

Complying with EU GMP Annex 1

Manufacture of Sterile Medicinal Products



PANEL DISCUSSION

Pat Bailey - Merck & Company
Angel Salaman - Janssen Pharmaceuticals
Mitch Garber - 2seventybio

April 19, 2023

A Critical Session to Attend for all Personnel

**Venue at the Desmond Hotel
and Conference Center:**

Attendee Cost: \$80.00

5:00-6:00: Networking and Cash Bar

6:00-7:30: Dinner Buffet

7:30-9:00: Presentation

REGISTER TODAY

Attendee Cost: \$80.00

www.pdadelval.org

The Delaware Valley Chapter of PDA



EU GMP Annex 1

What are GMP companies doing to comply?

About the Presentation

This presentation is focused towards the following disciplines:

- ✍ Quality Assurance
- ✍ Quality Control
- ✍ Validation
- ✍ Production
- ✍ Product Development
- ✍ R&D
- ✍ Clinical Development and Manufacturing
- ✍ Regulatory Compliance
- ✍ And more.....

This presentation focuses on:

A panel discussion that incorporates audience questions surrounding the implementation of the newly released EU Annex 1.

The panel is made up of representatives from Merck & Company, Johnson and Johnson and 2seventybio. The group of GMP personnel are currently implementing a EU GMP Annex 1, Manufacture of Sterile Medicinal Products, compliance plan throughout their organizations. The audience will have the ability to ask blind question through the moderator or by verbally asking during the panel discussion. Truly, this meeting is a way to see how other organizations are addressing guidance writings from the European Commission.

About our Speakers

PAT BAILEY - MERCK & COMPANY

Pat Bailey is currently a Director of Global Quality & Compliance at Merck where he partners with internal and external manufacturing sites across the globe to deploy global Quality Manual requirements including Annex 1. He actively supports global technical transfers, new capital projects, continuous improvement initiatives and significant issue resolution with a focus on microbiology and sterility assurance. For nearly 30 years, he has held roles of increasing responsibility in technical, operating and quality positions supporting non-sterile, sterile and low bioburden manufacturing.

ANGEL SALAMAN - JANSSEN PHARMACEUTICALS

Angel Salaman is currently a Principal Process Scientist in Microbiology for Janssen Research and Development, CAR-T Manufacturing Facility in Spring House, PA. With over 20 years' experience in sterile and non-sterile pharmaceutical manufacturing, Angel has high level experience in Environmental Monitoring (EM) Classified Rooms, Quality systems, Analytical Microbial Methods verification/validation, Microbiology / manufacturing non-conformance investigations, Quality Risk Assessment and Process Excellence

MITCH GARBER 2seventybio

Mitch Garber is currently Head of the Drug Product Facility Build at 2seventybio where he leads and oversees the construction, start up and validation of a new clinical cell and gene therapy facility where previously he was the head of quality assurance. Mitch has over 35 years of professional experience in quality, aseptic manufacturing, GMP auditing, regulatory compliance and sterile product/process development of pharmaceutical, cell therapy and biological products. He is active in various industry groups and has served on various committees within the PDA and the local PDA Delaware Valley Chapter.

To Register Visit:
<http://www.pdadelval.org>

DIRECTIONS TO THE DESMOND GREAT VALLEY HOTEL AND CONFERENCE CENTER



The Desmond

One Liberty Blvd. • Malvern, PA 19355 • (610) 296-9800 • <http://www.desmondgv.com>

Directions from Philadelphia

Take the Schuylkill Expressway (1-76) West Follow 1-76 West to Route 202 South. Take Route 202 South to the Great Valley/Route 29 North Exit.

Directions from South Jersey

Take 1-95 South to Route 322 West Take 322 West to US Route 1 South to Route 202 North. Take Route 202 North to Great Valley/Route 29 North Exit. Turn right onto route 29 North. Turn right at second light onto Liberty Blvd. Hotel will be on the left.

Directions from Philadelphia Airport

Take 1-95 South to 476 North. Follow 476 North to the Schuylkill Expressway (1-76) West to Route 202 South. Take Route 202 South to the Route 29 North Exit. At the end of the ramp, proceed through the light onto Liberty Boulevard. The

Directions from Wilmington and Points South (Delaware& Maryland)

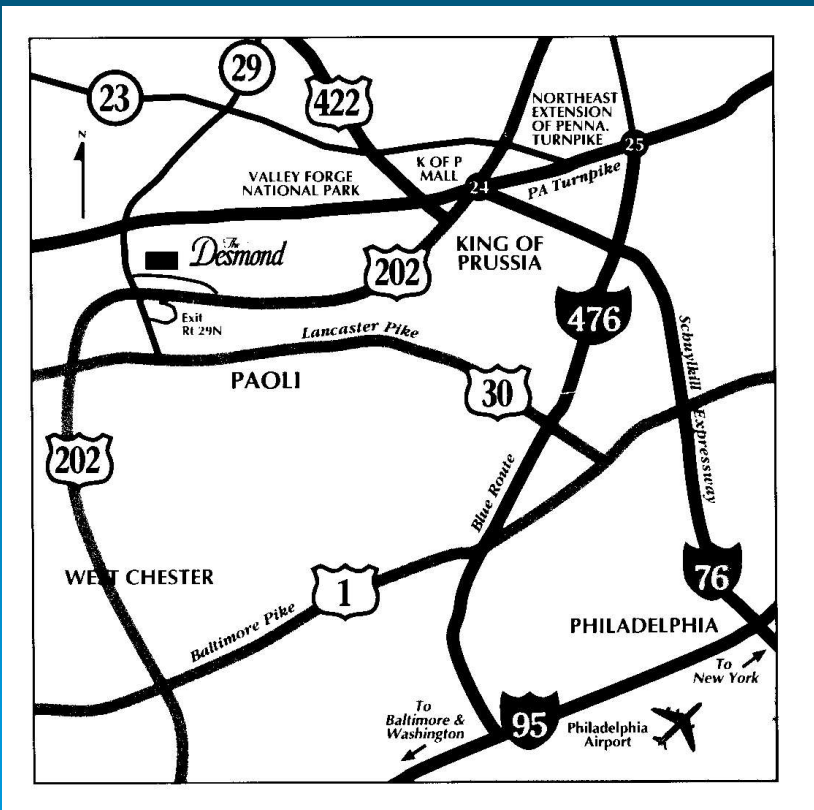
Take 1-95 North to Route 202 North. Follow Route 202 North to the Great Valley /Route 29 North Exit Turn right onto Route 29 North. Turn right at second light onto Liberty Blvd. Hotel will be on the left.

Directions from New York and Points North

Take the New Jersey Turnpike South to Exit 6, the Pennsylvania Turnpike extension. Follow the Turnpike West to Exit 24. Valley Forge. Take Route 202 South to the Great Valley/Route 29 North Exit. At the end of the ramp, proceed through the light onto Liberty Blvd. The Hotel will be on the right.

Directions from Harrisburg and Points West

Take PA Turnpike East to Exit 24, Valley Forge. Take Route 202 South to Great Valley/Route 29 North Exit at end of ramp, proceed through light onto Liberty Blvd.



THE DESMOND GREAT VALLEY HOTEL AND CONFERENCE CENTER

City	Distance
Atlantic City	85
Baltimore	90
Gettysburg	100
Harrisburg	81
Hershey	89
Lancaster	47
New Hope	40
New York City	117
Philadelphia	25
Washington	120