



## Patient-Centric Design of Long-Acting Injectable Drug Products

WORKSHOP | March 9-10, 2022



# Patient-Centric Design of Long-Acting Injectable Drug Products VIRTUAL WORKSHOP

**Wednesday, March 9, 2022**

**10:00 AM – 12:00 PM (EST)      Part 1: Overview of Current Landscape of LAI Drug Product Development**

10:00 AM – 10:10 AM	Introduction and Welcome Simone Alidori, Ph.D., GSK
10:10 AM – 10:40 AM	Introduction and Overview of LAIs in the market with a focus on sustained release formulations Rene Holm, Ph.D., SDU
10:40 AM – 11:10 AM	Formulation and manufacturability challenges/opportunities for design and development of LAIs Rob Lee, Ph.D., Lubrizol
11:10 AM – 11:40 AM	Current status and gaps in biopredictive in-vitro method development and in vivo models for LAI mechanistic understanding Diane Burgess, Ph.D., University of Connecticut
11:40 AM – 12:00 PM	Panel Discussion and Closing Remarks

**2:00 PM – 4:00 PM (EST)      Part 2: Regulatory Learnings and Opportunities for Improvement/Acceleration of LAI DP Development**

2:00 PM – 2:05 PM	Introduction and Welcome Banu Zolnik, Ph.D., US Food and Drug Administration
2:05 PM – 2:35 PM	Current status and gaps in in vivo method development for LAI mechanistic understanding Jaymin Shah, Ph.D., Pfizer
2:35 PM – 3:05 PM	Current status and gaps in mechanistic in-silico modeling for clinical translation and performance Viera Lukacova, Ph.D., Simulation Plus

3:05 PM – 3:35 PM	<p>Opportunities and challenges for LAI development from a Regulatory Perspective</p> <p>Banu Zolnik, Ph.D., US Food and Drug Administration</p> <p>Melody Courtney, Ph.D., GSK</p>
3:35 PM – 4:00 PM	Panel Discussion and Closing Remarks

#### Thursday, March 10, 2022

<b>10:00 AM – 12:00 PM (EST)</b>	<b>Part 3: Development Journeys</b>
10:00 AM – 10:05 AM	<p>Introduction and Welcome</p> <p>Raju Subramanian, Ph.D., Gilead</p>
10:05 AM – 10:50 AM	<p>Lenacapavir</p> <p>Raju Subramanian, Ph.D., Gilead</p> <p>Martin Rhee, Ph.D., Gilead</p>
10:50 AM – 11:50 AM	<p>Cabenuva</p> <p>Bill Spreen, Ph.D., ViiV</p> <p>Deepak Mundhra, Ph.D., GSK</p>
11:50 AM – 12:00 PM	<p>Closing Remarks</p> <p>Raju Subramanian, Ph.D., Gilead</p>
<b>2:00 PM – 4:00 PM (EST)</b>	<b>Part 4: Final Panel Discussion and Road Map</b>
2:00 PM – 2:05 PM	<p>Introduction and Welcome</p> <p>Chris Rhodes, Ph.D., Baywind Bioventures</p> <p>Liping Zhou, Ph.D. AstraZeneca</p>
2:05 PM – 2:55 PM	<p>Development Journey: Long Acting Injectables</p> <p>Wenyu Dong, Ph.D., Janssen</p>
2:55 PM – 3:45 PM	<p>Panel Discussion: Development Journeys</p> <p>Chris Rhodes, Ph.D., Baywind Bioventures</p> <p>Liping Zhou, Ph.D. AstraZeneca</p> <p>Raju Subramanian, Ph.D., Gilead</p> <p>Bill Spreen, Ph.D., ViiV</p> <p>Deepak Mundhra, Ph.D., GSK</p> <p>Wenyu Dong, Ph.D., Janssen</p>
3:45 PM – 4:00 PM	<p>Closing Remarks</p> <p>Simone Alidori, Ph.D., GSK</p> <p>Banu Zolnik, Ph.D., US Food and Drug Administration</p>