Scope and Objectives for 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 *IVIV*C
2. Discuss applications and potential benefits of *IVIV*C.
3. Review and evaluate different methodologies and their potential use in *IVIV*C Assessment.
4. Assess advantages and limitations for *IVIV*C in formulation development – when and how it may be established.
5. Develop the basis for a summary paper on *IVIVC* and a publication as a PQRI document.

Agenda

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. Gonzàlez, 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 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. Gonzàlez, 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 Duan, Ph.D., U.S. Food and Drug Administration
Derek A. Ganes, 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. Ganes, 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, MS, DFS Consulting, LLC

Breakout Session G
Focus on MR Dosage Forms
Mario A. Gonzàlez, Ph.D., P'Kinetics International, Inc.
John 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: 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