com/pharma • **imagroup.com**
FOLLOW IMA