

FUNDAMENTALS

OF

BLENDING, COMPRESSION AND COATING OF TABLETS AND TOOLING

SEPTEMBER 15-17, 2009

ATTEND THIS COURSE...

and maximize your knowledge of tablet manufacturing, tooling care and tablet presses while identifying and addressing common industry pitfalls.

WHO SHOULD ATTEND?

Individuals in the tablet manufacturing industry that desire to improve their fundamental skills.

LOCATION

Natoli Engineering Company, Inc.
 Technical Training Center
 St. Louis/St. Charles, MO



THIS COURSE COVERS:

- Tablet shapes and design
- Methods of granulating and blending processing
- Powder feed system variables
- Wash-in-place technology
- Film coat troubleshooting
- Advances in tablet press containment
- Punch and die options
- TSM tool specifications and tooling options
- Hands-on tool maintenance and polishing
- Tablet press set-up and operation
- Quick changeover philosophy
- Tablet press force monitoring
- Punch inspection and tool management
- Impact of excipient and process choices on tablet manufacture



KNOWLEDGE IS POWER 

TECHNICAL TRAINING BEYOND TEXT BOOKS.

Bill Turner –Mr. Turner is the Technical Service Manager of Tooling and Tablets at Natoli Engineering Company, Inc. Prior to that position he was the Engineering Manager and Tablet and Tool Designer for 20 years as well as a Technical Customer Service Representative for over 15 years. He educates and trains Natoli sales and service staff and conducts training seminars to the industry in tablet design, tool design, and troubleshooting, both in-house, and on site.

Greg Smith –Mr. Smith is Vice President of Sales and Engineering at Vector Corporation and has been with the company for 16 years. Greg graduated from Iowa State University in Electrical Engineering and worked for a Controls Engineer at Vector Corporation. Greg was the lead developer for Vector's fully validated automated control system that was introduced in 1995, the Compu control system. Through the years, Greg remained involved with the development process of the Compu control system and was co-inventor of a software development patent that is currently being used in Compu control systems today.

Adam Kevra –Mr. Kevra is Global Applications Manager at Colorcon and has been with the company for 7 years. Prior to moving into this position in early 2005, he worked as a Colorcon Area Technical Manager, supporting customer projects and troubleshooting film coating and tableting processes. Before coming to Colorcon, Adam worked as a solid dosage formulator for approximately 10 years and has worked in the formulation departments of Wyeth and Mutual Pharmaceutical.

Doug Kirsch –Mr. Kirsch is the technical service manager for the tablet press division at Natoli Engineering Company, Inc. With over 40 years of experience in the tablet compression industry, Mr. Kirsch has been with Natoli for 28 years and has trained press operators and maintenance technicians worldwide. He began his career training in the U.K. with Manesty machines and then served as a technical service representative for Manesty tablet presses for over 10 years. For the next three years, he served as a maintenance manager for tablet compression at General Nutrition Corporation.

Dr. Jerry Claunch, Ph.D. –Dr. Claunch is President of Claunch & Associates. Prior to Claunch & Associates, Inc. he was employed by Kawasaki Motors Corp. for six years and was responsible for the Just-In-Time implementation at Kawasaki. The work that was completed by Jerry there has been written about in the Wall Street Journal, New York Times, and by Richard Schoenberger, in his books: Japanese Manufacturing Techniques and World Class Manufacturing. Jerry's industry experience includes repetitive and discrete manufacturing, printing, filling and packaging as well as distribution. He has more than 37 years experience in manufacturing. Jerry has authored four books; Just-In-Time Purchasing, Supplier Certification, Set-Up Reduction and Set-Up Reduction. Jerry contributed a chapter on Set-Up Time Reduction in the Cellular Manufacturing Handbook published by John Wiley and Sons in March 1999.

Roger Barnum –Mr. Barnum is a Senior Consultant with Jenike & Johanson, Inc. in Tyngsboro, Massachusetts. Jenike & Johanson is a specialized engineering firm focusing on providing reliable bulk solids flow while achieving product quality requirements. Roger is heavily involved in consulting, particularly within the pharmaceutical industry, with projects ranging from portable bin design for reliable flow to solving solid dosage form content uniformity problems by analyzing entire solids handling systems. He has participated as a speaker in past AAPS and InterPhex conference programs, and has taught two and three day in-house classes for numerous pharmaceutical firms.

Rich Grogan –Mr. Grogan is Vice President of Engineering & Sensor Group Manager at Helm Instrument Company in Maumee, OH, and has been with the company for 24 years. Helm is a long standing and innovative manufacturer of force sensors, load cells, and electronic process/automation controls for a variety of manufacturing industries. Those include metal stamping, die cast, injection molding, pharmaceutical, packaging, and weighing. Duties include directing mechanical and electrical design activities with special emphasis on force sensors and new product development.

Dale Natoli –Mr. Natoli is director of Natoli Engineering Company, Inc., and has over 31 years of worldwide experience in the tablet compression industry. Natoli has published many articles for major pharmaceutical trade publications as well as authored printed chapters in “Developing Solid Oral Dosage Forms,” the 3rd Edition of “Pharmaceutical Dosage Forms: Tablets” and Vol. 15 of the “Encyclopedia of Pharmaceutical Technology.” In addition, he chaired and served as a board member for revisions in the 3rd Edition of the “Tablet Specification Manual” sponsored by the American Pharmaceutical Association. Currently, he presents lectures for universities, pharmaceutical associations and tablet manufacturers in the U.S., Europe and Asia. His topics of expertise include: tablet design, tool configurations and troubleshooting. Mr. Natoli is the driving force behind establishing new technologies and special tool configurations for the tablet compression industry. He continuously works to enhance tablet production, quality and extend tool life.

Joseph Zeleznik –Mr. Zeleznik is the Associate Director, R&D for JRS PHARMA LP and has been with the company for 6 years. He holds a Master’s Degree in Chemistry from the State University of New York, is a member of the American Chemical Society and the American Association of Pharmaceutical Scientists, and has over 15 years experience in the pharmaceutical industry specializing in excipient technologies and the development and application of high performance excipients for the enhancement of pharmacologically active compounds. He holds several patents registered in the US and worldwide on these subjects. He has also authored papers and posters presented at the American Association for Pharmaceutical Scientists (AAPS) during his time in the industry. Mr. Zeleznik is responsible for developing and promoting JRS PHARMA’s high-performance excipients and excipient technologies, and processing technologies.

James Mossop –Mr. Mossop is the New Business/Project Manager at Fette America, and has been with the company for 8 years. He is in direct management of new business opportunities and new equipment sales spanning North America, Canada and Puerto Rico. He is also the Key Account Manager for Johnson & Johnson world-wide. In addition to sales he manages the Reconditioned Equipment Division and the Tooling and Segment business. James has a 29 year tenure, concentrating in tablet compression technologies, and has held all positions within the Compression Hierarchy and Manufacturing Maintenance Technical Team. He holds 3 patents for breakthrough development of Tylenol Soft Chewable process, and has received both the *McNeil APEX Award* for development of new compression equipment and the *Johnson & Johnson Achievement Award* for new product design and process development.

Rob Caruso –Mr. Caruso provides software support for Natoli Engineering Company, Inc., and has been with the company for 14 years. After graduating from the University of Missouri with a B.A. in Computer Science, Rob has spent the last 24 years working as a software developer and consultant. He has worked with Natoli Engineering since 1992 in a wide range of areas including Customer Service, Work Order Production, Accounting, Shipping and Tool Inspection. Since 1998 Rob has overseen the development of the Natoli Tool Management II (TM2) inspection and tool control system. He has been involved in a number of areas including: software design and development; installation and customer support.

Dave Perry –Mr. Perry is currently an Assistant Plant Manager for Natoli Engineering Company, Inc., and has worked with the company for almost 28 years. He started working at Natoli at the age of 18 and his past job duties include: stock polishing, overseeing the Buffing Department, Hob Production, running various manufacturing equipment, Department Manager and Assistant Plant Manager.

DAY 1 TUESDAY, SEPTEMBER 15, 2009

- 8:00–8:30am Registration at Natoli training center, continental breakfast provided
- 8:30–8:45am Welcome, announcements and introduction
- 8:45–9:15am **Tablet Shapes and Design**, *Bill Turner*, Natoli Engineering Company
- Ensuring tablet design success
 - Cup configuration
 - Bisects
 - Tablet basics
 - Logo and engraving cut design
- 9:15–9:30am **BREAK**
- 9:30–10:30am **Pharmaceutical Granulation Methods**, *Greg Smith*, Vector Corporation
- Advantages/disadvantages of:
 - Roll compaction granulation
 - Top spray fluid bed granulation
 - High shear granulation
 - Rotary fluid bed granulation
- 10:30–10:45am **BREAK**
- 10:45–11:45am **Troubleshooting Film Coating**, *Adam Kevra*, Colorcon, Inc.
- Identification of typical tablet defects and root causes for tablet defects
 - Defects related to coating process, parameters and tablet substrate
 - Changes likely to eliminate defects
- 11:45–12:45pm **LUNCH**
- 12:45–2:00pm **Press Operation/Causes and Effects**, *Doug Kirsch*, Natoli Engineering Company
- Press History
 - Common set-up errors
 - Maintenance
 - Factors affecting tablet quality
 - Operation/troubleshooting
- 2:00–2:15pm **BREAK**
- 2:15–4:00pm Natoli plant tour
- 4:00–5:30pm Reception

DAY 2 WEDNESDAY, SEPTEMBER 16, 2009

- 8:00–8:30am Continental breakfast at the training center
- 8:30–10:30am **Advantages Tablet Press Quick Changeover**, *Jerry Claunch*, Claunch & Associates
- The process
 - Personnel training
 - Planning and scheduling
 - Case study
- 10:30–10:45am **BREAK**
- 10:45–11:45am **Analyzing and Solving Dosage Unit Uniformity Problems**
Roger Barnum, Jenike and Johanson, Inc.
- Characterizing trends in dosage unit uniformity data
 - Use of a troubleshooting diagram to identify root causes of identified data trends
 - Primary segregation mechanisms for most pharmaceutical blends, and how the flow sequence through equipment can affect dosage uniformity
 - What underlying flow problems can occur during powder handling and transfer
- 11:45–12:45pm **LUNCH**

DAY 2 CONTINUED

- 12:45–1:45pm **Tablet Press Force Monitoring Instrumentation Technology**
Rich Grogan, HELM Instrument Company, Inc.
- Force-related machine operations that can be monitored
 - Load cell, sensor and instrumentation types and configurations
 - Tablet quality control by means of force monitoring and machine adjustment
 - Software features and configurations, including SPC data acquisition and alarm/downtime tracking
- 1:45–2:00pm **BREAK**
- 2:00–3:30pm **Punch and Die Options**, *Dale Natoli, Natoli Engineering Company, Inc.*
- Understanding TSM specifications
 - Tooling options
 - Tablet and tool troubleshooting
- 3:30–3:45pm **BREAK**
- 3:45–4:45pm **The Impact of Excipient and Process Choices on Tablet Manufacture**
Joseph Zeleznik, JRS Pharma
- Binder deformation mechanisms and synergies
 - Lubrication effects on blending and tablet manufacture
 - Capping and lamination causes and prevention
 - High performance tableting ingredients

DAY 3 THURSDAY, SEPTEMBER 17, 2009

- 8:00–8:30am Continental breakfast at the training center
- 8:30–9:30am **Advances in Tablet Press Containment, Wash-in-Place Technology (WIP)**
James Mossop, Fette America, Inc.
- New advances in containment
 - What is WIP
 - What are the various levels of containment
 - Why and how would containment be considered
- 9:30–9:45am **BREAK**
- 9:45–10:45am **Punch Inspection and Tool Management**, *Rob Caruso, Natoli Engineering Company, Inc.*
- Punch inspections
 - Working length analysis and tool matching
 - Tooling database
 - Drawing management
 - Monitoring tool usage
- 10:45–11:00am **BREAK**
- 11:00–12:00pm **Tool Reworking and Polishing**, *Dave Perry, Natoli Engineering Company, Inc.*
- Hands-on demonstration
 - Tooling rework, maintenance and how to properly buff and polish
- 12:00–12:15pm Closing remarks and evaluations
- 12:15pm **LUNCH**

Today's Date: _____
Registration Code: _____

Course Fees– \$1,095.00 per person (\$1,040.00 per person with 5% group discount)

Group Discount– Receive a 5% discount when two or more people from your organization register to attend the same course.

Registration Form: Space is limited. Early registration is recommended.

Course Date: September 15–17, 2009

Course Name: Fundamentals of Blending,
Compression, and Coating of Tablets and Tooling

Name: _____ Title: _____

Company: _____

Address: _____

City/State/Zip: _____ / _____ / _____ Country: _____

Phone: _____ Fax: _____ E-mail: _____

Special needs and dietary requests: _____

How did you learn about this course: _____

4 Easy Ways to Enroll

1. Phone Registration: 636.926.8900 and ask for the Training Coordinator
2. Mailing Address: Natoli Engineering Company
Attn: Training Coordinator
28 Research Park Circle • St. Charles, MO 63304
3. Fax Registration: 636.926.8910
4. E-mail: training@natoli.com

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 course attendance.

Invoice Company: _____ P.O. Number: _____

Check– Please make checks 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 Debby Austin 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 reservation. 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.

Hotel Accommodations: Hotel accommodations are not included in the price of the course. Book your reservations at the Drury Plaza Hotel in Chesterfield, MO two weeks prior of course dates to receive the Natoli Engineering Company rate of \$109.99 plus tax. After the deadline, rates are subject to availability. The hotel provides a free shuttle service to and from Natoli. The hotel does not offer an airport shuttle. The hotel is located 30 minutes from Lambert International Airport, 5 minutes from Natoli and 30 minutes from downtown St. Louis. Please call 1.800.325.0720 for reservations.

Lambert St. Louis International Airport: Transportation from the airport to local hotels is available via taxis, rental cars or through Bogey Hills Airport Transportation at 636.947.7717. The airport is located 30 minutes from Natoli.

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.



YOU DEMAND. WE DELIVER.