

PharmaED's

Register by
April 7th and
receive a \$300
Discount!

Practical Pharmaceutical Manufacturing

*A Two-day, Hands-on Multimedia Workshop
Covering Solid Dose Manufacturing*

JUNE 22-23, 2009, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Key Learning Objectives:

- Understand the core regulatory components of cGMP
- Understand the three main types and the functions and components of mixing
- Understand why granulation is necessary and wet/dry granulation differences
- Learn about new technologies and how they can be utilized
- Understand the key guidances and current interpretation
- Learn about the principles and tools used for tableting
- Review the key considerations for tablet tooling
- Understand principles and equipment considerations for coating
- Understand encapsulation and manufacturing considerations for soft- and hard-shell capsules

About Your Trainer:

Victor Shulman, Dip Pharm., M.R. Pharm. S.

Darvic Consulting, Inc.

- *3rd Generation Pharmacist with Over 40 Years Industrial Experience in Industry & GMP Compliance*
- *Learned the art of Pharmaceutical production with 10 years "hands on" experience*
- *Worked for various Pharmaceutical companies, including both brand name & generics*
- *Years of practical technical transfer and batch scale up experience*
- *Versatile trainer in Basic Pharmaceuticals and cGMP Compliance for operators in mixing, tableting, tableting troubleshooting, encapsulation, coating, improved product elegance*
- *Developed a tablet maintenance section for tooling cleaning, inspection, & measurement*
- *Re-designed tooling engraving to enhance product elegance and eliminate production problems such as capping, sticking & weight variation as well as improving coating elegance*



PharmaED
RESOURCES, Inc.

WHO SHOULD ATTEND

This two-day course is valuable for Directors, Managers, Supervisors, Associates in the Pharmaceutical, Biopharmaceutical, Vitamins, Herbals, Medical Devices and allied industries with daily responsibilities in the following areas:

- Manufacturing
- Regulatory Affairs
- Analytical Laboratory
- Documentation and Technical Writing
- Quality Control
- Project Management
- Quality Assurance
- Product Development
- R&D – Product Submission
- Technical Reviewers
- Validation
- Training

COURSE OVERVIEW

This intensive two-day multimedia presentation is a comprehensive course, providing participants with a solid understanding of the principles behind the Solid Dosage manufacturing process. The course starts with the reasons for regulatory aspects affecting formulation and production of pharmaceutical products and describes the history of today's cGMP's as they relate to modern day production. The course then progresses to various aspects of powder and granulation technology, formulation of solid dosage forms, manufacturing processes and equipment including scale-up and technology transfer always relating to the key regulatory constraints that must be considered at each stage. The course shares experience from "Hands on" manufacturing and product scale up offering participants with up-to-date knowledge of the current practices and future trends in the field. This is a practical course with emphasis on why things are done with a common sense approach to the subject matter at all times.

COURSE OUTLINE

INTRODUCTION

cGMP's - how the cGMP's came into being - regulations and goals for formulation and production

MIXING

Pharmaceutical Mixing

- Three main types of Pharmaceutical mixes, Principles of mixing, what constitutes a mix and the function of each ingredient in a mix?
- Materials for Direct Compression the function of these ingredients in a mix.
- The use of Binders, Fillers, Glidants, Lubricants, Disintegrants in formulations.
- Particle size reduction Screening and Sieving

GRANULATION

Why granulate?

- Dry Granulation – (Roller Compaction, Chilsonation)
- Wet Granulation - High Shear, Low Shear, Spray Granulation.
- Fluid bed Technology – Granulation, Drying, Coating.

NEW TECHNOLOGY

- (IBC) In-bin blending
- Benefits - elimination of cross contamination – cycle time reduction.

SUPAC GUIDANCES

Practical applications of the guidances in manufacturing

- How acceptable changes can be made for cost effective production.

COURSE OUTLINE CONTINUED

TABLETTING

Principles and Equipment Utilized in Tableting

- The Seven Stages of Compression
- Functions & stages of the tablet compression process.
- Tight punches, Weight Variation, Capping, Sticking.
- Maximum allowable punch tip loading. Tablet press Overload systems.
- Problem solving - general troubleshooting

TABLET TOOLING

Elegant products are dependent on tooling design

- Incorrect concavity causes uneven force distribution resulting in friable tablets.
- Incorrect engraving causes sticking.

COATING

- Principles and Equipment Utilized in Coating
- Sugar Coating Film Coating, Modified release Coating
- Understanding colours, polymers and spray application
- Troubleshooting

ENCAPSULATION

- Manufacture of Soft-shell & Hard-shell Capsules
- Principles and Equipment Utilized in Encapsulation
- Troubleshooting

AGENDA, DAY ONE:

Approximate Times this will depend on Participant interaction

8:30	<i>Registration & Continental Breakfast</i>
9:00	Introduction to the GMP's – Overview on Mixing
10:45	<i>Mid-Morning Break</i>
11:00	Overview on Mixing (Contd.) Screening
12:45	<i>Luncheon</i>
1:45	Supac Guidances – In Bin Blending
3:30	<i>Afternoon Break</i>
3:45	Dry Granulation (Roller Compaction)
5:00	<i>Close of Day One</i>

AGENDA, DAY TWO:

8:30	<i>Continental Breakfast</i>
9:00	High Shear Granulation & Fluid Bed Technology
10:45	<i>Mid-Morning Break</i>
11:00	Tableting & Tablet Tooling
12:45	<i>Luncheon</i>
1:45	Tablet Coating
3:30	<i>Afternoon Break</i>
3:45	Encapsulation
5:00	<i>Close of Day Two</i>



About your conference destination:

The Radisson-Plaza Warwick is located in the heart of downtown Philadelphia, and adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center and the Avenue of the Arts and numerous shops, hotels and excellent restaurants!



REGISTRATION INFORMATION

Register for the conference using one of four options:

Online: www.pharmaedresources.com Phone: (217) 355-7322 Fax: (847) 589-0708

Mail: 2810 Robeson Park Drive, Champaign, IL 61822

PLEASE COMPLETE THE FOLLOWING:

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP: _____ COUNTRY CODE: _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

Please register me for:

PRACTICAL PHARMACEUTICAL MANUFACTURING:

A two-day hands-on multimedia workshop covering Solid Dose Manufacturing

June 22-23, 2009, Radisson-Plaza Warwick, Philadelphia, PA

\$1,695 USD

REGISTER BY APRIL 7 AND TAKE \$300 OFF

PAYMENT METHOD

CREDIT CARD REGISTRATION:

CREDIT CARD VISA MASTERCARD AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #: _____

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.

VENUE INFORMATION:

Dates: June 22-23, 2009
Hotel: Radisson Warwick Plaza Hotel
Hotel Address: 1701 Locust Street
Philadelphia, PA 19103
Reservations: (888) 201-1718 US
Hotel Telephone: (215) 735-6000
Fax: (215) 789-6105
Email: rhi_plph@radisson.com