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

TROUBLESHOOTING OOS OR UNEXPECTED DISSOLUTION RESULTS

AN ADVANCED COURSE USING ROOT CAUSE ANALYSIS WITH THE TEN MOST COMMON CAUSES

June 13, 2017 | One Day Course | Lecture | Fee: $495.00

Generating out of specification (OOS) or unexpected dissolution results generally triggers a flurry of activity and creates anxiety in the lab. What are the implications of the results? What caused them? How can we keep this from happening again? This course offers a methodical approach to evaluate whether the result truly represents a product failure and a troubleshooting guide to aid in identifying the root cause of the problem, which have proven useful for many practitioners in the dissolution field. The course also offers practical guidance on documenting the investigation, aligned with the FDA Guidance on Investigating OOS Results, including Batch Disposition and CAPA

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 Attendees Needs*
2. *What Constitutes An OOS or Unexpected Dissolution Result?*
3. *How Does USP Staged Testing Influence Next Steps?*
4. *The Basic Strategy For Investigating Undesired Dissolution Results*
5. *Determining the Root Cause*
6. *General Investigation Procedure*
7. *Troubleshooting Undesired Dissolution Results: Learning from Others Experiences*
8. *Documenting the Investigation*
9. *Batch Disposition/CAPA*
10. *Interactive Problem Exercise: Attendees Respond to Instructor-provided Unexpected Results*
11. *Attendee Questions and Discussion (Including Opportunity to Discuss Your Unique Issues)*

Learning Objectives

- *Learn to Recognize to OOS or Unexpected Results, and Understand How USP Staged Testing Fits In*
- *Learn Basic Strategies for Investigating Undesired Dissolution Results*
- *Using Root Cause Analysis to Find the True Underlying Cause, So It Can Be Avoided in the Future*
- *Learn Some of the Most Common Causes for Undesired Dissolution Results*

Course Accomplishments

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

1. *Respond appropriately to different types of OOS or other unexpected dissolution results.*
2. *Understand USP staged testing for dissolution, and how to apply it when undesired results are generated.*
3. *Devise a strategy for investigations that will lead to root cause identification.*
4. *Be familiar with some of the common causes of undesired dissolution results.*
5. *Be able to document the investigation, including batch disposition and CAPA, in a manner that is consistent with FDA expectations.*