DISSOLUTION SEMINAR SERIES
Advanced Dissolution: Principles and Theory

About the course
Advanced Dissolution: Principles and Theory is a two-day program designed for the advanced dissolution analyst, as well as those involved in drug metabolism, drug disposition, pharmacokinetics and analytical methods development. The participant will learn dissolution theory and participate in focused discussion on current practices with the compendial devices, USP Apparatus 1 through 7 and non-official dissolution techniques. Special attention is devoted to the development of meaningful in vitro / in vivo correlation, design and development of dissolution methods and the use of dissolution data in bioavailability / bioequivalence assessments. Hands-on laboratory sessions put theory into practice.

Topics covered
• Dissolution theory: How and why
• Dissolution testing devices: Tools of the trade
• Compendial and regulatory agencies
• Dissolution method development
• Dissolution dosage forms: Conventional and modified
• Dissolution in new product development (NDA)
• Predicting bioequivalence from dissolution (ANDA)
• Maintenance and calibration of USP apparatus
• In vitro / in vivo correlations

This course includes a hands-on workshop on the use and operation of Apparatus 1, 2, and 3.

Upon successful completion of this course, the attendee should be able to:
• Name USP Apparatus 1 through 7
• Describe dissolution theory and principal
• Outline method development
• Compute and interpret data
• Define dissolution and bioavailability
• Categorize basic principals of in vitro / in vivo correlation

NOTICE: This document contains references to Varian. Please note that Varian, Inc. is now part of Agilent Technologies. For more information, go to www.agilent.com/chem.
Day One Syllabus
8:30 – 10:30  Overview
• Fundamentals of dissolution testing
  º Definition
  º Intrinsic dissolution and apparent dissolution
  º Diffusion layer model
  º Interfacial layer model
  º Applications of intrinsic dissolution
• Compendial dissolution testing methods
  º USP Method I and II
    - Allowable variations
    - Use in non-official tests
  º Constraints common to USP Methods I and II
  º Dissolution acceptance criteria
    - Meaning and interpretation of Q
    - Q in relation to dosage form types
    - Application and setting up of Q

10:30 – 10:45  Break

10:45 – 12:30  Dissolution Testing Demonstration and Workshop

12:30 – 1:30  Lunch

1:30 – 3:00  Compendial Dissolution Testing Methods II
• USP Method III
• USP Method IV
• Topicals, dermal and transdermal products
  º USP Method V, VI and VII
  º Enhancer cell
  º Franz cell (percutaneous uptake)
• Modifications in USP Apparatus 7

3:00 – 3:15  Break

3:15 – 4:30  Dissolution Testing Demonstration and Workshop

Day Two Syllabus
8:30 – 10:30  Dissolution Testing: The Act
• Factors influencing dissolution rate
• Controlling variables in dissolution testing
• Dissolution protocol checklist
• Meeting calibration limits
• Selecting method and checklist for method protocol
• Practical problems and solutions
• Dissolution of pharmaceutical systems

10:30 – 10:45  Break

10:45 – 12:30  Dissolution Testing Demonstration and Workshop

12:30 – 1:30  Lunch

1:30 – 3:00  Dissolution Data: Computation and Interpretation
• Computation of measurement results
• Desirable characteristics of a dissolution profile
• Simulation and analysis of dissolution performance
• Product design based on simulation
• New product and generic product development
• Dissolution of conventional and modified release products

3:00 – 3:15  Break

3:15 – 4:30  Dissolution and Bioavailability (Introduction to IVIVC)
• In vitro / in vivo correlations
• Rationale for correlation
• Types of correlations
• Parameters for correlations
• Official levels of correlations

4:30 – 5:00  Closing Remarks and Evaluations

Refund Policy
• 100% refund for cancellations received 10+ business days prior to course date.
• 50% refund for cancellations received six to nine business days prior to course date.
• No refund for cancellations received five or fewer business days prior to course date.
• No refund for no-shows.