PQRI Workshop on Application of IVIVC in Formulation Development

September 5 - 6, 2012
Bethesda, Maryland

Co-sponsored with
PQRI

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.

SCOPE AND OBJECTIVES FOR THE WORKSHOP

In vitro in vivo correlation (IVIVC) is an important concept and a tool in the development and evaluation of pharmaceutical dosage forms, especially modified release dosage forms. The workshop will review recent developments in the area of IVIVC, explore different modeling techniques. It has scheduled eight different interactive breakout sessions allowing for a thorough dialogue and exchange among the workshop participants and identifying key points which may help in drafting a workshop summary. The major goals and objectives of the workshop are:

1. Review the current status of IVIVC
2. Discuss applications and potential benefits of IVIVC.
3. Review and evaluate different methodologies and their potential use in IVIVC assessment.
4. Assess advantages and limitations for IVIVC in formulation development—when and how it may be established.
5. Develop the basis for a summary paper on IVIVC and publication as a PQRI document.

PLANNING COMMITTEE MEMBERS

Vinod P. Shah, Ph.D., Pharmaceutical Consultant, Co-Chair
Avraham (Avi) Yacobi, Ph.D., Independent Consultant, Co-Chair
Barbara M. Davit, Ph.D., U.S. Food and Drug Administration
Jennifer Dressman, Ph.D., University of Frankfurt
John Z. Duan, Ph.D., U.S. Food and Drug Administration
Derek A. Ganes, Ph.D., Independent Consultant
Mario A. González, Ph.D., P’Kinetics International, Inc.
Tahseen Mirza, Ph.D., U.S. Food and Drug Administration
James E. Polli, Ph.D., University of Maryland
Erika S. Stippler, Ph.D., U.S. Pharmacopeia

WEDNESDAY, SEPTEMBER 5, 2012

8:45 am – 12:30 pm

SESSION I: FOUNDATION OF AND ADVANCES IN IVIVC

Welcome and Introduction

MODERATORS
Vinod P. Shah, Ph.D.
Pharmaceutical Consultant
Avi Yacobi, Ph.D.
Independent Consultant

9:00 am
Traditional IVIVC Using Deconvolution: Advantages and Drawbacks
Mario A. González, Ph.D.
P’Kinetics International, Inc.

9:30 am
Review of GI Physiology and Use of Bio-relevant Dissolution Media
Jennifer Dressman, Ph.D.
University of Frankfurt

10:00 am
EMA Guidance on MR Dosage Form
Theresa Shepard, Ph.D.
Medicines and Healthcare Products Regulatory Agency (MHRA)

10:30 am
Coffee Break

11:00 am
Applications of IVIVC in Formulation Development
Doug F. Smith, MS
DFS Consulting, LLC

11:30 am
Use of IVIVC to Facilitate Product Development via “Quality by Design” Approach
Tahseen Mirza, Ph.D.
U.S. Food and Drug Administration
12:00 pm
Question and Answer Session

12:30 pm
Lunch

1:30 pm – 3:15 pm
SESSION II: NEW METHODOLOGIES ASSESSMENT—SIMULATION OF IVIVC

MODERATOR
Maziar Kakhi, Ph.D.
U.S. Food and Drug Administration

1:30 pm
IVIVC Perspective, Generic Pharmaceuticals
Russell J. Rackley, Ph.D.
Mylan Pharmaceuticals, Inc.

2:00 pm
IVIVC Perspective
Rong Li, Ph.D.
Pfizer Inc.

2:30 pm
GastroPlus Program
Michael B. Bolger, Ph.D.
Simulations Plus, Inc.

2:45 pm
SimCyp Program
David B. Turner, Ph.D.
SimCyp Limited

3:00 pm
Pharsight
Jason Chittenden, M.S.
Pharsight, a Certara Company

3:15 pm
Coffee Break

3:30 pm – 5:30 pm
BREAKOUT SESSIONS—4 SESSIONS IN PARALLEL; ONE HOUR IN DURATION; INDIVIDUALS CAN SELECT 2 SESSIONS

BREAK OUT SESSION A
Evolution of Traditional IVIVC with an Eye to QbD
Barbara M. Davit, Ph.D., U.S. Food and Drug Administration
Mario A. González, Ph.D., P’Kinetics International, Inc.

BREAKOUT SESSION B
Understanding the Role of Bio-relevant Dissolution Testing—It’s Not Just About the Media
Jennifer Dressman, Ph.D., University of Frankfurt
Erika S. Stippler, Ph.D., U.S. Pharmacopeia

BREAKOUT SESSION C
Role of Physiological Modeling in IVIVC
Michael B. Bolger Ph.D., Simulations Plus, Inc.
David B. Turner, Ph.D., SimCyp Limited.

BREAKOUT SESSION D
Role of Population Approaches in IVIVC
John Z. Duan, Ph.D., U.S. Food and Drug Administration
Derek A. Gaines, Ph.D., Independent Consultant

6:00 pm – 7:00 pm
Reception and Exhibitor Demos of Physiological Modeling

SEPTEMBER 6, 2012

8:30 am – 10:30 am
SESSION III: APPLICATION OF IVIVC

MODERATOR
Russell J. Rackley, Ph.D.
Mylan Pharmaceuticals, Inc.

8:30 am
When is IVIVC Applicable?—A Practical View
Derek A. Gaines, Ph.D.
Independent Consultant

9:00 am
How Can IVIVC/IVIVR Be Used?
James E. Polli, Ph.D.
University of Maryland

9:30 am
FDA’s Experience on IVIVC—New Drugs
Sandra Suarez-Sharp, Ph.D.
U.S. Food and Drug Administration
10:00 am
FDA’s Experience on IVIVC—Generic Drugs
Barbara M. Davit, Ph.D.
U.S. Food and Drug Administration

10:30 am
Coffee Break

11:00 am – 1:00 pm
Breakout Sessions
4 sessions in parallel; one hour in duration; individuals can select 2 sessions

BREAKOUT SESSION E
Use of IVIVC Data to Support Biowaiver
James E. Polli, Ph.D., University of Maryland
Tahseen Mirza, Ph.D., U.S. Food and Drug Administration

BREAKOUT SESSION F
IVIVC and IVIVR for IR Dosage Forms
Maziar Kakhi, Ph.D., U.S. Food and Drug Administration
Doug F. Smith, M.S., DFS Consulting, LLC

BREAKOUT SESSION G
Focus on MR Dosage Forms
Mario A. González, Ph.D., P’Kinetics International, Inc.
John Z. Duan, Ph.D., U.S. Food and Drug Administration

BREAKOUT SESSION H
Untangling the Regulatory Knots—The Road Map to Harmonized Guidances Worldwide
Theresa Shepard, Ph.D., MHRA
Sandra Suarez-Sharp, Ph.D., U.S. Food and Drug Administration

1:00 pm
Lunch

2:00 pm – 5:30 pm
SESSION IV: Where do we go from here?
MODERATORS
Vinod P. Shah, Ph.D., Pharmaceutical Consultant
Avi Yacobi, Ph.D., Independent Consultant

2:00 pm
Summary and Discussion of Break-out Sessions

2:00 pm
Breakout Session -A

2:15 pm
Breakout Session -B

2:30 pm
Breakout Session -C

2:45 pm
Breakout Session -D

3:00 pm
Breakout Session -E

3:15 pm
Breakout Session -F

3:30 pm
Breakout Session -G

3:45 pm
Breakout Session -H

4:00 pm
Question and Answer Session

4:15 pm
Coffee Break

4:30 pm
“What is in the Future?”
Tony DeStefano, Chair, PQRI Steering Committee

5:00 pm
Conclusions and Next Steps
Vinod P. Shah, Ph.D., Pharmaceutical Consultant
Avi Yacobi, Ph.D., Independent Consultant

SEPTEMBER 7, 2012
Planning Committee Members Only

8:30 am – 4:00 pm
Workshop Evaluation and White Paper Construction
**PQRI MISSION STATEMENT**

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**PQRI MEMBER ORGANIZATIONS**

- **AAPS**
  American Association of Pharmaceutical Scientists
- **CHPA**
  Consumer Healthcare Products Association
- **FDA/CDER**
  U.S. Food and Drug Administration, Center for Drug Evaluation and Research
- **HC**
  Health Canada
- **IPEC-Americas**
  International Pharmaceutical Excipients Council of the Americas
- **USP**
  United States Pharmacopeia

**BOARD OF DIRECTORS**

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- Glenn Van Buskirk, Ph.D., Treasurer
- Anthony DeStefano, Ph.D.
- Avraham Yacobi, Ph.D.
- Rachael Roehrig, Ph.D.

**PQRI STEERING COMMITTEE**

(Representative and Alternates)

- Anthony DeStefano, Ph.D., Chair
- Rachael Roehrig, Ph.D., Vice Chair
- **AAPS** Lynn Van Campen, Ph.D., John Lisack, Jr., CAE, Stacey May, M.A.
- **CHPA** John Punzi, Ph.D.
- **FDA** Helen N. Winkle, Nakissa Sadrieh, Ph.D., Raj Uppoor, R.Ph., Ph.D.
- **HC** Anita DiFranco
- **IPEC-Americas** Dave Schoneker
- **USP** Kevin Hool, Ph.D.

**VENUE AND REGISTRATION**

The workshop is being held at the Bethesda North Marriott Hotel and Conference Center and reservations may be made by calling Reservations Toll Free: 1-(877)-212-5752 and referring to the PQRI Workshop on Application of IVIVC.

Hotel reservations can also be made online at [https://resweb.passkey.com/Resweb.do?mode=welcome_ei_new&eventID=8702506&utm_source=2644099&utm_medium=email&utm_campaign=11292436](https://resweb.passkey.com/Resweb.do?mode=welcome_ei_new&eventID=8702506&utm_source=2644099&utm_medium=email&utm_campaign=11292436) and enter your check-in and check-out date link to make sure you get the discounted rate of $179 per night for single and double occupancy.

Registration for the workshop can be made by going to the SignMeUp website at [www.signmeup.com/82155](http://www.signmeup.com/82155).

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

Bethesda North Marriott’
5701 Marinelli Road
Bethesda, MD 20852
(301) 822-9200

Please register for the workshop on Sign Me Up at [www.signmeup.com/82155](http://www.signmeup.com/82155).