A Dissolution Seminar
PREDICTING BIOEFFICACY [BA and BE] IN DRUG DEVELOPMENT:
Role of dissolution testing & applications of IVIVC

by
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Venue: Shaw Foundation Alumni House, NUS
22 – 23 October 2018

Dissolution testing is a regular quality control procedure that is a tool to predict biological availability. For predicting biological performance, the role of in vitro – in vivo correlation is important in drug development. Drug development leading to successful demonstration of bioefficacy relies heavily on in vitro dissolution test, right from formulation screening. In vitro dissolution is required by regulatory authorities to serve as proxy indicator of the product's bio-performance and adoption of the good manufacturing practices. Several compendial dissolution tests have been employed with increasing success to predict bioavailability and bioequivalence, along with the more commonly used USP Methods 1 and 2.

This 2-day course will provide a comprehensive overview of the role of in vitro drug dissolution testing (biorelevant dissolution and discriminatory analysis) and the benefits of compendial [USP] methods along with modifications and other innumerable designs / methods in predicting bioefficacy. Additionally, principles and applications of IVIVC will be discussed along with an insight into the future role of dissolution testing in drug development.

For more details & registration:
www.geanus.nus.edu.sg

Programme:

DAY 1
- Introduction, Course Objectives
- Definitions and Terminologies
- Fundamentals of Dissolution, BA and BE
- Role of Dissolution in predicting Bioefficacy
- Types of Pharmaceutical Systems
- BA of Pharmaceutical Systems
- Factors influencing BA
- Biopharmaceutics Classification System (BCS)
- Factors influencing Bioefficacy
- Essentials of in vitro Dissolution Testing
- Intrinsic and apparent Dissolution Testing
- Dissolution Testing in Drug Development
- 'Biorelevant' Dissolution Test in Drug Development
- USP Methods 1 and 2: Uses in Drug Development
- USP Methods 3, 4 and 7: Uses in Drug Development
- Noncompendial 'Biorelevant' Dissolution Test Method Development

DAY 2
- USP Methods 1-4 and 7: Uses in Drug Development
- Establishing in vitro Equivalence
- Basics of IVIVC
- IVIVC in Drug Development [Part I]
- IVIVC in Generic Drug Development [Part II]
- Performance Based Correlations
- Fractional Response Time Concept
- BE and Dissolution Performance Equivalence
- In Vitro Dissolution in Drug Development
- Regulatory Requirements and Expectations
- Regulatory Guidance(s)
- Biowaver Considerations
- Beyond Guidance(s): Satisfying Regulatory Agency Queries

Comprehensive Focus Presentation

"Predicting Bioavailability from Dissolution: Unlocking the mystery(ies)!!"
- Concluding Remarks
- Questions and Answers

Who Should Attend:
Personnel involved in education, marketing, R&D and manufacture of pharmaceuticals:
- Quality assurance, Quality control
- Pharma product formulation & development
- Pharma production, Contract manufacturing

Who We Are:
Umesh Banakar, Course Conductor
Umesh V. Banakar, Ph.D. is Professor of Pharmaceutics and an Independent Consultant / Advisor to Pharm Industry and Academia worldwide, in drug product development and evaluation (in vitro and clinical). He was a Professor of Pharmaceutics, Director of Research, Chairperson of Dept of Pharm Sciences and Head/Dean of Graduate School at 3 US Universities. Currently, he is on the Intl Scientific Advisory Board of several pharma corporations worldwide, and has planned and executed the development of several NDAs and ANDAs and been involved in over 50 patent litigations. He is the Founding Chairperson of 2 Intl CROs and has executed almost 400 clinical trials. He has authored over 100 publications, several book chapters, monographs and editorials and is in the editorial boards of several scientific journals. He has received numerous awards for excellence in teaching, research/scholarly activities and services.

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GEA-NUS
GEA-NUS Pharmaceutical Processing Research Laboratory was established in April 1997 in the Dept of Pharmacy, NUS, under the auspices and support of the National Science and Technology Board (currently known as A*STAR), NUS and GEA. GEA-NUS focuses on pharmaceutical technology research for oral solids and manupower training.

Please note: Information provided is only a guide for the Seminar. Contents may be modified, in cases of unforeseen circumstances.

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