MONDAY, SEPTEMBER 16, 2019 | Symposium 8 | 1:30 – 5:00 PM

Clinical Drug Development for Modified-release Drug Products: Regulatory Considerations & Application of Model-informed Exposure-Response Analysis to Waive Efficacy Studies

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-008-L01-P

ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP

TARGET AUDIENCE:

This Symposium will be useful for scientists working in clinical drug development and regulatory agencies and scientists/academics working in the field of biopharmaceutics and clinical pharmacology.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Describe regulatory considerations for modified-release drug development from a clinical pharmacology perspective and gain insight into US Food & Drug Administration review experience with modified-release drug development;
2. Analyze case examples where model-based exposure-response analysis was used to waive efficacy studies by establishing a bridge between the modified-release product and a reference immediate-release product;
3. Evaluate the application of a mechanistic physiologically-based pharmacokinetic *in vitro/in vivo* correlation approach to develop a modified-release product by targeting a desired pharmacokinetic profile.

1:30 – 1:45 PM

Regulatory & Clinical Pharmacology Considerations for Clinical Drug Development of Modified-release Drug Products

Mehul Mehta, PhD, Director, US Food & Drug Administration, Clinical Pharmacology I, OCP/CDER

1:45 – 2:10 PM

Regulatory Experience With Modified-release Drug Development

Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP

2:10 – 2:35 PM

Application of Exposure-Response Analyses to Establish the Pharmacodynamic Similarity of a Once-daily Regimen to an Approved Twice-daily Dosing Regimen for the Treatment of HCV Infection

Rajeev M. Menon, PhD, Senior Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:35 – 3:00 PM

Application of Model-informed Development to Support the Registration of a Once-daily Regimen of an Extended-release Formulation

Sriram Krishnaswami, PhD, Medicine Team Lead, Pfizer Inc, Global Product Development and Manisha Lamba, PhD, Director, Celgene Corp, Clinical Pharmacokinetics and Modeling & Simulation

3:00 – 3:30 PM / **Break**

3:30 – 4:00 PM

Case Study of the Evaluation of a Flexible Drug Concentration Monitoring Approach in Patients Receiving Extended-release Tablets of a Narrow Therapeutic Index Drug

Daniel R. Stevens, PharmD, Director of Medical Affairs, Veloxis Pharmaceuticals Inc

4:00 – 4:30 PM

Utility of Mechanistic *In Vitro/In Vivo* Correlation & Mechanistic *In Vitro* Dissolution Modeling in the Development of Modified-release Formulations

Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

4:30 – 5:00 PM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations