

An AAPS Virtual Event

Roadmapping the Clinical and Regulatory Paths of Subcutaneous Products and Technologies

FEBRUARY 23, 2023



Roadmapping the Clinical and Regulatory Paths of Subcutaneous Products and Technologies

VIRTUAL WORKSHOP

Thursday, February 23, 2023

11:00 AM – 1:00 PM (EST) Part 1: Technologies to Facilitate High-Dose SC Administration

11:00 AM – 11:05 AM **Introduction and Welcome**
Ryan Nolan, Ph.D., Halozyme

11:05 AM – 11:30 AM **Subcutaneous Injection Technologies: A Non-Aqueous Approach**
Steven Prestrelski, Ph.D., MBA, Xeris Pharmaceuticals

11:30 AM - 12:05 PM **Viscosity Reduction and Stability Enhancement of Monoclonal Antibody Formulations Using Derivatives of Amino Acids**
Arvind Srivastava, Ph.D., Avantor Sciences

12:05 PM - 12:40 PM **High Dose Payload Delivery Using Bioerodible Subcutaneous Implants**
Stephanie Reed, Ph.D., Secant Group

12:40 PM – 12:55 PM **SC Design Considerations to Minimize Regulatory and Execution Burden for High-Dose SC Biologics**
Gautum Shetty, Ph.D., Congruence Medical Solutions

12:55 PM – 1:00 PM **Closing Remarks**
Ryan Nolan, Ph.D., Halozyme

3:00 PM – 5:00 PM (EST) Part 2: Trial Designs and Regulatory Considerations for SC Development Paths

3:00 PM – 3:05 PM **Introduction and Welcome**
Ryan Nolan, Ph.D., Halozyme

3:05 PM – 3:35 PM	Ultralong Acting Injectables for HIV Treatment and Prevention: Clinical Pharmacology Consideration for Developing the Next Generation of Therapeutics Andrew Weber, MS, ViiV Healthcare
3:35 PM – 4:00 PM	Developing Subcutaneous Dosing Alternatives to High-Dose Intravenous Infusions for Monoclonal Antibodies - Clinical Bridging Approach Beate Bittner, Ph.D., F. Hoffmann - La Roche
4:00 PM – 4:55 PM	Moderated Panel: Trial Designs and Regulatory Considerations for SC Development Paths including Role of Virtual Data in Successful Bridging Studies Kaoutar Abbou Oucherif, Ph.D., Eli Lilly Beate Bittner, Ph.D., F. Hoffmann - La Roche Steve Gowers, MS, TPP Ramesh Kashi, Ph.D., Bristol-Myers Squibb Yow-Ming Wang, Ph.D., US Food and Drug Administration (FDA) Andrew Weber, MS, ViiV Healthcare
4:55 PM – 5:00 PM	Closing Remarks Ryan Nolan, Ph.D., Halozyme