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        Introduction
    Xiaohui (Jeff) Jiang, PhD
    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 &
FDA Panel Representatives
André Raw, PhD (PDEBI/DIPAP/OPPQ/OPQ)
Dale Conner, PhD (OB/OGD)
Katherine Tyner, PhD (SS/OPQ)
Daniela Verthelyi, PhD (DBRIII/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)
Audience Questions

4:15 – 4:30 pm        Closing Remarks
Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS)
OGD/CDER/FDA