Dissolution Workshop

Presenter:
Dr. Carine Page, PharmaIntelligence Consulting

Introduction:
Dissolution testing is performed:

1. as an essential part of product development
2. in support of an application for a waiver of bioequivalence testing
3. to obtain information on test batches used in bioavailability/bioequivalence studies and pivotal clinical studies
4. to support specifications for quality control
5. to demonstrate batch-to-batch and lot-to-lot consistency during manufacture
6. to support product variations

To fully understand the quality, safety and efficacy attributes of your product during its entire life cycle, it is advisable to understand dissolution testing requirements, setting dissolution specifications, interpretation of dissolution profiles, F1 and F2 values and reporting on dissolution testing.

Who should take this course?

1. R&D pharmacists / scientists and managers
2. Regulatory Affairs pharmacists / scientists and managers
3. Quality Affairs pharmacists / scientists and managers

Course format:
Microsoft Teams

Course Content:
Day 1: 28 January 2021 (9:00 – 13:00)

1. Setting dissolution test specifications
2. Dissolution test methods
3. Dissolution profiles
4. Reporting on dissolution testing

Day 2: 29 January 2021 (9:00 – 13:00)

1. Biowaivers
2. Proportional similar dosage forms
3. Foreign reference products
4. Variations

Course Outcomes:

At the end of this course the attendee will have a clear understanding of:

1. When dissolution studies are applicable and required.
2. How dissolution studies are conducted, and what the minimum requirements and specifications are.
3. How to report on dissolutions studies and where in the CTD / ZA-CTD dossier the information finds its home.
4. How to use dissolution studies in special cases, such as for the application of biowaivers, when working with multiple strengths and proportional similar dosage forms, in support of using a foreign reference product in a bioequivalence study and when applying for different types of variations to the dossier.