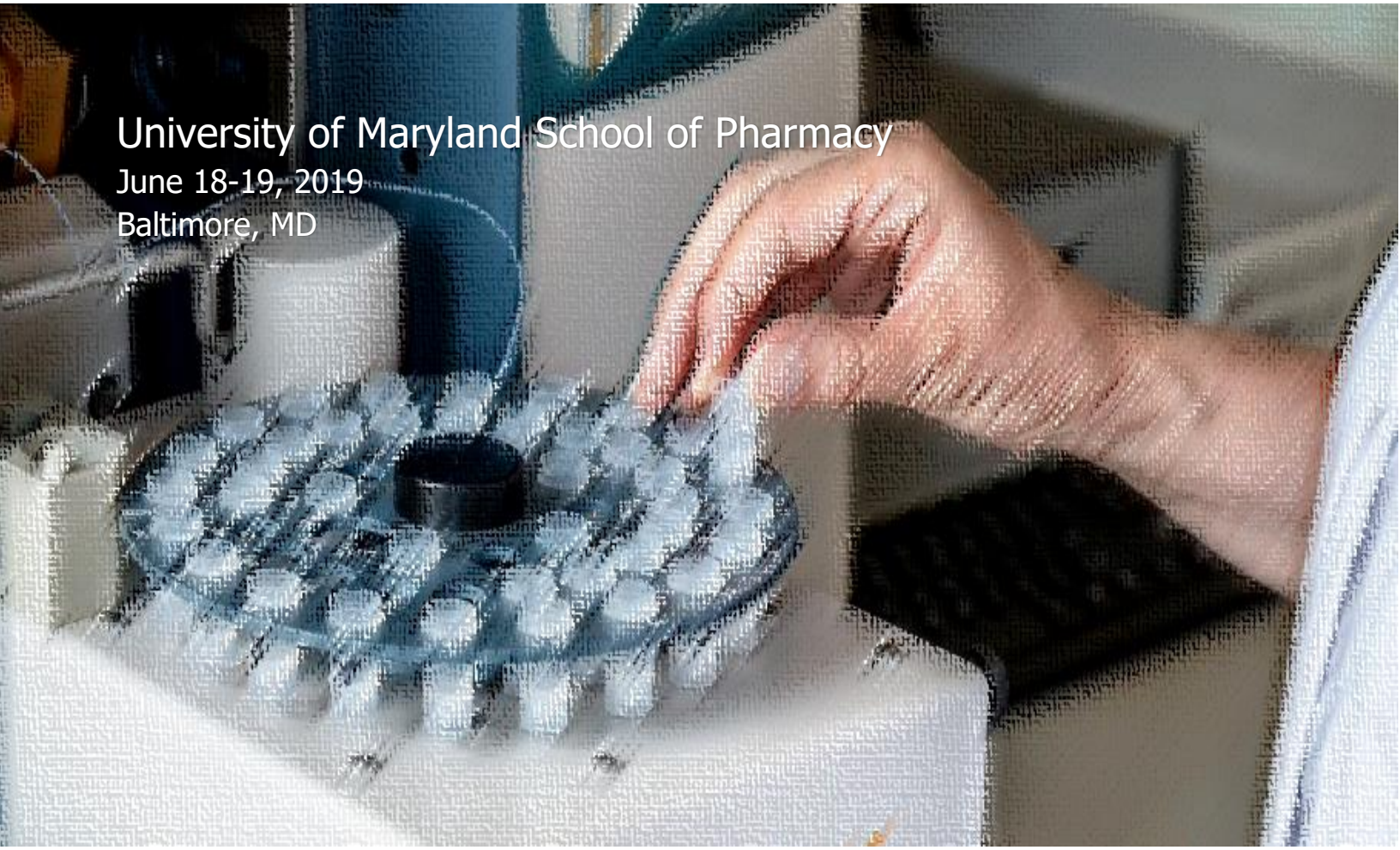
The University of Maryland Center of Excellence in Regulatory Science and Innovation, in Collaboration with IQ Consortium, Presents:

Pediatric Formulation Development: Challenges of Today and Strategies for Tomorrow



University of Maryland School of Pharmacy
June 18-19, 2019
Baltimore, MD

Conference Agenda

Tuesday, June 18, 2019

Agenda:

Time	Activity
7:45-8:30 a.m.	**Registration and Breakfast** **Steve Hoag** University of Maryland School of Pharmacy
8:30-8:40 a.m.	**Introduction and Welcome** **Steve Hoag** University of Maryland School of Pharmacy
8:40-8:55 a.m.	**Highlights of M-CERSI/EuPFI Workshop: Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products (June 8-9, 2016 | College Park, MD)** **Trupti Dixit** Navigant Pharma Consulting
8:55-9:15 a.m.	**Expectations for 2019 Workshop Outcomes** **Arzu Selen** U.S. Food and Drug Administration
9:15-9:35 a.m.	**Formulation: Pediatric Patients Inspiring and Shaping Drug Development** **Arzu Selen** U.S. Food and Drug Administration
9:35-9:45 a.m.	**Formulation: Industry Formulation Perspective** **Karen Thompson** Merck
9:45-10:30 a.m.	**Formulation Break-Out 1: Excipients** **Moderator:** Darren Fegley (FDA)
10:30-10:45 a.m.	**Break and Networking**
10:45-11:30 a.m.	**Formulation Break-Out 2: Acceptability** **Moderator:** Robert Ternik (Eli Lilly)
11:30 a.m. – 12:15 p.m.	**Formulation Break-Out 3: Devices** **Moderator**: Matthew Santangelo (Pfizer)
12:15-1:15 p.m.	**Group Photo, Lunch, and Networking**
1:15-2:15 p.m.	**Formulation Summary and Panel Discussion** **Moderator:** Matthew Santangelo (Pfizer)

2:15-2:30 p.m.	**Analytical: Testing and Release Strategies for Mini-Tablets** **Asha Rajapakshe** Merck
2:30-2:45 p.m.	**Analytical: Considerations for In-Use Stability and Compatibility with Vehicles** **Ramesh Sood** U.S. Food and Drug Administration
2:45-3:30 p.m.	**Analytical Break-Out 1: Mini-Tablets Specification** **Moderators:** Elizabeth Galella (Bristol-Myers Squibb), Asha Rajapakshe (Merck), and Biplob Mitra (Celgene)
3:30-3:45 p.m.	**Break and Networking**
3:45-4:30 p.m.	**Analytical Break-Out 2: Dosing Vehicles** **Moderators:** Ramesh Sood (FDA), Steven Mount (Astra Zeneca), and Paul Seo (FDA)
4:30-4:45 p.m.	**Break and Networking**
4:45-5:45 p.m.	**Analytical Summary and Panel Discussion** **Moderator**: Elizabeth Galella (Bristol-Myers Squibb)
5:45-7:45 p.m.	**Evening Reception and Poster Session**

Wednesday, June 19, 2019

Time	Activity
8:00-8:30 a.m.	**Breakfast**
8:30-8:45 a.m.	**Summary of Day 1** **Elizabeth Galella** Bristol-Myers Squibb
8:45-9:00 a.m.	**Perspectives on the Need for Improved Pediatric Formulations** **Ann Zajicek** National Institutes of Health
9:00-9:15 a.m.	**Clinical: Clinical Considerations in Pediatric Drug Product Development from an Industry Perspective** **Jack Cook** Pfizer
9:15-9:30 a.m.	**Clinical: Value of Pharmacokinetics in Pediatric Clinical Trials** **Hao Zhu** U.S. Food and Drug Administration

9:30-10:15 a.m.	**CLINICAL BREAK-OUT 1: PHARMACOKINETICS** **Moderators:** Jian Wang (FDA) and Shailly Mehrotra (Otsuka Pharmaceutical)
10:15-10:30 a.m.	**BREAK**
10:30-11:15 a.m.	**CLINICAL BREAK-OUT 2: STUDY DESIGN** **Moderators:** Jing Liu (Pfizer) and Hari Sachs (FDA)
11:15 – Noon	**CLINICAL BREAK-OUT 3: BIOSTUDIES TO SUPPORT FORMULATION** **Moderators:** Karen Thompson (Merck) and Elmika Fletcher (FDA)
Noon – 12:45 p.m.	**LUNCH AND NETWORKING**
12:45-1:45 p.m.	**CLINICAL SUMMARY AND PANEL DISCUSSION** **Moderator:** Jack Cook (Pfizer)
1:45-2:00 p.m.	**REGULATORY AND INDUSTRY: BUILDING ON REGULATORY EXPERIENCES TO ADVANCE PEDIATRIC FORMULATION DEVELOPMENT** **Erica Radden** U.S. Food and Drug Administration
2:00-2:15 p.m.	**REGULATORY AND INDUSTRY: LOOKING INTO THE FUTURE OF PEDIATRIC DEVELOPMENT** **Daniel Schaufelberger** Schaufelberger Consulting
2:15-3:00 p.m.	**REGULATORY AND INDUSTRY BREAK-OUT 1: REGULATORY LESSONS LEARNED** **Moderators:** Erica Radden (FDA) and Mona Khurana (FDA)
3:00-3:15 p.m.	**BREAK AND NETWORKING**
3:15-4:00 p.m.	**REGULATORY AND INDUSTRY BREAK-OUT 2: FUTURE LANDSCAPE** **Moderators:** David Tan (AbbVie) and Daniel Schaufelberger (Schaufelberger Consulting)
4:00-4:15 p.m.	**BREAK AND NETWORKING**
4:15-5:15 p.m.	**REGULATORY AND INDUSTRY SUMMARY AND PANEL DISCUSSION** **Moderator:** David Tan (AbbVie)
5:15-5:30 p.m.	**CLOSING AND SUMMARY** **David Tan** AbbVie