

2022 PDA Aseptic Processing of Biopharmaceuticals Conference

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Organised by the Parenteral Drug Association (PDA), the 2022 PDA Aseptic Processing of Biopharmaceuticals Conference is an in-person event that will be held on 25-26 October 2022 at the Sheraton Grand Incheon Hotel, South Korea.

It will address topics related to the manufacturing of sterile drug products and patient-friendly applications. This year's conference will build up topics involving challenges in isolators, glove leak testing, prefilled syringe installations, use of robotics in aseptic filling, and recent innovations in visual inspections. It will also introduce Industry 4.0 in Aseptic filling, advances in glass technologies and Quality in Biotherapy Production.

Our regulatory section will include the participation of MFDS, India and ex-US FDA inspectors providing Regulatory information about changes that will affect the pharmaceutical manufacturing environment and how to manage regulatory inspections. Presentation topics will be divided into three sections:

Manufacturing:

- Aseptic Manufacturing using Isolators, design, new technologies
- Use of Robotics in Aseptic filling
- Glove leak rate detection
- RABS case study
- Developing a Pass through Decon best practice
- Primary packaging sourcing, advancement in Glass technology
- Regulatory expectations for Extractables & Leachables on packaging systems
- Important considerations for Aseptic techniques

Regulatory Updates

- MFDS perspective in vaccines (topic in progress)
- Best practices in Regulatory Inspections

Quality Assurance

- Aseptic operations, managing risks, quality monitoring
- Implementation of Novel systems

*Simultaneous Interpretation/Translation (SI) **English - Korean** will be available.*

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