PDA Ready-to-Use Primary Drug Container Solutions Workshop 2026

Agenda

Monday, 13 April

CEST Daylight Time (UTC +2:00)

09:00 – 09:05	**Welcome and Introduction** **Francesca Ciraldo PhD**, Primary Packaging Principal Engineer, *Johnson & Johnson* **David Riesop PhD** Research Fellow *AbbVie*
09:05 – 09:15	**General Introduction and Overview of the Scope** This interactive session will provide a practical, case-based approach to evaluating the implementation of ready-to-use vials versus bulk vials. Participants will work through a realistic case to assess technical, operational, and economic factors influencing the decision to switch to RTU vials or continue with bulk processes. Moreover, participants will develop an implementation strategy to support the transition from bulk vials to RTU vials that addresses technical feasibility, regulatory pathway, sterility assurance, validation scope, equipment compatibility, cleanroom and automation changes, timeline, cost considerations, and risk mitigation. **Francesca Ciraldo PhD**, Primary Packaging Principal Engineer, *Johnson & Johnson* **David Riesop PhD** Research Fellow *AbbVie*
09:15 – 09:30	**Perspective From a Primary Packaging Provider** *Unlocking RTU Potential: Collaborative Pathways to navigate Implementation Challenges* From the perspective of primary packaging providers within the RTU Alliance, the increasing adoption of RTU containers reflects a clear shift toward greater flexibility and efficiency in the development of injectable drug products. As manufacturers seek faster time-to-market and more streamlined aseptic processing, RTU formats are becoming a key enabler. Primary packaging suppliers support this shift by offering pre-validated, contamination-controlled solutions that facilitate scalable and reliable manufacturing. Looking ahead, successful implementation will require addressing remaining challenges such as supply-chain integration, regulatory alignment, and compatibility across formats. A phased, low-risk approach will be essential to ensure smooth adoption and to fully leverage the advantages that RTU systems can bring to future manufacturing strategies. **Robert Lindner PhD**, Global Product Manager Bulk and Sterile Cartridges, *SCHOTT Pharma*
09:30 – 09:45	**Perspective From Machine Manufacturers** *Comparing Bulk and RTU Fill & Finish Processes: A Machine Manufacturer's Perspective* *Highlighting Key Differences between Technologies* This presentation provides one possible impression of existing processes of how Bulk and Ready-to-Use (RTU) processes compare within Fill & Finish manufacturing, viewed from the perspective of equipment manufacturers. It highlights key differences between the two approaches, examines their influence on machine design and process workflows, and discusses associated challenges. The goal is to offer a representative, but not exhaustive, perspective on how these technologies diverge and what this means for manufacturing operations. **Christian Vaas** , Product Manager / Business Development Manager, *groninger*
	Perspective from Fill & Finish User *From Bulk to Ready to Use: Evaluating RTU Vial Implementation for Pharmaceutical Companies* As industry discussions about RTU vial integration continue to evolve, this presentation aims to support pharmaceutical leaders in evaluating practical implementation approaches, anticipating future developments, and optimizing sterile

09:45 – 10:00	manufacturing efficiency. While RTU cartridges and prefilled syringes (PFS) are widely regarded as the gold standard and broadly adopted across the industry, the transition from traditional “bulk” vials to RTU vials remains a topic of active debate. This presentation focuses on RTU vials and examines the advantages and challenges of their implementation from the perspective of pharmaceutical companies. Key considerations include cost structures, equipment compatibility, sterility assurance strategies, cleanroom configurations, levels of automation, and the scope of validation required to integrate RTU vials into established manufacturing lines originally designed and qualified for handling and filling “bulk” vials. **Francesca Ciraldo PhD**, Primary Packaging Principal Engineer, *Johnson & Johnson* **David Riesop PhD** Research Fellow *AbbVie*
10:00 – 10:30	**Networking Coffee Break**
10:30 – 12:00	**Interactive Session Part I**
12:00 – 13:00	**Networking Lunch Break**
13:00 – 14:45	**Interactive Session Part II**
14:45 – 15:15	**Networking Coffee Break**
15:15 – 15:45	**Continue Interactive Session Part II**
15:45 – 16:30	**Group Discussion and Outcome**
16:30 – 17:00	**Summary of the Workshop and Take-Home Messages** Finally, participants will gain clear learning points and take-home messages to support informed decision-making on RTU vial implementation. **Francesca Ciraldo PhD**, Primary Packaging Principal Engineer, *Johnson & Johnson* **David Riesop PhD** Research Fellow *AbbVie*
17:00 – 17:00	**End of Workshop and Farewell**

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