Nanomaterial Drug Products: Current Experience and Management of Potential Risks

January 14-15, 2014
USP Meeting Center
Goals and Objectives:
1. Review analytical science and methods for characterizing nanomaterials. Discuss their application to the characterization and quality control of drug products.
2. Share experience and results using multiple formulation platforms for the same API: Effects on quality, safety, and efficacy of drug products containing nanosize constituents.
3. Discuss approaches to the management of potential risks of nanomaterials in drug products starting from early drug development and throughout product lifecycle. Implication for maintaining quality, safety, and efficacy will be highlighted.
4. Gather input regarding the considerations for utilizing nanotechnology in pharmaceutical products.
5. Present experience and perspectives from international regulatory agencies and standards setting organizations on the use of nanotechnology in pharmaceutical products.
6. Discuss areas where additional research on the effects of nanosize API on Absorption, distribution, metabolism, elimination and toxicity (ADMET) may be needed.

Expected Outcomes:
1. Establish opportunities for collaboration between academia, industry, and government sponsored research programs.
2. Develop a summary report of the workshop discussions and recommendations.

Planning Committee Members:
Don L. Henry, Co-Chair
U.S. Food and Drug Administration

Nanda Subbarao, Ph.D., Co-Chair
Biologics Consulting Group

Jeremy A. Bartlett, Ph.D.
Pfizer Inc.

W. Mark Eickhoff
Merck & Co.

Abigail Jacobs, Ph.D.
U.S. Food and Drug Administration

Elaine Morefield, Ph.D.
Vertex Pharmaceuticals

Robert K. Prud’homme, Ph.D.
Princeton University

Nakissa Sadrieh, Ph.D.
U.S. Food and Drug Administration

Rajendra Upoor, R.Ph., Ph.D.
U.S. Food and Drug Administration
DAY 1, JANUARY 14, 2014

7:30 am – 5:00 pm
Registration

8:30 am – 12:30 pm
SESSION I: NANOMATERIALS IN DRUG PRODUCTS:
REGULATORY EXPERIENCE AND STANDARDS PERSPECTIVE

MODERATORS
Celia N. Cruz, Ph.D.
U.S. Food and Drug Administration
Nanda Subbarao, Ph.D.
Biologics Consulting Group

8:30 am
Welcome and Introduction
Elaine Morefield, Ph.D.
Vertex Pharmaceuticals

8:45 am
FDA’s Approach to Regulation of Nanotechnology Products
Ritu Nalubola, Invited
U.S. Food and Drug Administration

9:15 am
FDA/CDER Perspectives on Nanotechnology Derived Drug
Products Overview
Nakissa Sadrieh, Ph.D., Invited
U.S. Food and Drug Administration

9:45 am
CDER Risk Assessment to Evaluate Potential Risks from the Use of
Nanomaterials in Drug Products
Celia N. Cruz, Ph.D., Invited
U.S. Food and Drug Administration

10:15 am – 10:35 am
Coffee Break

10:35 am
Health Canada’s Experience on the Use of Nanotechnology Drug
Products
Hripsime Shahbazian, Ph.D.
Health Canada

11:05 am
European Medicines Agency (EMA) Experience on the Use of
Nanotechnology Drug Products
Sabine Haubenreisser
European Medicines Agency

11:35 am
International Standards Organization (ISO) Perspective on Standards
Related to Nanotechnology
Ajit Jillavenkatesa
National Institute of Standards and Technology

12:05 pm
Question and Answer Session

12:30 pm
Lunch Break

1:30 pm – 3:10 pm
SESSION 2: CONSIDERATION FOR THE CHARACTERIZATION,
DEVELOPMENT, MANUFACTURING, AND POST
COMMERCIALIZATION OF NANOMATERIALS IN DRUG
PRODUCTS

MODERATORS:
Katherine M. Tyner, Ph.D.
U.S. Food and Drug Administration
Robert K. Prud’homme, Ph.D.
Princeton University

1:30 pm
Considerations Regarding the Impact of Nanomaterials on Drug
Products
Katherine M. Tyner, Ph.D., Invited
U.S. Food and Drug Administration

1:40 pm
Analytical Considerations for the Characterization of Nanomaterial
Drug Products
Christie Sayes, Ph.D.
RTI International
2:10 pm
Panel Discussion: Manufacturing Considerations for Nanomaterials in Drug Product
• Gary Liversidge, Ph.D., Alkermes Inc.
• Neil Desai, Ph.D., Celgene
• Donna Cabral-Lilly, Ph.D., Celator Pharmaceuticals, Inc.
• Lawrence Tamarkin, Ph.D., CytImmune

3:10 pm – 3:30 pm
Coffee Break

3:30 pm – 5:30 pm
Breakout Sessions: Characterization and Manufacturing of Stable Nanotechnology Drug Products

SESSION A (ONE HOUR, REPEATED AFTER FIRST HOUR)
Analytical Methods Used for the Characterization of Nanomaterials: Limitations and Need for Additional Research

MODERATORS:
Christie Sayes, Ph.D.
Center for Aerosol & Nanomaterials Engineering
Nanda Subbarao, Ph.D.
Biologics Consulting Group
Katherine M. Tyner, Ph.D.
U.S. Food and Drug Administration

SESSION B (ONE HOUR, REPEATED AFTER FIRST HOUR)
Current and Emerging Technologies for Manufacturing Stable Nanomaterial Containing Drug Products

MODERATORS:
W. Mark Eickhoff
Merck & Co.
Celia N. Cruz, Ph.D., U.S.
U.S. Food and Drug Administration

6:00 pm – 7:00 pm
Networking Reception

DAY 2, JANUARY 15, 2014
8:30 am – 12:30 pm
SESSION 3: SAFETY AND ADMET CASE STUDIES OF NANOTECHNOLOGY DERIVED DRUG PRODUCTS

MODERATORS
Abigail Jacobs, Ph.D.
U.S. Food and Drug Administration
Jeremy A. Bartlett, Ph.D.
Pfizer Inc.

8:30 am
Safety and Toxicological Effects of Nanotechnology on Drug Products
Abigail Jacobs, Ph.D., Invited
U.S. Food and Drug Administration

8:40 am
Case Study: Safety and ADMET Aspects of Nanotechnology in Parenteral Drug Products
William C. Zamboni, Ph.D., Pharm.D.
University of North Carolina

9:10 am
Case Study: Safety and ADMET Aspects of Nanotechnology in Topical Products (Sun screens/Wound Healing/Topical/Ophthalmic Products)
Dr. Mary Flack/ Dr. Susan Ciotti
Nanobio

9:40 am
The Effect of Nano-sized Excipients on ADMET
Raymond M. David, Ph.D., DABT
BASF Corporation

10:10 am – 10:30 am
Coffee Break
10:30 am to 12:30 pm
Breakout Sessions: Risks associated with nanomaterial containing drug products

SESSION C (ONE HOUR, REPEATED AFTER FIRST HOUR)
The Effect of Nano-sized Excipients on ADMET

MODERATORS:
Nanda Subbarao, Ph.D.
Biologics Consulting Group
Paul Brown, Ph.D.
U.S. Food and Drug Administration

12:30 pm – 1:30 pm
Lunch Break

1:30 pm – 2:10 pm
SESSION 4: REGULATORY PANEL DISCUSSION

MODERATORS
Celia N. Cruz, Ph.D.
U.S. Food and Drug Administration
Rajendra Uppoor, R.Ph., Ph.D.
U.S. Food and Drug Administration

PANELISTS:
Ritu Nalubola, Invited
U.S. Food and Drug Administration
Nakissa Sadrieh, Ph.D., Invited
U.S. Food and Drug Administration
Sabine Haubenreisser,
European Medicines Agency
Ajit Jilavenkatesa,
National Institute of Standards and Technology

2:10 pm – 3:10 pm
Presentation of breakout session summaries

2:10 pm
Breakout Session A

2:25 pm
Breakout Session B

2:40 pm
Breakout Session C

2:55 pm
Breakout Session D

3:10 to 3:30 pm
Closing Remarks
Nakissa Sadrieh, Ph.D., Invited
U.S. Food and Drug Administration

PQRI MISSION STATEMENT
The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development.

By virtue of its diverse membership, PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.
VENUE AND REGISTRATION
The workshop is being held at the USP Meetings Center located at
12601 Twinbrook Parkway
Rockville, Maryland 20852

Reservations can be made at the Bethesda North Marriott using the
USP Corporate rate by going to the booking site at
https://resweb.passkey.com/go/6f3c46f2

Registration for the workshop can be made by going to the SignMeUp
website at www.signmeup.com/93666

For additional information, please contact
Vicki Penn at PennV@pqri.org or by phone at 703-248-4719.