TABLET MANUFACTURING
Process Training

MARCH 8-11, 2020
Long Island University, Brooklyn, NY

LECTURES & LABORATORY EXERCISES
Formulation Development • Tablet Tooling Design
Modified Release Technologies • Tablet Scale-Up Issues
also, HANDS-ON LEARNING where YOU OPERATE the equipment!

With the completion of the course, participants
will earn 21.5 ACPE Pharmacists Accreditation hours.

EVENT HIGHLIGHTS

Granulation
• Overview of granulation principles and hot-melt extrusion, including best practices presented using case studies, equipment and discussion.

Formulation
• Overview of common excipients and their designed functions.

Coating
• A host of factors can influence successful tablet coating. Learn the ins and outs of this process from industry leaders.

Compression
• How to utilize data from an instrumented rotary tablet press. Participants will receive a hands-on training opportunity.

Analytical
• It all starts with powder. Our experts will explain the importance of characterization, measurement, blending and more.

CLICK HERE TO REGISTER NOW!
WELCOME!

When we founded the Natoli Institute for Industrial Pharmacy Research and Development, it was my intention that the laboratory would serve not only as a resource for research and troubleshooting, but also to provide opportunities for educational advancement in the industry. We are delighted to report that we have met, and surpassed, these aspirations and the institute continues to conduct critical research studies on tablet manufacturing.

We have organized an elite group of knowledgeable industry experts to present the Tablet Manufacturing Process Training. This course offers a comprehensive, hands-on experience regarding the tablet manufacturing process from formulation development to tablet design to tablet compression – all presented in our state-of-the-art lab on the Brooklyn campus of Long Island University.

Please join us to learn how to overcome a wide variety of tableting challenges and issues as well as the science behind industry best practices. We are very excited to announce that participants will earn 21.5 hours of ACPE Pharmacists Accreditation through completion of this course.

We look forward to welcoming you to our facility and encourage you to register early as we anticipate the course filling quickly!

DALE NATOLI
President
Natoli Engineering Company
636.926.8900 • natoli.com

WHO SHOULD ATTEND

This course is designed for contract pharmacists, formulators, managers, pharmaceutical engineers and those who want to better understand the tablet manufacturing process.

LEARNING OBJECTIVES

Participants of Tablet Manufacturing Process Training will finish with a working knowledge of:

- Fluid Bed Operations
- Dry Granulation
- Wet Granulation
- Hot-Melt Extrusion
- Tablet Coating
- Tablet Press Operations

ABOUT NATOLI INSTITUTE

The Natoli Institute can facilitate simple one-of-a-kind experiments or assist a client in building a program for ongoing formulation compression and testing. Equipment used at the Natoli Institute includes:

- Roller Compactor
- Fluid Bed System
- 8- and 16-Station Rotary Tablet Press
- Single-Station Tablet Press
- High-Shear Wet Granulator
- Hot-Melt Extruder
- Vector GMX-Lab Micro
- Lab Dev Coating System
- Vector VFC-LAB 1 Flo Coater

Typical projects addressed at the Natoli Institute include:

- Tablet Sticking and Picking Screening
- Formulation Development
- Tablet Scale-Up Troubleshooting
- Coating Studies
- Bioavailability and Dissolution Studies
TRAINING COURSE SCHEDULE DETAILS

DAY ONE | SUNDAY, MARCH 8, 2020

5:00 pm  Registration/Course Kickoff
5:30 pm  Welcome Dinner LIU
6:30 pm  Course Overview & Speaker Introduction

DAY TWO | MONDAY, MARCH 9, 2020

8:00 am  Compression Tools, Standards, Options and Practical Troubleshooting
          Bill Turner
          Technical Service Manager of Tooling and Tablets
          Natoli Engineering Company
          Presentation topics:
          • Tool terminology
          • Understanding TSM & EU specifications
          • Common, and not-so-common, tool configurations
          • Troubleshooting typical tool and tablet compression issues:
            • Critical tool dimensions and how they affect tablet quality and consistency
            • Sticking & picking
            • Capping and laminating
            • Head wear
            • Spots and dark specs on tablets
            • Tool binding
            • Tablet twinning
            • Tablet logo legibility

10:30 am  Break
10:50 am  Tablet Design Basics
          Bill Turner
          Technical Service Manager of Tooling and Tablets
          Natoli Engineering Company
          Presentation topics:
          • Project communication and product characteristics
          • Tablet terminology
          • Tablet shapes: standard and unusual
          • Cup configurations
          • Selecting the proper tablet size
          • Logos, fonts and engraving cuts
          • Breaklines, bisects & multiple scores

9:30 am  Tablet Press Fundamentals
          Robert Sedlock
          Director of Technical Training & Development
          Natoli Engineering Company
          An overview of industry tablet presses. A focus on the rotary tablet press process from the die filling process, compression events, ejection and take-off stage. Common industry compression/scalability issues will be discussed and ways to remediate them with an instrumented tablet press. Compaction profile and strain rate data will be provided to show the comparison of a robust and problematic formulation.

12:20 pm  Lunch & Group Photo

LABORATORIES

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<tr>
<th>1:30 pm Lab Session 2A</th>
<th>GROUP 1</th>
<th>GROUP 2</th>
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### Day Three | Tuesday, March 10, 2020

**8:00 am**  
**Roller Compaction Granulation Technology**  
*Nick Slater*  
**Senior Process Development Scientist**  
**Freund-Vector Corporation**  
An overview of Roller Compaction Technology that will cover equipment design, formulation issues and troubleshooting common granulation problems.

**9:00 am**  
**Wet Granulation: High-Shear and Fluid Bed Drying**  
*Nick Slater*  
**Senior Process Development Scientist**  
**Freund-Vector Corporation**  
An overview of wet granulation methods will be presented along with the following discussion: equipment design, process principles and important process factors. Case studies will be used to illustrate differences between the methods.

**11:20 am**  
**Coating of Tablets**  
*Charles W. Gayser, Jr.*  
**Formulation Technologies Manager**  
**Colorcon**

**Course objectives:**
- Why Film Coat?
  - Physical Reasons
  - Blister Packing Lines
  - Safety and Patient Compliance
  - Improve/Modify Functionality
- Critical Components of Film Coating
  - Typical Polymers
  - Film Properties
  - Moisture/Oxygen Protection
  - Plasticizers
  - Effect on Glass Transition Temperature
  - Pigments
  - Colorant Properties and Function
- Case Study
  - Comparison of PVA Based System vs. HPMC Based System

**10:00 am** Break

**10:20 am**  
**A Guide to Rational Tablet Formulation**  
*Tony Carpanzano*  
**Director of R&D**  
**JRS Pharma**

This presentation outlines key considerations for selecting excipients for a formulation. Common excipients used for solid oral dosage forms will be discussed. The function and properties of each excipient will be covered as well as advantages and disadvantages of each excipient.

**12:20 pm** Lunch

### Laboratories

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### ACPE - Pharmacists Accreditation

Credit Hours: 21.5  
Expiration Date: 08/20/2021  
ACPE UPN: 0042-0000-18-025-L04-P  
Release Date: 08/20/2018

The Arnold & Marie Schwartz College of Pharmacy and Health Sciences is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Credit will be issued upon attendance at complete activity and completion of post course evaluation at LIU RxSchool.

Target audience: Pharmacists involved in tablet formulation.

This is a knowledge-based activity.

We will not be giving partial credit. Credit will be given only to those completing the entire course and after completion of the evaluation.
DAY FOUR | WEDNESDAY, MARCH 11, 2020

8:00 am  **Excipients with a Purpose**
*Michelle Quinn*
Associate Director of Business Development for Formulation
*MilliporeSigma*

Presentation topics:
- Directly compressible excipients
- Strategies to enhance solubility
- Excipients for hot melt extrusion
- Functional excipients for oral sustained release formulations
- Case study examples

9:00 am  **Modified Release Overview**
*Charles W. Gayser, Jr.*
Area Technical Manager
*Colorcon, Inc.*

A discussion of the most economical manufacturing method for the preparation of solid oral dosage forms. Key properties for the preparation of robust tablets will be discussed as well as considerations for low dose products. Cases studies will be used to support the discussion.

10:00 am Break

10:20 am  **Incorporating QbD Principles with the Product Development Process**
*Dr. Kenneth Morris*
Director, Lachman Institute for Pharmaceutical Analysis
*Long Island University*

The Quality by Design (QbD) FDA initiative was launched in response to demands from the changing state of pharmaceutical products and the industry. The principles remain the same, good science for sound product and process design. What has evolved is the agency’s approach to encouraging QbD and the technologies to help with implementation at pharmaceutical companies. This offering will review the QbD paradigm and provide a framework to aid in incorporating the principles into a rationale product development process.

11:20 am  **Hot-Melt Extrusion**
*Dr. Rutesh Dave*
Director, Division of Pharmaceutical Sciences
*Long Island University*

Course objectives:
- What is solid dispersion and its role in current pharmaceutical related industries?
- Enhancement of solubility using melt extruder
- Difference between single and twin screw extruder
- Tableting consideration after utilizing melt extruder
- Stability concerns
- Formulation development consideration while using melt extruder

12:20 pm  Lunch & Wrap Up
DR. RUTESH DAVE is currently Associate Professor and Division Director of Pharmaceutical Sciences at the Arnold and Marie Schwartz College of Pharmacy and Health Sciences at LIU. He teaches Pharm.D. and graduate pharmaceutics related courses and maintains an active research laboratory. Prior to joining academia, he worked in the pharmaceutical industry as a senior scientist and as a group leader developing small molecules and new technologies.

Dr. Dave’s lab is divided into four major areas of research: new technology for delivery of insoluble drugs; generic development; fundamental formulation studies and; powder characterization. Dr. Dave has published papers extensively in peer-reviewed journals and presented at several global conferences. He is also a reviewer of several peer-reviewed journals and sits on one of the editorial boards. Dr. Dave is a recipient of the Founders Award for his exceptional service and the Newton Award for excellence in teaching at LIU.

BILL TURNER is the Director of Technical Training and Development for Natoli Engineering Company, Inc. Previously, he was the Engineering Manager and Tablet and Tool Designer for 20 years, as well as a Natoli Technical Customer Service Representative for over 15 years.

He educates and trains Natoli sales and service staff and conducts training seminars for the industry in tablet design, tool design, and troubleshooting, both in-house and on site.

ROBERT SEDLOCK is the Director of Technical Training and Development for Natoli Engineering Company. He has been serving the tablet compression industry for over 20 years. His early experience includes strain gauge force measurement technology and data acquisitions systems.

Mr. Sedlock has been published in Pharmaceutical Technology, and American Association of Pharmaceutical Scientists, among others. He is a past technical advisory board member for Tablets and Capsules. He also presents at many hands-on training seminars hosted by various universities worldwide.

Mr. Sedlock’s areas of expertise include instrumentation systems, troubleshooting compression and scale-up issues, optimizing formulations and comprehensive tablet press training. His current responsibilities include global solid dosage customer support, training seminars, contract compression services and continual research at the Natoli Institute of Industrial Pharmacy located at the Long Island University AMS College of Pharmacy and Health Sciences in Brooklyn, New York.

NICHOLAS SLATER is a senior process development scientist with primary responsibilities at Freund-Vector includes working closely with customers on process development, scale-up, and process troubleshooting. He has worked extensively with pharmaceutical, nutraceutical, agricultural, pyrotechnics, and food industries.

Mr. Slater has also presented and conducted hands-on laboratory training at multiple seminars throughout the world. These seminars have covered roller compaction, fluid bed granulation, fluid bed coating, and pan coating technology. He received his Bachelor of Science from Iowa State University and currently sits on the Board of Directors for the Institute of Briquetting and Agglomeration.
TONY CARPANZANO worked in pharmaceutical product development for 32 years. His experience includes liquids formulation, pre-formulation, exploratory development, technical services and clinical manufacturing, with a major focus on advanced solid dosage form and modified release dosage form development. He holds patents on modified release technologies and abuse-resistant/abuse-deterrent technologies.

He has worked for numerous global companies, including Richardson-Vicks, Procter & Gamble, generic manufacturers, Schein and Copley Pharmaceutical, Purdue Pharma and Penwest, and has spent the last four years working in the excipients industry for JRS Pharma, LP, as Director of R&D. He is also a licensed Pharmacist.

DR. KENNETH MORRIS holds a dual B.S. in Chemistry and Aquatic Biology, and an M.S. in Pharmaceutical Chemistry. He received his Ph.D. from the University of Arizona and joined E.R. Squibb and Sons where he developed the Physical Characterization group and co-developed the Materials Science function. He went on to form the Preformulation/Physical Pharmacy group in the Bristol-Myers Products organization, while concurrently serving as an adjunct professor at Rutgers College of Pharmacy and St. John's University. In 1997, he moved to the Industrial and Physical Pharmacy department at Purdue, continuing work in Pharmaceutical Materials Science and Industrial Pharmacy as a professor and associate head. In 2008, Dr. Morris helped establish the new College of Pharmacy and Ph.D. program in Pharmaceutical Sciences at the University of Hawaii at Hilo where he was Department Chair and Graduate Council Chair.

Dr. Morris currently serves as Professor and founding Director of the Lachman Institute for Pharmaceutical Analysis at LIU. His research and teaching interests include: analytical tools for solid state characterization, the study of the impact of processing on the physical characteristics of formulation components and on subsequent dosage form performance, pharmaceutical unit operation optimization, advanced applications of powder x-ray diffraction and dielectric analysis, the study of the association of water with pharmaceutical solids, and modeling and methods for monitoring processing unit operations. Dr. Morris is an AAPS fellow and was the Purdue University Site Leader for the NSF Engineering Research Center for Structured Organic Composites. He is a special government employee and past-chair of the U.S. FDA Scientific Advisory Committee for the Office of Pharmaceutical Sciences.
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March 8-11, 2020 • Natoli Institute • 75 Dekalb Avenue, Brooklyn, NY 11201

Book Your Room Early! Rooms and Special Rates are Limited!

NEW YORK MARRIOTT BROOKLYN BRIDGE
333 Adams Street,
Brooklyn, New York 11201

To make reservations, guests can call the reservations department at +1 718-246-7000 and request the negotiated rate for Natoli Engineering. You may also make reservations online at https://book.passkey.com/go/LIUNatoliTraining

Please book your room early as rooms available at this rate are limited. Reservations made late will be subject to prevailing rate availability.

Questions? Comments?
Do you have a question or comment that you would like to be addressed at this event? Please email Robert Sedlock at rsedlock@natoli.com

Entrance to Long Island University located at 75 Dekalb Avenue

NATOLI INSTITUTE
Arnold & Marie Schwartz College of Pharmacy and Health Sciences
75 Dekalb Avenue, Brooklyn, NY, 11201
natoli.com/natoli-institute

NATOLI ENGINEERING COMPANY
28 Research Park Circle
St. Charles, MO 63304
636-926-8900 • info@natoli.com
natoli.com
TABLET MANUFACTURING PROCESS TRAINING
March 8-11, 2020 • Natoli Institute • 75 Dekalb Avenue, Brooklyn, NY 11201

Individual Course Fee: $2495.00 per person
Group Course Discount: $2245.50 per person (three or more people from your organization)

Space is Limited! Early Registration is Recommended!

Name: ________________________________________________  Job Title: _____________________________
Company: ___________________________________________________________________________________
Street Address _______________________________________________________________________________
State/Province: ___________________________Zip: __________________Country: ______________________
Phone: ____________________  Fax: _____________________Email: _________________________________

Special needs and dietary requests: ______________________________________________________________
How did you learn about this course: _____________________________________________________________

Payment Methods

Full payment in US currency is due no later than two weeks prior to the event. If payment has not been received, a credit card will be required to secure payment for the course attendance.

☐ Invoice Company ___________________________________________  ☐ P.O. Number ________________________
☐ Check - Please make check payable to Natoli Engineering Company
☐ Credit Card: ☐ Mastercard  ☐ Visa  ☐ American Express  Course Fee: __________
    Card#: _________________________________  Exp. Date: __________________  Security Code: __________
    Cardholder’s Name: _____________________________  Signature: _____________________________

General Information

Cancellations/Substitutions: Substitutions will be accepted at any time prior to the course without penalty. To receive a full refund, please notify the training coordinator no later than seven business days prior to the course. All cancellations received inside of seven business days will be subject to a $125.00 cancellation fee. No-shows are ineligible for a refund.

Course Fees Includes: Course materials, three continental breakfasts, breaks with refreshments, three lunches, reception with food and beverages and course certificate.

Course Confirmation: A course confirmation will be e-mailed to participants upon receipt of their registration. Final course details including a timed agenda and maps will be e-mailed approximately 14 days prior to the event. The course will be conducted in English.

Travel Information: Information regarding discounted hotel accommodations, airport transportation, and more, will be sent via email with the course confirmation.

Please Note: Natoli Engineering Company does not anticipate any changes to this course, but we reserve the right to alter the program and/or speakers without prior notice. In the unlikely event of course cancellation, Natoli’s liability is limited to refunding only the course registration fee.

4 Easy Ways to Enroll

1 WEB REGISTRATION
Complete form and payment information online at: natoli.com/liu-training

2 PHONE REGISTRATION
636.926.8900
Contact: Jennifer Bergauer

3 MAIL REGISTRATION
Complete form and mail to:
Natoli Engineering Company
Attn: Jennifer Bergauer
28 Research Park Circle
St. Charles, MO 63304

4 EMAIL REGISTRATION
Email Jennifer Bergauer at:
jbergauer@natoli.com

Click Here to Register!