COBBLESTONE

COURSE ID 3108

NEW!

Developing and Optimizing Roll Compacted Granulations for Tableting

DIRECTED BY

Cecil Propst, Managing Director at Propst Consulting Services

2.5 Hours

ACCREDITED COURSE

- Overview of equipment/ process/benefits/ risk; Roll compaction (RC), finished mix and tableting
- Setting process variables to maximize granulation properties; Adjustments for density; Particle size; Maintaining/obtaining Tabletability
- Formulation. When needed/Ingredient selection; Roll of moisture; Ingredient particle size
- Benefits/ risk/ testing of recycling material
- Characterization of RC granulation; Density, size, shape, durability, dissolution
- Impact on finished mix and in tablet performance

about the course

Granulating is the most popular way to prepare materials for tableting. Many excipients and actives used in modern direct compression processes are granulated. The granulation process, using only pressure for particle size enlargement is dry granulation (Roll compaction (RC)).

The RC process, even though simple in principle, can be quite complex. Besides proper machine setup, formulation and roll choices, multiple primary adjustments (Feed screw, tamp screw, roll speeds; Roll pressure) need to be balanced to obtain the desired outcomes (Gap, density, particle size enlargement). Then we have the complication of the screening/milling step that follows to consider obtaining the desired particle size.

Our target for the granulation step is to improve the quality of the tablet and the efficiency of the tableting process. The RC granulation is a milling formed granule and as such is most often not round and smooth and thus even though enlarged/densified needs to be finished, mixed, and handled to reduce potential particle erosion issues. Also, early in the RC granulation development process, the change in compact ability of the processed materials needs to be considered.

In this 2.5-hour fully accredited course, participants will develop skills in balancing the optimization of RC process while reducing risk associated with performance in the final tableting process and tableted product performance. This course will include numerous examples to review and help advance the decision-making skills of the participants.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This course is intended for personnel who work in the Pharmaceutical, Nutritional, Food and related industries who develop, support, and/or troubleshoot granulations to be used in tablet manufacturing. The following departments will find this course to be of great benefit:

- R&D
- Manufacturing
- Formulation
- Quality

learning objectives

Upon completion of this course, you will be able to:

- Identify and select ingredients on a need to use criteria
- Qualify setup and RC design choices and performance impact
- Explain how to effectively adjust RC process controls
- Develop and justify granulation control ranges/specifications
- Maximize RC granulation benefits/ minimize tablet risk

course outline

Review of Learning Objectives

Introduction

- Introduction to Roll Compacting (RC) and Tableting process
- Benefits/risk in using roll compaction (RC)
- RC machine and roll design considerations
- Formulating/use of: binders, moisture, lubrication, anti-adherents, disintegrants, wetting agents
- Impact of RC granulation on tableting process and tablet performance

Compaction Process

- Adjusting compaction process component controls to maximize performance
- Pressure application and recycling
- Benefits/ risk of recycling
- Optimization of milling and screening

Characterization/Optimization

- Granulation characterization
- Example RC granulations; Performance failures and adjustments

Optional: 30-Minute Question and Answer Session

Assessment Opportunity

course instructor

Dr. Cecil W. Propst is Managing Director at Propst Consulting Services, a formulation and engineering support LLC located in Norton Shores MI. He was Director of R&D (Grand Haven site) at SPI Pharma until 2015. He served as Director of Quality Assurance and Technical Services at Fleming and Company, and before that, President of Manufacturing Chemists. His duties included system design, product and process development and regulatory affairs. Previously, he served as cGMP Facilities Director for the University of Maryland at Baltimore, in connection with the University's SUPAC contract with the 4 FDA. Dr. Propst also served as Director of Technical Development for Stellar Manufacturing; Director of Quality Compliance for SmithKline Beecham; Director, Quality Assurance for Norcliff Thayer (a Revlon Company); and Group Leader/Product Development and Manager/Quality Control for Lewis Howe Company. He serves as a consultant in area of product development and process improvement.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 2.5 contact hours, or .3 CEUs. For further information, visit www.iacet.org