

**ACT NOW, Seating is Limited!**



# Aseptic Barrier Technical Summit 2016 & Tour of Production Facility

October 4-5, 2016  
Raleigh, NC

sponsored by:



## Key Technology Topics

- Aseptic/Potent/Biologics/Vaccines Filling
- Aseptic Ophthalmic Bottle Filling
- H<sub>2</sub>O<sub>2</sub> Material Air Locks
- Sterile Stopper Processing/Transfer
- RABS vs. Isolation Technologies
- Nested Syringe Filling w/EBeam
- Wireless Glove Testing
- Aseptic Vial Filling w/Automated Load/Unload
- Freeze Dryer
- Operating Costs
- Facility Design Comparison
- Bulk Syringe Filling
- Modular Small to Medium Scale Aseptic Processing Isolators



# Aseptic Barrier Technical Summit Agenda

**DAY ONE** Tuesday, October 4, 2016

**7:30–8:30 am** Registration & Breakfast

**8:30–8:45 am** Welcome

Bill Friedheim, Corporate Director, Key Accounts, SKAN US



**8:30–9:15 am**

## **Baxalta** Baxalta Covington, GA

\$1.2B Fill Finish Facility with Vial Filling Isolator and Sterility Testing Isolator to produce blood-based treatments. Operations include plasma fractionation, purification, fill-finish and testing laboratories. The PSI-L, a modular isolator located within the new Georgia Bioscience Training Center, will also be discussed.

Presenter: Brant Bulgarelli, Engineering Specialist

**9:15–10:00 am**



## **Cantrell Drug Company** Westborough, MA

This presentation is focused on the AT robotic closed vial filling within the PSI-L isolator within the Company's 503B Compounding Pharmacy, which produces sterile products and also "bridges the gap" of commercial product drug shortages.

Presenter: Dell McCarley, P D., CEO and Pharmacist

**10:00–10:30 am** Networking Break

**10:30–11:15 am**



## **Sanofi Pasteur** Toronto, Canada

Restricted Access Barrier System (RABS) retrofit to an existing filling system. The 22-hectare Toronto campus is the company's global NA Center of Excellence in analytical and bioprocessing R&D with strategic assets for the research, development and manufacturing of vaccines for 90+ countries around the world.

Co-Presented: Len Pauzer, Senior Process Engineer, IPS-Integrated Project Services  
Irina Mejia, Manager, Capital Projects-Sanofi

**11:15–12:00 am**



## **Hospira/Pfizer** Rocky Mount, NC

This presentation will focus on the modernization of existing sterile manufacturing facilities, including the deployment of Ampoule and Vial Filling Isolator and SKANFOG® MAL (H<sub>2</sub>O<sub>2</sub> Material Air Locks) technology. Isolators and MALs are also being used for sterile stopper processing and transfer to Grade B Fill Suites.

Presenter: Dennis Tate, Managing Engineer, Global Process and Equipment

**12:00–1:00 pm** Lunch

**1:00–1:45 pm**



## **Evonik Corp.** Birmingham, AL



Installation of Flexible VarioSys Solution within the new multi-chamber PSI-L for powder/liquid vial filling and freeze drying of sterile potent products.

Presenter: Bob Adkins, Director of New Project Development

**1:45–2:30 pm**



## **Elanco** Augusta, GA

This \$100MM project, to increase animal health manufacturing operations within a 40,000sf facility, offers technical details involving the implementation of a production isolator within a filling line and a semi-automated, powder handling coning isolator/MAL solutions.

Presenter: Walt Senour, Assoc. Senior Consulting Engineer

**2:30–3:00 pm** Networking Break

**3:00–3:45 pm**

## **Boehringer Ingelheim** Fremont, CA



At one of the largest biopharmaceutical production facilities in Europe, presentation discusses going beyond cleanrooms into new technologies; offering insight into the evolution from Cleanrooms to RABS to Isolation Technology.

Presenter: Paul Tyson, Principal Engineer, Aseptic Filling and Packaging

**3:45–4:30 pm**



## **Genentech** Hillsboro, OR



Expansion of sterile fill finish operations, increased capacity to meet demand, and provided the opportunity to retrofit existing filling isolators with Wireless GT, an advanced and fully automated glove leak testing system.

Presenter: Zach Price, Sr. Manager MSAT

**4:30–5:30 pm** Q&A/Roundtable Discussion with Presenters

**6:00–10:00 pm** Cocktails/Dinner — *The Matthews House, Cary, NC*  
Transportation provided

**Guarantee Your Spot at the Most Informative and Hands-on Aseptic Barrier Conference of the Year!**

Join industry experts as they discuss their capital project achievements and experiences with aseptic barrier technologies in an informal setting. Learn about new methodologies, new and existing technologies and challenges/solutions encountered during installation, validation and operations.

*The content is non-commercial and only includes presentations by actual technology implementers and users.*



## DAY TWO Wednesday, October 5, 2016

7:30-8:30 am *Breakfast*

8:30-9:15 am



### Amgen Thousand Oaks, CA

Installation of a flexible, nested syringe and vial filling isolator at Amgen's HQ campus provided greater mobility within the new drug substance manufacturing facility.

Presenter: Miguel Cerezo, Director, Engineering

9:15-10:00 am



### United Therapeutics Silver Spring, MD

An update on this award-winning building that for years has manufactured orphan drugs using a vial filling isolator right in the FDA's backyard and now has become a training site for inspectors. Filling technologies include: automated freeze dryer load/unload and Blow Fill Seal.



Co-Presented: Sterling Kline, RA, Vice President  
IPS-Integrated Project Services  
Patrick Poisson, Senior Vice President  
and Chief Manufacturing Officer

10:15-10:30 am *Networking Break*

10:30-11:15 am



### Allergan Waco, TX

The 22,000sf addition expansion to existing manufacturing operations increased production capacity and the opportunity to implement ophthalmic plastic bottle filling isolators.

Presenter: Ameet Motwani, PMP, Project Engineer

11:15-12:00 pm *Q&A/Roundtable Discussion with Presenters*

12:00-12:45 pm *Lunch*

## Tour Options

12:45-1:30 pm



Travel to Seqirus, Holly Springs from Embassy Suites Brier Creek  
OR  
Travel to SKAN US, Raleigh from Embassy Suites Brier Creek

### Option #1. 1:30-5:00 pm *Guided Tour of the Seqirus Facility*

A tour presentation on what we will see at this breakthrough \$1B+ cell culture vaccine facility; operations include a syringe isolator with EBeam for filling the H1N1 Flu Vaccine.

Presenter: Speaker to be confirmed

Space is limited; this Tour excludes equipment suppliers. Transportation to/from hotel/Seqirus facility is included.



### Option #2. 1:30-5:00 pm *Guided Tour of SKAN US Facility*

See INTERPHEX Biotech Innovation Award Winner, VarioSys®, a flexible processing line. A special isolator enables production in clean room class A conditions, individual production modules can be installed that fit on the lock-and-key principle.

Presenter: Siera Talbott, Argos,  
Senior Project Manager, Mfg Science &  
Technology

Transportation to/from hotel/SKAN US facility is included.



## Case Studies Presented by Industry Leaders from Leading Manufacturers

- Amgen  
Thousand Oaks, CA
- Baxalta  
Covington, GA
- Boehringer Ingelheim  
Fremont, CA
- Cantrell Drug Company  
Westborough, MA
- Elanco  
Augusta, GA
- Evonik Corp.  
Birmingham, AL
- Genentech  
Hillsboro, OR
- Hospira/Pfizer  
Rocky Mount, NC
- Sanofi Pasteur  
Toronto, Canada
- United Therapeutics  
Silver Spring, MD
- Guided Tour of Seqirus Facility  
Holly Springs, NC
- Guided Tour of SKAN US Facility  
Raleigh, NC





# Aseptic Barrier Technical Summit 2016 & Tour of Production Facility

## Reserve Your Seat!

### Online:

<http://tinyurl.com/jy9h5np>



### eMail or fax to:

[sofie.romatzick@us.skan.ch](mailto:sofie.romatzick@us.skan.ch) | 919.354.6411

First: \_\_\_\_\_  
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City: \_\_\_\_\_ State/Prov.: \_\_\_\_\_ Zip: \_\_\_\_\_  
Country: \_\_\_\_\_  
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### Send Payment:

Mail Check Payable to: SKAN US  
Sofie Romatzick  
SKAN US, Inc.  
7409 ACC Blvd.  
Raleigh, NC 27617

### Or call with your credit card information:

Sofie Romatzick, 919.354.6381

### If you have any questions contact:

Sofie Romatzick at 919.354.6381 or  
[sofie.romatzick@us.skan.ch](mailto:sofie.romatzick@us.skan.ch).

## Summit and Tour Fee \$695\*

Register by September 4 — Tours are limited

**Summit Special: Save \$200 — REGISTER by September 1, 2016**

Fee includes all meals and coffee breaks as outlined in the summit agenda, including the tour of the Seqirus facility and transportation to/from Holly Springs, NC. Fee is non-refundable

### Hotel Accommodations

Embassy Suites  
Raleigh–Durham Airport/Brier Creek  
8001 Arco Corporate Drive  
Raleigh, NC 27617  
919.572.2200

When making reservations, please contact the Embassy Suites Raleigh at 919.572.2200 and request the “SKAN US” rate, group code “AKX” (\$179 plus tax) or book online at: <http://tinyurl.com/jmwjnhp>

### Space is Limited

Please be sure to make your hotel reservations as space is limited and available until September 15, 2016.

### Directions

Embassy Suites is located 5-10 minutes from the Raleigh Durham Airport (RDU) and has a complimentary hotel shuttle service.

### Conference Attire

Business Casual

**Questions?** Contact Sofie Romatzick at 919.354.6381 or [sofie.romatzick@us.skan.ch](mailto:sofie.romatzick@us.skan.ch).



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