

## Inaugural SAAMnow Annual Scientific Workshop – 2018

### ***Streamlining Generic Drug Development by Matching Reference Product Composition and Performance, In Vitro and In Vivo***

October 18 - 19, 2018

Embassy Suites near the Inner Harbor

222 St. Paul Place, Baltimore, MD

Our inaugural workshop addresses the issues surrounding reverse engineering methods and strategies in the context of Q1/Q2/Q3 comparisons, with an eye toward reducing the clinical burden of generic drug development programs via BCS class 3 biowaivers, *in vitro*-only pathways for locally-acting and complex drug products, and, where biowaivers are not possible, streamlining complex human bioequivalence studies. The program was developed to appeal to stakeholders across a broad range of disciplines and to span a diverse group of product classes. The agenda covers cutting-edge approaches to facilitate the development of solid oral, semi-solid (locally- and systemically-acting topical and vaginal), long-acting injectable (suspension and liposomal), and oral inhalation products. The workshop brings key industry leaders, researchers, and regulators together to present the latest strategies for deformulation, process optimization, and bioequivalence study design. We believe this is the first comprehensive workshop to focus on the challenges industry faces in taking advantage of these streamlined development pathways.

## Inaugural SAAMnow Annual Scientific Workshop – 2018

### ***Streamlining Generic Drug Development by Matching Reference Product Composition and Performance, In Vitro and In Vivo***

#### **Day 1 Key activities:**

Registration: 7:30 AM – 9:00 AM

Continental Breakfast: 7:30 AM – 8:45 AM

#### **Day 1: Semi-solids and Complex Liquids; Session 1 *In Vitro*-Based BE Approaches**

Talk #	Time	Tentative Title
	8:45 AM – 9:00 AM	Welcome & Introduction to SAAM
1	9:00 AM – 9:30 AM	Understanding FDA's Rules and Expectations Surrounding Q1/Q2 Determinations
2	9:30 AM – 10:00 AM	State-of-the-Art Approaches to Deciphering Semi-solid and Complex Liquid Compositions
3	10:00 AM – 10:30 AM	Using Biological Assays to Gauge the Clinical Relevance of Microstructural (Q3) Differences in Formulations
	10:30 AM – 11:00 AM	<i>Networking Coffee Break</i>
4	11:00 AM – 11:30 AM	Getting to Q3: Novel Approaches to Optimizing Generic Manufacturing Processes
5	11:30 AM – 12:00 PM	<i>In Vitro</i> Data Analysis Issues: IVPT Analyses and Other Challenges

## Day 1: Semi-solids and Complex Liquids; Session 2 *In Vivo*-Based BE Approaches

Talk #	Time	Tentative Title
6	12:00 PM – 12:30 PM	Invited panel discussion on In Vitro BE Approaches
	12:30 PM – 2:00 PM	<i>Lunch and Networking</i>
7	2:00 PM – 2:30 PM	Bioequivalence Methods and Waiver Options: Topical Products for Local Action
8	2:30 PM – 3:00 PM	PK Studies on Long-Acting Intramuscular Injectables: Challenges and Solutions
9	3:00 PM – 3:30 PM	PK Studies on Liposomal Products: Challenges and Solutions
	3:30 PM – 4:00 PM	<i>Networking Coffee Break</i>
10	4:00 PM – 4:30 PM	Adaptive Sequential Designs for Clinical Endpoint Bioequivalence Studies
11	4:30 PM – 5:00 PM	Invited panel discussion on In Vivo BE Approaches
	5:00 PM – 6:00 PM	<i>Networking Reception</i>

### **Day 2 Key Activities:**

Registration and Continental Breakfast: 7:30 AM – 8:30 AM

## Day 2: Solid Oral and Orally-Inhaled Products; Session 3A Solid Orals: *In Vitro*-Based BE Approaches

Talk #	Time	Tentative Title
12	8:30 AM – 9:00 AM	Reverse-Engineering Strategies for Solid Oral Dosage Forms: Getting to Q1 – Which Excipients and What Grades are in the RLD?
13	9:00 AM – 9:30 AM	Reverse-Engineering Strategies for Solid Oral Dosage Forms: Getting to Q2 – Precise Quantitation of Excipients in the RLD
14	9:30 AM – 10:00 AM	Invited panel discussion on In Vitro BE Approaches

## Day 2: Solid Oral and Orally-Inhaled Products; Session 3B Orally-Inhaled Products: *In Vitro*-Based BE Approaches

Talk #	Time	Tentative Title
15	8:30 AM – 9:00 AM	OIP Reverse-Engineering Part 1: Formulation Q1/Q2/Q3
16	9:00 AM – 9:30 AM	OIP Reverse-Engineering Part 2: Matching Device Performance
17	9:30 AM – 10:00 AM	Invited panel discussion on In Vitro BE Approaches
	10:00 AM – 10:30 AM	<i>Networking Coffee Break</i>

## Day 2: Solid Oral and Orally-Inhaled Products; Session 4 *In Vivo*-Based BE Approaches

Talk #	Time	Tentative Title
18	10:30 AM – 11:00 AM	Designing and Analyzing PK Studies in Patients: Practical Considerations
19	11:00 AM – 11:30 AM	Analysis of the User Interface of a Generic Product: Threshold analyses and Comparative Use Human Factor Studies
20	11:30 AM – 12:00 PM	Invited panel discussion on In Vivo BE Approaches
	12:00AM – 12:30 PM	<i>Open Forum- Feedback on Workshop and SAAM</i>
	12:30PM – 2:00 PM	<i>Lunch and Networking</i>

**Lunch is included both days with Cocktails available the first evening during the Networking Reception.**

Registration fees: \$750.00

Government: \$450.00

Early bird by September 14, 2018: \$650.00

Registration fees includes calendar year 2018 and 2019 membership dues (\$100 value)

Hotel Information:

Embassy Suites near the Inner Harbor

222 St. Paul Place, Baltimore, MD

Unfortunately the SAAMnow block with the special room rate has been filled, but we still encourage you to stay for the event! Please view the Embassy Suites' website below to book your room at a standard rate.

[Book your hotel room HERE](#)

## Sponsorship Opportunities

SAAMnow has prestigious opportunities to showcase your company at this inaugural workshop. There are various levels: Founding, Holmium and Hafnium Sponsors. Our inaugural sponsorships provide significant exposure to the workshop participants, including multiple networking venues.

### *Founding Sponsor*

*\$10,000 includes memberships for 5 persons for calendar year 2018 and 2019\**

- *Benefits:*
  - *Large Logo prominent on the SAAMnow website*
  - *Large Logo on prominent display at the workshop*
  - *Conference announced recognition prior to each session*
  - *Access to Attendee list 3 weeks in advance*
  - *3-year recognition as a Founding Sponsor in our Honor Roll on the website*

### *Holmium Sponsor*

*\$5,000 includes memberships for 3 persons for calendar year 2018 and 2019\**

- *Benefits:*
  - *Medium Logo prominent on the SAAMnow website*
  - *Medium Logo on prominent display at the workshop*
  - *Conference announced recognition once each day*
  - *Access to Attendee list 2 weeks in advance*
  - *2-year recognition as a Holmium Sponsor in our Honor Roll on the website*

### *Hafnium Sponsor*

*\$2,500 includes memberships for 2 persons for calendar year 2018 and 2019\**

- *Benefits:*
  - *Small Logo prominent on the SAAMnow website*
  - *Small Logo on prominent display at the workshop*
  - *Conference announced recognition on the first day*
  - *Access to Attendee list 1 weeks in advance*
  - *1-year recognition as a Hafnium Sponsor in our Honor Roll on the website*

\*The fees for the workshop will be reduced by \$100.00 for each member included in the sponsorship categories above.