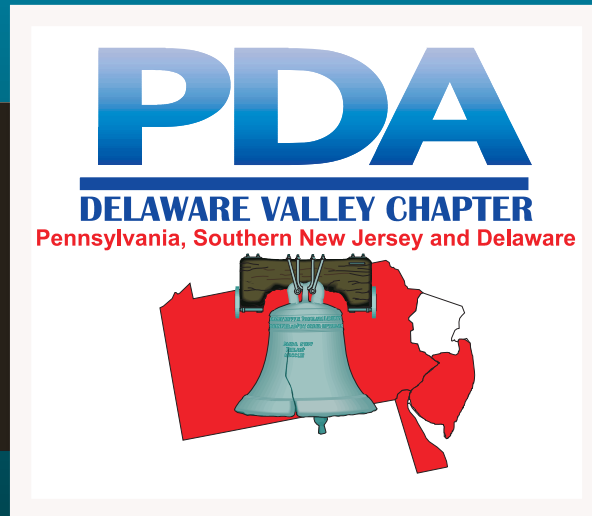


Overview of CMC Regulatory Submissions

**How
Does a Firm
Manage
Worldwide
Regulatory
Submissions?**



**A Critical
Session
for Regulatory
and Quality
Assurance
Personnel
to Attend!**

April 21, 2010

A Must See Event!

At the Desmond Hotel and Convention Center

5:00-6:30: Cocktails, Networking and Vendors

6:30-7:30: Dinner Buffet

7:30-9:00: Presentation

The Delaware Valley Chapter of PDA

Overview of CMC Regulatory Submissions

About the Presentation

This presentation is focused towards:

Anyone whom is part of the worldwide registration and approval process.

- Quality Assurance
- Quality Control
- Compliance Departments
- Regulatory Management Personnel

This presentation focuses on:

- This presentation is an overview of the different regulatory requirements (FDA, EMEA, Asia Pacific, Latin America) for new drug applications/new biologics application, regulatory requirements for changes, and an overview on international registrations.

About our Speaker

Nisha D. Pandya and Sonia Trivic McNiel Consumer Health

Nisha D. Pandya has over 14 years experience in biologics, consumer and pharmaceuticals in compliance, quality assurance, and regulatory affairs. Nisha received her BS from Ursinus College, and recently attained her RAC (Regulatory Affairs Certification) from the Regulatory Affairs Professional Society (RAPS) in December 2008. Nisha has supported audits and inspections by multiple health authorities (FDA, EMEA, Japan, Latin America) as well as prepared regulatory submissions and assisted in answering questions for the FDA, EMEA, and other health authorities.

Sonia Trivic has over 17years experience in the pharmaceutical industry in quality, regulatory, engineering, and validation. Sonia received her BS from Drexel University in Chemical Engineering, and recently attained her RAC (Regulatory Affairs Certification) from the Regulatory Affairs Professional Society (RAPS) in December 2008. Sonia also possesses a Drug Development Certificate from Temple University. Sonia has diverse experience in performing due diligence activities, pre-approval inspections, authoring regulatory submissions, facilitating approvals, and international registrations for multiple health authorities.

**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)

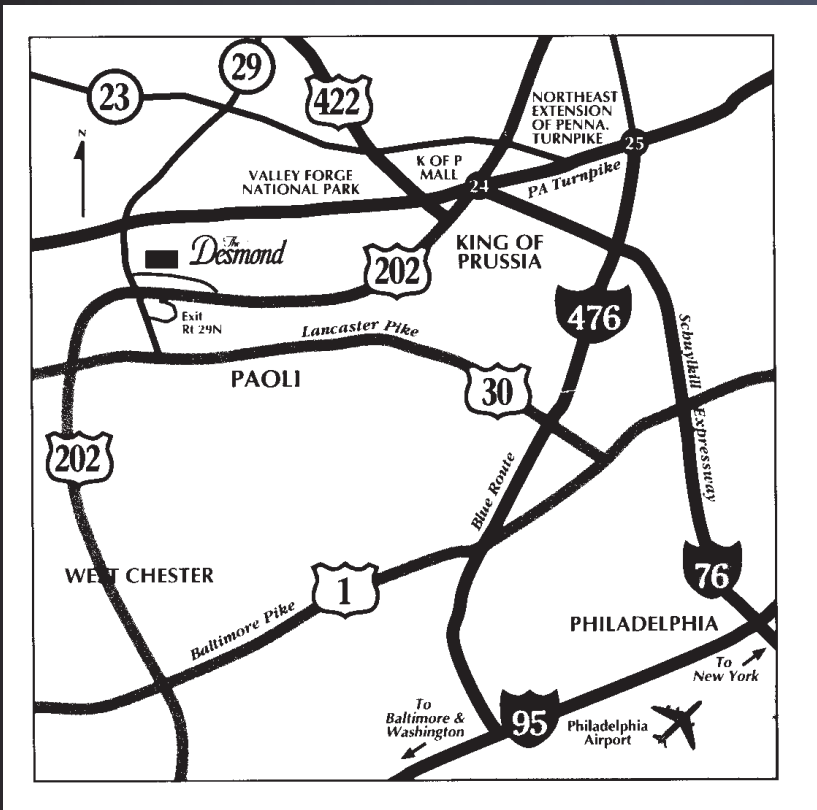
Take 1-95 North to Route 202 North. Follow Route 202 North to the Great Valley /Route 29 North Exit Turn right onto Route 29 North. Turn right at second light onto Liberty Blvd. Hotel will be on the left.

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
Wahington	120