Demonstrating Equivalence of Generic Complex Drug Substances and Formulations

October 6, 2017
FDA White Oak – Bldg. 31, Rm. 1503

Agenda

8:00 – 8:15 am — Opening Remarks
John Peters, M.D.
Deputy Director, Office of Generic Drugs (OGD)
CDER/FDA

8:15 – 8:45 am
Xiaohui (Jeff) Jiang, PhD — Introduction
Deputy Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"Introduction to complex products and FDA considerations"

Session I: Demonstrating Complex API Sameness

8:45 – 9:00 am
Deyi Zhang, PhD
Chemist, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"Introduction: Demonstrating Complex API Sameness"

9:00 – 9:30 am
Ram Sasisekharan, PhD
Alfred H. Caspary Professor of Biological Engineering and Health Sciences & Technology
Massachusetts Institute of Technology (MIT)
"Comparative characterization of highly heterogeneous drugs"

9:30 – 10:00 am
Daniela Verthelyi, PhD
Biologist, Office of Biological Products
OPQ/CDER/FDA
"*Comparative immunogenicity assessment of impurities in drug products"*

10:00 – 10:15 am — Break

Session II: Characterization of Complex Excipients and Formulations

10:15 – 10:30 am

Yan Wang, PhD
Scientific Lead, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"Introduction: Characterization of Complex Excipients and Formulations"

10:30 – 11:00 am
Kinam Park, PhD
Showalter Distinguished Professor of Biomedical Engineering & Professor of Pharmaceutics
Purdue University
"*Characterizations of PLGA polymers"*

11:00 – 11:30 am
Diane Burgess, PhD
Board of Trustees Distinguished Professor & Professor of Pharmaceutics
University of Connecticut
"IVRT and IVIVC of PLGA microspheres"

11:30 – 12:00 pm
Steven P. Schwendeman, PhD
Chair and Ara G. Paul Professor of Pharmaceutical Sciences & Professor of Biomedical Engineering
University of Michigan
"Formulation characterization of PLGA microspheres"

12:00 – 1:15 pm **Lunch/ Poster Session**

Session III: Novel IVRT for Complex Formulations

1:15 – 1:30 pm
Darby Kozak, PhD
Team Lead, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"Introduction: Novel IVRT for Complex Formulations"

1:30 – 2:00 pm
Michael J. Sailor, PhD
Distinguished Professor of Chemistry and Biochemistry
University of California, San Diego
"In vitro drug release testing of ophthalmic suspensions"

2:00 – 2:30 pm
Robert Bellantone, PhD
President and Chief Scientific Officer,
Physical Pharmaceutica, LLC.
"Pulsatile microdialysis of suspension and emulsion products"

2:30 – 3:00 pm

Alex Nivorozhkin, PhD
President and Chief Scientific Officer,
Neo-Advent Technologies, LLC.
"Liposomal Formulations of Amphotericin B"

3:00 – 3:15 pm **Break**

3:15 – 4:15 pm Panel Discussion &
Audience Questions

FDA Panel Representatives
Andre Raw, PhD (PDEBI/DIPAP/OPPQ/OPQ)
Dale Conner, PhD (OB/OGD)
Katherine Tyner, PhD (SS/OPQ)
Daniela Verthelyi, PhD (DBRRIII/OBP/OPQ)
Xiaoming Xu, PhD (PQBII/DPQR/OTR/OPQ)
Darby Kozak, PhD (DTP/ORS/OGD)
Yan Wang, PhD (DTP/ORS/OGD)
Eric Pang, PhD (DTP/ORS/OGD)

4:15 – 4:30 pm Closing Remarks

Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS)
OGD/CDER/FDA