Advance your freeze drying knowledge and ability to transfer freeze drying cycles from one machine to another-

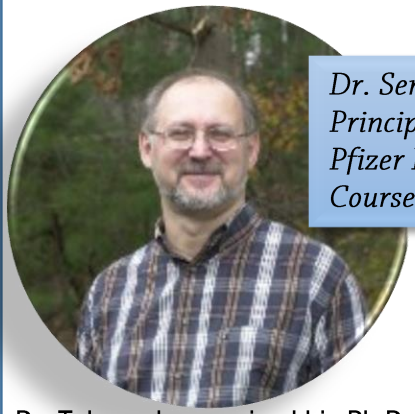
Course Title: Freeze Dryer Characterization and Considerations for Cycle Transfer

Dates: May 16 - 18, 2017 8 am to 5

Location: Millrock Technology Inc. 39 Kieffer Lane, Kingston, NY 12401

This course will guide students through the processes that provide the most efficient cycle transfer and scale-up from one freeze dryer to another. Included will be detailed information on how to properly characterize your freeze dryers and to understand the development and use of Kv and Pmin among other parameters. Students will receive a mathematical model that will be presented in detail that has been developed to successfully assist the Pfizer staff in cycle scale-up and transfer. Students should leave this course with the knowledge required for successful cycle transfer via the use of freeze drying characterization and the use of the model.
A follow-up webinar will be scheduled so that students can discuss any issues, questions or concerns applying their new knowledge to their own product(s).

Registration Fee: $3250. Includes all meals, lab fees, course materials and hotel (Marriott Residence Inn) from 5/15 – the morning of 5/19. Also includes one webinar conference question and answer follow-up with all students after they apply their coursework practically to their own work. Does not include transportation. Contact creiter@millrocktech.com 845.339.5700 to register



Dr. Serguei Tchessalov,
Principle Research Scientist
Pfizer Biotherapeutics
Course Director

Dr. Tchessalov received his Ph.D. from Institute of Applied Biochemistry (Moscow) on development of novel methods for formulation and process control during lyophilization. He furthered his studies at the University of Connecticut as a post-doctoral fellow. Previously he worked on the various aspect of lyophilization of a variety of pharmaceutical products. His current research is focused on process scale-up and cycle transfer as well as the use of modeling in freeze drying.

Anthony Gudinas
Principle Scientist
Pfizer Biotherapeutics
Instructor

Anthony Gudinas He has more than 20 years experience in cell culture, development, scale-up and transfer of drug product manufacturing processes for both clinical and commercial protein therapeutics. He graduated from UMass Lowell with a MS degree in Chemical Engineering and a Master's certificate in Bioprocessing. He has experience with characterizing freeze dryers transfer and scale-up of lyophilization processes.

3 day Schedule at a Glance:

Topics
Introduction of Course, Instructors and Attendees

Lyo characterization: why additional to typical FAT testing is needed?

Lyo characterization: methodology of Kv measurement

Lyo characterization: methodology of Pmin and SR max measurements

Kv measurements set up: demonstration and actual experiments set up

Pmin measurements: manufacture of trays for water tests and temperature measurement devices
Water tests (Pmin) set up

Completion of Kv test, calculation of Kv, initiation of Pmin test

Introduction to primary drying model

Principles and methods of cake resistance measurement

Demonstration of primary drying model

Training on primary drying: class exercise (estimation of cake resistance from cycle data)

Training on primary drying: class exercise (cycle design; part 1)

Training on primary drying: class exercise (cycle design; part 2)

Completion of Pmin test, calculation of Pmin=f(SR)

Formulation 101, introduction to formulation design template

Formulation and cycle design exercise: groups competition

Application of model for scale up and transfer

Process robustness strategy, choice of process tolerances, generating of process design space

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