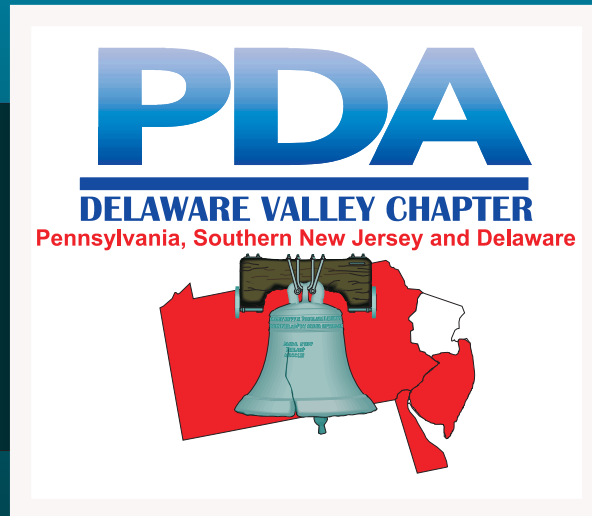


Current FDA Initiatives

What are the current FDA initiatives and how do we meet them?

What are the current initiatives from FDA? Do you know?



A Critical Session for Quality Assurance and Production Personnel to Attend!

September 30, 2009

Featuring the Delaware Valley Vendor Night Extravaganza

SCHEDULE

at the Desmond Hotel and Convention Center:

4:00-7:00: Cocktails, Networking, Raffle, and Dinner Buffet
7:00-9:00: Presentation

The Delaware Valley Chapter of PDA

Current FDA Initiatives

What are FDA Current Initiatives and how do we meet them?

About the Presentation

This presentation is focused towards:

- Production supervisors and management
- Quality Assurance
- Quality Control Engineers
- Critical Systems and Maintenance
- Training Department
- Documentation Department
- Auditing Department
- Legal Departments

This presentation focuses on:

Current FDA Initiatives - What are the requirements and how do we meet them?

This talk will address recent regulatory initiatives at FDA's Center for Drug Evaluation and Research. FDA has used risk-based strategies as part of its regulatory process for over a decade, but has refined its views in guidance and harmonization processes through its "Pharmaceutical cGMPs for the 21st Century" (2002) and its "Council for Pharmaceutical Quality" (2005). As a result of these efforts, the CMC review program in microbiology is committed to improving the regulatory process through Quality by Design (ICH Q8r1) approaches that will enhance product and process knowledge throughout the product life-cycle, and also emphasizes these in product development, e.g., the IND.

Advantages of obtaining product and process knowledge will be discussed and examples of regulatory initiatives that work with this knowledge will be presented in the context of moving toward the desired state in the pharmaceutical industry.

About our Speaker

David Hussong Associate Director for New Drug Microbiology, CDER

David Hussong is the Associate Director for New Drug Microbiology in the Office of Pharmaceutical Science in FDA's Center for Drug Evaluation and Research. He directs the staff that reviews microbiological quality aspects described in the Chemistry, Manufacturing and Controls technical section of new drug applications. He is also a member of USP's 2005-2010 Microbiology and Sterility Assurance committee.

David earned his M.S. and Ph.D. in microbiology from the University of Maryland and has served as a laboratory researcher at the US Department of Agriculture, and the Office of Naval Research. He has published several papers on microbial populations in the natural environment, and published focused studies of Salmonella and Legionella that included new methods for their detection. He also performed research at FDA's Center for Biologics, studying antigens of Pertussis and Mycobacteria spp. He has 25 years of FDA experience and is a Commissioned Officer in the US Public Health Service.

**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)

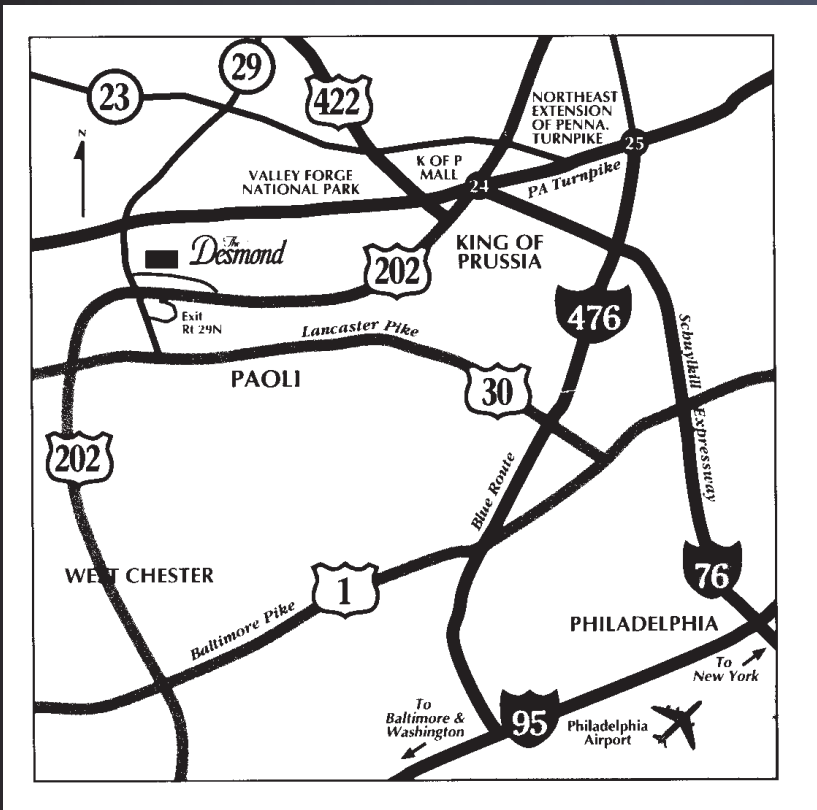
Take 1-95 North to Route 202 North. Follow Route 202 North to the Great Valley /Route 29 North Exit Turn right onto Route 29 North. Turn right at second light onto Liberty Blvd. Hotel will be on the left.

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