GENERAL INFORMATION

ABOUT US

Distek's training center is designed to provide our customers with a comfortable, state-of-the-art facility to learn and develop the day to day skills necessary to perform and enhance their job functions.

REGISTRATION

For more information or to register please visit the Distek Training & Development page at www.distekinc.com/company/training.asp or send an email to training@distekinc.com.

REGISTRATION FEE

Fee includes: Registration, Breakfast, Lunch, Breaks, Presentation & Training Certificate. Multi-person / multi-course discounts available.

HOTEL ACCOMMODATIONS

The Staybridge Suites North Brunswick is conveniently located within walking distance to Distek. Just mention you are a Distek guest at registration to receive a discounted rate.

VENUE

All the courses will take place at the Distek, Inc. Training Center unless otherwise noted.

Distek, Inc.
121 North Center Drive
North Brunswick, NJ 08902
(732) 422-7585
www.distekinc.com
info@distekinc.com

CANCELLATION POLICY

Cancellation or rescheduling must be made within 10 business days prior to the start of the course to avoid a 50% billing fee to the attendee. A one-day cancellation or non-attendance will result in full billing.

Distek, Inc. reserves the right to cancel any course 5 business days prior to the course where the minimum enrollment is not met. The purchase of non-refundable airline tickets is not recommended due to possible course cancellations.

INSTRUCTOR

Greg Martin is President of Complectors Consulting (www.complectors.com) which provides consulting and training in the area of Pharmaceutical Analytical Chemistry. Mr. Martin has over 25 years' experience in the pharmaceutical industry and was Director of Pharmaceutical Analytical Chemistry (R&D) for a major Pharma company for a number of years. In addition, he has volunteered for the USP for over 10 years, and currently serves as Vice Chair of the General Chapters – Physical Analysis Expert Committee, and serves on Expert Panels on Validation and Verification, Weights and Balances, Residual Solvents and Use of Enzymes for Dissolution Testing of Gelatin Capsules.

Mr. Martin has been providing consulting and training services, focusing on analytical method development, validation, transfer and OOS troubleshooting, to pharmaceutical, generic, OTC and dietary supplement companies for over 6 years.

He has particular interest in QbD/Lean approaches to dissolution testing, impurity methods, method lifecycle (development/validation/transfer) and instrument qualification, and is passionate about using good science and sound logic to achieve high quality results, consistent with cGMPs, while minimizing resources. He is also Past Chair of the AAPS In Vitro Release and Dissolution Testing Focus Group. Mr. Martin is author of several papers in the areas of dissolution and analytical method validation. He can be contacted at greg.martin@complectors.com.

TRAINING COURSE

DISSOLUTION METHOD DEVELOPMENT FOR GENERIC PRODUCTS

May 10, 2017 | One Day Course | Lecture | Fee: $495.00

This interactive course will address some of the issues facing those developing dissolution methods for generic products, as well as the opportunities that exist for changing existing methodology. It will discuss immediate release and extended release products, including addressing poorly water soluble compounds (BCS Class 2 and 4). Recommended approaches for proposing and justifying specifications will be covered. Attendees will participate in an exercise to 'develop' (virtually) dissolution methods for an immediate release and an extended release generic product.

Who Should Attend?

Chemists (Research, Quality Control, and CRO; Human, Veterinary or Generic) involved with dissolution method development or testing and their managers, formulators who rely on dissolution data and regulatory affairs/CMC personnel responsible for filings involving dissolution.

Course Overview

1. *Assessment of the attendees goals*
2. *What are the expectations and opportunities for dissolution methods for generic products?*
3. *Development of dissolution tests for generic immediate release products*
4. *Development of dissolution tests for generic extended release products*
5. *Validation of dissolution methods for generic products*
6. *Setting specifications for a generic product based on available dissolution data*
7. *Problem-solving exercise*
   i. *Given a USP monograph for an immediate release product, proceed to develop a dissolution method for a generic product and propose a specification.*
   ii. *Given a USP monograph for an extended release product, proceed to develop a dissolution method for a generic product and propose a specification.*
8. *Problem-solving exercise*

Learning Objectives

- *Learn about expectations for dissolution methods for generic products, including opportunities to change compendial or FDA dissolution methods*
- *Learn how to approach dissolution method development for generic immediate release or extended release products*
- *Learn about taking advantages of biowaivers: using dissolution data in place of expensive bioequivalence testing*
- *Expectations for validation of dissolution methods for generic products*
- *Perform a group exercise 'virtually' developing dissolution methods for generic immediate release and extended release products*

Course Accomplishments

Upon completion of this course the attendee will be able to:

1. *Understand the expectations and opportunities associated with developing a dissolution method for a generic product.*
2. *Develop a dissolution method for a generic immediate release or extended release product.*
3. *Develop a dissolution method for an extended release product.*
4. *Validate the dissolution method.*
5. *Propose and justify dissolution specifications.*