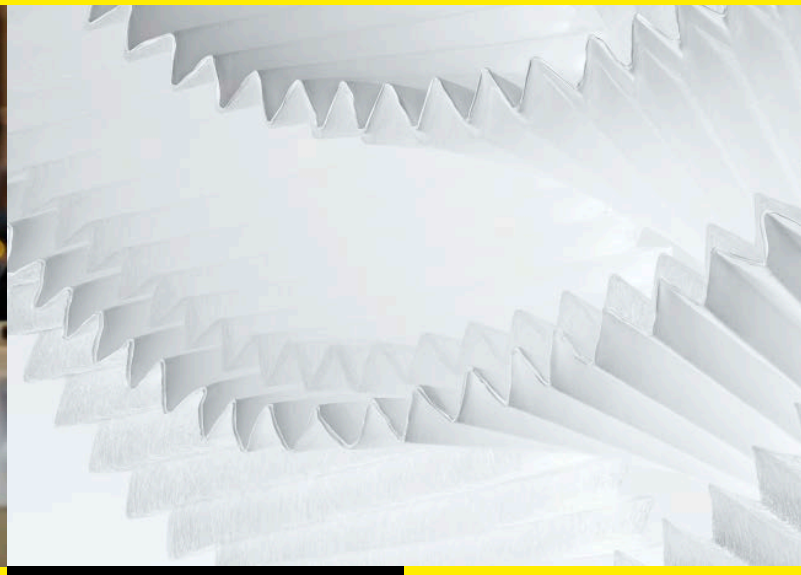
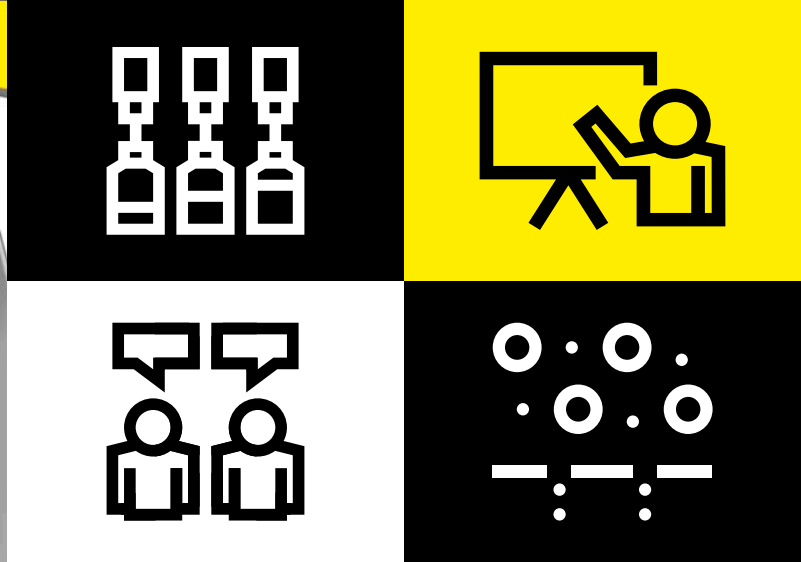
SARTORIUS

Fill & Finish Days

Put Your Fill & Finish Steps in the Spotlight

September 30-October 1, 2025
Aubagne, France





What You Don't Want to Miss

Expert Guidance
Join workshops led by subject matter experts on Annex 1, particle control, and sustainability. Get practical support for regulatory compliance and implementing strategies that work in your facility.

Real-Life Case Studies
See how strong partnerships can transform final formulation and filling processes through co-presentations with clients and real-world applications.

Stay Competitive
Explore the latest trends and technologies—like single-use solutions for CDMOs and Sartopore Evo®—that are shaping the future of sterile manufacturing.

Networking With Peers
Connect with industry leaders and fellow professionals to exchange ideas, experiences, and solutions in aseptic processing.

Hands-On Experience
Engage in product demos and guided tours of our Application Center to see innovations like final fill, freeze and thaw, and integrity testing in action.

Unforgettable Venue and Atmosphere
Enjoy the event in our newly opened Conference Center, featuring delicious food and an evening dinner to enhance your networking and learning experience.

Event homepage:
Sartorius Fill & Finish Days

Workshops

Over two days, we offer three workshops and an Application Center tour. Participants will be divided into smaller groups to ensure everyone can attend each session.

Workshop 1
The Pursuit of Annex 1: Leveraging Contamination Control Strategies With Single-Use Systems

Guest Speaker:
Dr. Marc Uerdingen
Director Technical Customer Support Europe, West Pharmaceutical Services

Workshop 2
Particle Control – How to Set Up the Standard?

Workshop 3
The Evolution of Single-Use Systems for Sustainability in Fill and Finish

Application Center Tour

Preliminary Agenda* | Day 1

Tuesday, September 30

Start	End	Topic	Speaker
9:00 a.m.	9:30 a.m.	Arrival and registration	
9:30 a.m.	10:00 a.m.	Welcome coffee	
10:00 a.m.	10:30 a.m.	Introduction to Fill & Finish Days and day 1	**Peter Holl** Head of Sales BPS EMEA, Sartorius
10:30 a.m.	11:00 a.m.	Optimizing Filling Applications: Co-Developing Single-Use Systems and Final Filling Machine Technology	**Sarah Springer** Global Product Manager - Vial, Ampoule and Filling Systems, Syntegon Technology **Lucie Clavel** Product Manager Fill & Finish, Sartorius
11:00 a.m.	11:30 a.m.	Coffee break	
11:30 a.m.	12:00 p.m.	Accelerating Drug Introduction to Market in a Smart and Fast Way With Simulation and Small-Scale Studies	**Greg Neal** Director CMC, argenx **Pierre Selva** Product Specialist FMT Hardware & Mixing, Sartorius
12:00 p.m.	1:00 p.m.	Lunch	

		Group 1	Group 2	Group 3	Group 4
1:00 p.m.	2:30 p.m.	Workshop 1	Workshop 2	Workshop 3	Application Center Tour
2:30 p.m.	3:00 p.m.	Coffee break			
3:00 p.m.	4:30 p.m.	Workshop 2	Workshop 3	Application Center Tour	Workshop 1
4:30 p.m.	4:45 p.m.	Closing of day 1			
4:45 p.m.	5:30 p.m.	Open visit of the Application Center			
7:00 p.m.		Networking dinner			

*Subject to change

Preliminary Agenda* | Day 2

Wednesday, October 1

Start	End	Topic	Speaker
9:00 a.m.	9:15 a.m.	Arrival	
9:15 a.m.	9:30 a.m.	Introduction day 2	
9:30 a.m.	10:00 a.m.	Challenges of the Implementation of PUPSIT and Progress in Point of Fill Filtration	**Ruben Wohlfarth** Senior Process Technologist Fill & Finish, Boehringer Ingelheim **Mathias Siebner** Product Specialist ST Filtration, Sartorius
10:00 a.m.	10:30 a.m.	Advanced Technologies to Enable Subcutaneous Delivery of High-Dose Drug Product	**Dr. Quanmin Chen** Vice President, Drug Product Development of Global Drug Product Operations, WuXi Biologics
10:30 a.m.	11:00 a.m.	Coffee break	
11:00 a.m.	11:30 a.m.	Strengthening Annex 1 Compliance With Expert-Driven Validation Services	**Markus Junior Maring** Product Manager Sterile Filtration, Sartorius **Marine Cannuel** Manager of Confidence Validation Services, Sartorius
11:30 a.m.	12:30 p.m.	Lunch	

		Group 1	Group 2	Group 3	Group 4
12:30 p.m.	2:00 p.m.	Workshop 3	Application Center Tour	Workshop 1	Workshop 2
2:00 p.m.	2:30 p.m.	Coffee break			
2:30 p.m.	4:00 p.m.	Application Center Tour	Workshop 1	Workshop 2	Workshop 3
4:00 p.m.	4:15 p.m.	Closing of day 2			

*Subject to change

Abstracts

1. **Optimizing Filling Applications: Co-Developing Single-Use Systems and Final Filling Machine Technology**
   In the evolving landscape of pharmaceutical manufacturing, the integration of single-use (SU) systems with advanced machine technology presents a transformative opportunity to enhance filling applications. This co-presentation with Syntegon, featuring insights from machine vendor partner, delves into the collaborative development of SU equipment and filling machinery. We address the critical risk of contamination posed by technical interfaces, such as port systems, and present a systematic approach to minimize these interfaces and streamline supplier interactions within the product path. By reducing complexity and enhancing compatibility, this partnership aims to deliver superior operational efficiency and product integrity. Join us to explore how strategic co-development can lead to innovative solutions that meet the rigorous demands of modern pharmaceutical production.

2. **Accelerating Drug Introduction to Market in a Smart and Fast Way With Simulation and Small-Scale Studies**
   Releasing a drug product to market requires demonstrating that quality is consistent and reproducible, regardless of the production equipment used. This becomes particularly challenging when working with multiple CDMOs, where equipment can vary significantly between sites.
   This presentation with argenx demonstrates how computational fluid dynamics (CFD) simulations can be leveraged to define and replicate process conditions across different equipment sizes and geometries. Applying the CFD results at small scale enables the reduction of both the volume of drug product needed for testing and the number of tests required. We will explore a case study applying this approach to the final formulation of a drug product manufactured across three different production lines.

3. **Challenges of the Implementation of PUPSIT and Progress in Point of Fill Filtration**
   Many pharmaceutical manufacturers encounter difficulties in implementing Pre-Use Post-Sterilization Integrity Testing (PUPSIT). To overcome these challenges, it is crucial to proactively conduct comprehensive risk assessments to ensure audit readiness.
   If PUPSIT is to be implemented, additional challenges must be addressed. A risk-based approach is essential during the process design phase, particularly regarding aseptic handling and overall processability. This presentation outlines a practical example of PUPSIT implementation within a greenfield project for an aseptic manufacturing facility, designed to meet both regulatory requirements and ensure product and operator safety.
   Significant advancements are underway in the area of final filling, with automation playing a central role. See how by integrating advanced automation into the PUPSIT setup, including steps like drying of single-use assemblies, these innovations reduce manual handling and improve process reliability. The PUPSIT filter assembly has also been optimized to support both manual and automated workflows. In parallel, newly developed sterilizing-grade membranes offer improved performance and reduced product loss, while providing alternative solutions that help you move away from PFAS-based materials.

4. **Advanced Technologies to Enable Subcutaneous Delivery of High-Dose Drug Product**
   The subcutaneous delivery of high-dose drug products presents unique challenges, including managing increased viscosity, ensuring robust fill & finish (F&F), and maintaining product stability at elevated concentrations. Overcoming these obstacles is essential for enhancing therapeutic efficacy, reducing administration volumes, and improving patient compliance while controlling costs. Drawing on extensive experience in the field, teams have implemented advanced technologies such as the WuXiHigh™ platform, which enables drug concentrations up to 240 mg/mL. This approach combines innovative viscosity reduction strategies, high-throughput formulation development, and robust drug substance/drug product manufacturing to address the complexities of high-dose delivery. The adoption of single-use (SU) systems has played a pivotal role, offering greater flexibility, minimizing cross-contamination risks, and accelerating development timelines across more than 110 projects involving monoclonal antibodies, bispecifics, fusion proteins, and ADCs. By sharing these experiences and solutions, this presentation aims to foster dialogue within the F&F sector, demonstrate the value of SU systems in overcoming high-dose delivery challenges, and inspire continued innovation in subcutaneous drug product development.

5. **Strengthening Annex 1 Compliance With Expert-Driven Validation Services**
   This presentation will showcase three customer case studies that exemplify strategic approaches to contamination control and risk mitigation, as outlined in Annex 1. The cases include:

   (1) A filter validation project with GSK incorporating PUPSIT as part of the BCT, previously presented at the PDA conference;
   (2) A process risk analysis for extractables and leachables (E&L); and
   (3) The usage of particle validation standards to enhance visual inspection training programs.

   Together, these examples demonstrate how a risk-based approach can support compliance and enhance product safety in pharmaceutical manufacturing.

Abstracts

6. **Workshop 1 | The Pursuit of Annex 1: Leveraging Contamination Control Strategies With Single-Use Systems**
   Achieving Annex 1 compliance is crucial for maintaining the cleanliness and integrity of pharmaceutical processes. A robust contamination control strategy (CCS) plays a vital role in this pursuit. This workshop explores the integration of single-use systems (SUS) as a means to bolster contamination control, emphasizing critical aspects such as material extractables and leachables (E&L), design complexity, robustness, integrity, sterility validation, and aseptic processing.
   We will explore comprehensive solutions that span the entire manufacturing process, from thawing to finishing, highlighting recent innovations that contribute to particle prevention and sterility assurance. Attendees will gain insights into how these strategies and technologies can enhance compliance and drive operational excellence in pharmaceutical manufacturing.
   This workshop will be supported by our leading partner in aseptic processing, West Pharmaceutical Services, who will present their interpretation of Annex 1. They will discuss the increased use of isolators driving the evolution of packaging and key considerations for new component packaging.
   Join us to discover the transformative potential of single-use systems in elevating your contamination control measures and achieving superior compliance standards.

7. **Workshop 2 | Particle Control — How to Set Up the Standard?**
   In recent years, the biopharmaceutical industry has increasingly adopted single-use systems due to their flexibility, cost-effectiveness, and reduced risk of cross-contamination. However, the presence of visible particle matter in these systems remains a critical concern, impacting product quality and patient safety. This workshop aims to address the challenges and advancements in detecting, analyzing, and mitigating visible particle matter in single-use systems. Key topics include:

   - **Detection Techniques:** Exploring the latest technologies and methodologies for identifying visible particles in single-use systems, including optical inspection and automated detection systems.
   - **Impact on Product Quality:** Understanding how visible particle matter affects the integrity and efficacy of biopharmaceutical products, and the regulatory implications.
   - **Material Selection and Design:** Discussing the role of material choice and system design in minimizing particle generation and contamination.
   - **Presenting Our Particle Knowledge and Approach:** Sharing insights into our comprehensive approach to particle management, including continuous manufacturing improvements that enhance system reliability and product safety.
   - **Addressing Future Market Needs:** Engaging in a collaborative brainstorming session to address the lack of existing standards and regulations for visible particles. We will explore expectations and potential testing methods and technologies, aiming to find a common path forward for industry-wide advancements.

   Join us as we delve into these critical topics, fostering collaboration and innovation to advance the quality and reliability of single-use systems in the biopharmaceutical industry.

8. **Workshop 3 | The Evolution of Single-Use Systems for Sustainability in Fill and Finish**
   By implementing life cycle thinking, Sartorius is significantly improving the environmental performance of its products, setting the standard for sustainable practices within the biopharmaceutical industry. This workshop will explore how life cycle thinking has driven advancements, such as ISCC+ certification and the development of PFAS-free products. We will also review the supporting documents we are currently sharing, underscoring our commitment to transparency and environmental responsibility. Participants will gain firsthand insights into pioneering sustainability initiatives and have the opportunity to offer feedback, fostering a collaborative understanding of sustainable innovation.