



Workshop: Flight Simulator: Learning How to Develop Complex Generic Drug Products
Saturday, November 3, 2018

- 9:00 am – 9:05 am **Welcome and Introductions**
Sameersingh Raney, Ph.D., U.S. Food and Drug Administration (*invited*)
Markham Luke, MD, Ph.D., U.S. Food and Drug Administration (*invited*)
- 9:05 am – 9:30 am **CGDPs with a Complex Active Pharmaceutical Ingredient (API)**
Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration (*invited*)
Adam Fisher, Ph.D., U.S. Food and Drug Administration (*invited*)
Kris Andre, M.S., U.S. Food and Drug Administration (*invited*)
Lei Zhang, Ph.D., U.S. Food and Drug Administration (*invited*)
- 9:30 am – 9:55 am **CGDPs with a Locally-Acting Route of Delivery including Topical Dermatological Drug Products**
Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration (*invited*)
Pahala Simamora, Ph.D., U.S. Food and Drug Administration (*invited*)
Andrew Babiskin, Ph.D., U.S. Food and Drug Administration (*invited*)
Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration (*invited*)
- 9:55 am – 10:20 am **CGDPs with Drug and Device Constituents: Transdermal Delivery Systems (TDS)**
Priyanka Gosh, Ph.D., U.S. Food and Drug Administration (*invited*)
Robert Berendt, Ph.D., U.S. Food and Drug Administration (*invited*)
Liang Zhao, Ph.D., U.S. Food and Drug Administration (*invited*)
Sameersingh Raney, Ph.D., U.S. Food and Drug Administration (*invited*)
- 10:20 am – 10:45 am **CGDPs with Drug and Device Constituents: Orally Inhaled and Nasal Drug Products (OINDPs)**
Denise Conti, Ph.D., U.S. Food and Drug Administration (*invited*)
Bhagwant Rege, Ph.D., U.S. Food and Drug Administration (*invited*)
Robert Lionberger, Ph.D., U.S. Food and Drug Administration (*invited*)
- 10:45 am – 11:00 am Coffee Break
- 11:00 am – 11:25 am **CGDPs with Complex Formulations including Nanotechnology Products**
Darby Kozak, Ph.D., U.S. Food and Drug Administration (*invited*)
Katherine Tyner, Ph.D., U.S. Food and Drug Administration (*invited*)
Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration (*invited*)



| | |
|---------------------|---|
| 11:25 am – 11:45 am | Participant Assignment to Breakout Sessions |
| 11:45 am – 12:30 pm | <p>Group A: (Pre-Lunch Session) Development of CGDPs with a complex API</p> <p>Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Adam Fisher, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Kris Andre, M.S., U.S. Food and Drug Administration (<i>invited</i>) Lei Zhang, Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |
| 11:45 am – 12:30 pm | <p>Group B: (Pre-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery</p> <p>Tannaz Ramezanli, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Pahala Simamora, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Andrew Babiskin, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |
| 11:45 am – 12:30 pm | <p>Group C: (Pre-Lunch Session) Development of CGDPs involving a TDS</p> <p>Priyanka Gosh, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Robert Berendt, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Liang Zhao, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Sameersingh Raney, Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |
| 11:45 am – 12:30 pm | <p>Group D: (Pre-Lunch Session) Development of CGDPs involving an OINDP</p> <p>Denise Conti, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Bhagwant Rege, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Robert Lionberger, Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |
| 11:45 am – 12:30 pm | <p>Group E: (Pre-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation</p> <p>Darby Kozak, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Katherine Tyner, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |
| 12:30 pm – 1:30 pm | Lunch |
| 1:30 pm – 2:30 pm | <p>Group A: (Post-Lunch Session) Development of CGDPs with a complex API</p> <p>Xiaohui (Jeff) Jiang, Ph.D., U.S. Food and Drug Administration (<i>invited</i>)</p> |



Adam Fisher, Ph.D., U.S. Food and Drug Administration (*invited*)
Kris Andre, M.S., U.S. Food and Drug Administration (*invited*)
Lei Zhang, Ph.D., U.S. Food and Drug Administration (*invited*)

1:30 pm – 2:30 pm

Group B: (Post-Lunch Session) Development of CGDPs with a locally-acting (topical) route of delivery

Pahala Simamora, Ph.D., U.S. Food and Drug Administration (*invited*)
Andrew Babiskin, Ph.D., U.S. Food and Drug Administration (*invited*)
Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration (*invited*)

1:30 pm – 2:30 pm

Group C: (Post-Lunch Session) Development of CGDPs involving a TDS

Priyanka Gosh, Ph.D., U.S. Food and Drug Administration (*invited*)
Robert Berendt, Ph.D., U.S. Food and Drug Administration (*invited*)
Liang Zhao, Ph.D., U.S. Food and Drug Administration (*invited*)
Sameersingh Raney, Ph.D., U.S. Food and Drug Administration (*invited*)

1:30 pm – 2:30 pm

Group D: (Post-Lunch Session) Development of CGDPs involving an OINDP

Denise Conti, Ph.D., U.S. Food and Drug Administration (*invited*)
Bhagwant Rege, Ph.D., U.S. Food and Drug Administration (*invited*)
Robert Lionberger, Ph.D., U.S. Food and Drug Administration (*invited*)

1:30 pm – 2:30 pm

Group E: (Post-Lunch Session) Development of CGDPs with a complex (nanotechnology) formulation

Darby Kozak, Ph.D., U.S. Food and Drug Administration (*invited*)
Katherine Tyner, Ph.D., U.S. Food and Drug Administration (*invited*)
Lanyan (Lucy) Fang, Ph.D., U.S. Food and Drug Administration (*invited*)

2:30 pm – 2:45 pm

Coffee Break

2:45 pm – 3:10 pm

Mock pre-ANDA meeting about a Hypothetical CGDP with a complex API

All Speakers

3:10 pm – 3:35 pm

Mock pre-ANDA meeting about a Hypothetical CGDP involving a locally-acting route of delivery

All Speakers



| | |
|-------------------|--|
| 3:35 pm – 4:00 pm | Mock pre-ANDA meeting about a Hypothetical CGDP involving a TDS product All Speakers |
| 4:00 pm – 4:25 pm | Mock pre-ANDA meeting about a Hypothetical CGDP involving an OINDP All Speakers |
| 4:25 pm – 4:50 pm | Mock pre-ANDA meeting about a Hypothetical CGDP with a complex formulation All Speakers |
| 4:50 pm – 5:00 pm | Closing Comments Robert Lionberger, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) |
| 5:00 pm | Adjournments Sameersingh Raney, Ph.D., U.S. Food and Drug Administration (<i>invited</i>) Markham Luke, M.D., Ph.D., U.S. Food and Drug Administration (<i>invited</i>) |