PQRI BTC 2020 Webinar Series

*Regulatory Requirements and Scientific Considerations for Biosimilar Products*

Moderator: Margareth R. C. Marques, M.Sc., Ph.D., USP

Presenters:
- Stacey Ricci, M.Eng., Sc.D., FDA
- Leah Christl, Ph.D., Amgen
- Sundar Ramanan, Ph.D., Biocon Biologics
I. Welcome and Overview of Webinar
   Moderator: Margareth R. C. Marques, M.Sc., Ph.D., USP

II. Biosimilar and Interchangeable Products in the United States: Scientific and Regulatory Concepts
   Stacey Ricci, M.Eng., Sc.D, FDA

III. Global Regulatory Requirements for Biosimilar Products – Established and Emerging Regions
   Leah Christl, Ph.D., Amgen

IV. Emerging Scientific Considerations in the Development of Biosimilars
   Sundar Ramanan, Ph.D., Biocon Biologics

V. Moderated Q&A Session with the speakers
This webinar is being recorded.

The recording will be posted on the PQRI website at [www.pqri.org](http://www.pqri.org) after the webinar.

**Your Participation**

- If you have not done so already, please press #[Your Audio Pin]#

- **Note:** Today’s presentation is being recorded.
Questions

- Submit written questions using the Questions Panel.
- Raise your hand to be unmuted for verbal questions.

*Note: Today’s presentation is being recorded.*
Mission:
PQRI is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation.
What Does PQRI Do?

- Unites thought leaders from regulatory agencies, standard setting bodies, industry and academia to conduct research and share knowledge on emerging scientific and regulatory quality challenges.

- Provides a unique, neutral forum to develop broad consensus among a diverse collection of industry organizations and regulatory bodies.

- Creates opportunities to accomplish mutual goals that cannot be achieved by individual organizations.

- Impacts global regulatory guidance and standards, bringing maximum value to members and patients.
PQRI Structure

- PQRI consists of two governing bodies – a Board of Directors and Steering Committee and three Technical Committees,

- Technical Committees each have a broad disciplinary focus that collectively spans the drug product regulatory lifecycle. They establish and provide scientific guidance, direction and oversight to PQRI working groups and research projects.

- Current PQRI Technical Committees:
  - Biopharmaceutics Technical Committee (BTC)
  - Development Technical Committee (DTC)
  - Product Quality Technical Committee (PQTC)

- This webinar is sponsored by the BTC.

- You can find out more information about the TCs on the PQRI website: [https://pqri.org/about-pqri/](https://pqri.org/about-pqri/)
PQRI Webinars

2020 Webinars

- **SEPTEMBER 16, 2020: Regulatory Requirements and Scientific Considerations for Biosimilar Products**: Presenters: Stacey Ricci, M.Eng., Sc.D, FDA; Leah Christl, Amgen; Sundar Ramanan, Ph.D., MBA, BioCon
- **BTC/PQTC Webinar Series: Excipient Considerations for Parenteral Drug Development (July 29, 2020)** Presenters: Janeen Skutnik-Wilkinson (Biogen) and Thomas Tice, Ph.D., Evonik
- **The Challenge and the Promise: Developing Complex Drug Products (April 28, 2020)** Presenters: Wenlei Jiang, Ph.D., FDA and Adrian Goodey, Ph.D., Merck

2019 Webinars

- **The Expanding IVIVC Toolbox to Enable Drug Product Quality and Clinical Pharmacology – Complementary Traditional and PBPK Based Approaches (June 7, 2019)** Presenters: Xianyuan (Susie) Zhang, Ph.D., FDA and Filippos Kesisoglou, Ph.D., Merck
- **Holistic QbD to Enable Product Quality Webinar (October 10, 2019)** Presenters: Ajit Narang, Ph.D., Genentech; Rakhi Shah, Ph.D., FDA; Xavier Pepin, Pharm.D, Ph.D; Divyakant Desai, Ph.D., BMS; Xavier Pepin, Pharm.D, Ph.D., AstraZeneca

2018 Webinars

- **A Science Based Approach to Simplifying the Regulatory Pathway for Topical Drugs (April 9, 2018)** Presenters: Vinod P. Shah, Ph.D., FAAPS, FFIP and Flavian Radulescu, Ph.D.
- **Questions about the Proposed Topical Classification System (TCS) and What To Do With It (June 19, 2018)** Presenter: Sam Raney, Ph.D., FDA
- **Performance Testing in Quality Control and Product Development, Where are We? (October 23, 2018)** Presenter: Raimar Löbenberg, Ph.D., University of Alberta
- **Biowaiver Approaches for Solid Oral Dosage Forms in New Drug Applications (December 6, 2018)** Presenter: Poonam Delvadia, Ph.D., FDA

Posted at [https://www.gotostage.com/channel/pqriwebinars](https://www.gotostage.com/channel/pqriwebinars)
Pre-Workshop Events

- Pre-Workshop Survey
  - Obtain feedback from possible workshop attendees to understand the types of challenges they have experienced with their own organizations during the implementation of ICH Q3D. The results of the survey will be blinded, aggregated and shared during the November Workshop.
  - Click here to complete the survey.

- FREE Pre-Workshop Preview Webinar
  - To be held on Monday, September 21st.
  - Click here to register.

4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements
November 9-10, 2020
LIVE VIRTUAL EVENT
Click here for registration.

Please register for the workshop (even if you can’t attend it live); sessions will be recorded and made available to registered attendees.

See https://pqri.org/4th-pqri-ei-workshop/ for more information
Stacey Ricci, M.Eng., Sc.D.
Director of Scientific Review Staff
Office of Therapeutic Biologics and Biosimilars (OTBB)
Center for Drug Evaluation and Research (CDER)
US Food and Drug Administration
Stacey.Ricci@fda.hhs.gov

Dr. Ricci is the Director of the Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars within the Office of New Drugs, CDER, FDA. Dr. Ricci leads a multidisciplinary team that provides oversight of biosimilar and interchangeable products at all stages of their development and ensures consistency in the cross-disciplinary scientific and regulatory advice provided to sponsors for their products. During her 15-year tenure at FDA, Dr. Ricci’s work has focused primarily on the scientific and regulatory review of biotechnology-derived therapeutic proteins, including making major contributions to FDA guidance and standards development for biosimilars and other protein therapeutics. Prior to joining FDA, Dr. Ricci completed post-doctoral research at the University of Pennsylvania, received a Doctor of Science from Tulane University, and a Master of Engineering and Bachelor of Science from Cornell University.
Today’s Presenters

Leah Christl, Ph.D.
Executive Director of Global Regulatory and R&D Policy
Amgen
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Dr. Christl is currently an Executive Director of Global Regulatory and R&D Policy at Amgen. She supports Global Biosimilars and serves as the ICON GRR&D Policy Lead. Prior to joining Amgen, Dr. Christl served as the Associate Director for Therapeutic Biologics in the Office of New Drugs (OND) in the FDA's Center for Drug Evaluation and Research (CDER). In this role, she developed and led CDER’s approach to implementation of the Biologics Price Competition and Innovation Act (BPCIA) of 2009. Dr. Christl was also the director of the Therapeutic Biologics and Biosimilars Staff (TBBS) at the US FDA and served as a scientific, regulatory, and policy expert to FDA, HHS, and external stakeholders, on biosimilar products. Dr. Christl also engaged in international activities by serving as a CDER and FDA strategist and lead for international activities related to biosimilars, including serving as FDA lead for the FDA-EMA-Health Canada-PMDA biosimilars cluster and the International Pharmaceutical Regulators Programme – Biosimilars Working Group. Dr. Christl received her PhD in Molecular and Cellular Biology and Pathobiology – Marine Biomedicine and Environmental Science from the Medical University of South Carolina in Charleston.
Today’s Presenters

Sundar Ramanan, Ph.D.
Vice President & Head – Global Regulatory Affairs
Biocon Biologics
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Dr. Ramanan is a seasoned regulatory affairs executive with expertise across biopharmaceutical drug development, operations, clinical & commercial strategy, policy and regulatory affairs. Prior to Biocon, he was responsible for Amgen’s International Regulatory Strategy and Policy for Biologics & Biosimilars, and helped shaped biosimilar standards globally. He has successfully led teams in the development of biopharmaceutical drug candidates from the early stages through commercialization, and life-cycle management across multiple therapeutic areas. He is also an internationally recognized expert in biologics, including biosimilars, for science-based policy engagement with regulators, health-ministry and industry trade organizations.

Sundar is also an accomplished author and speaker. He is a Chemical Engineer by training; holds a Ph.D. in Bioengineering from Oregon State University and MBA from the University of Michigan.
Thank you for attending the webinar!

For more information on PQRI, visit our website at:  
www.pqri.org

Questions? Contact the PQRI Secretariat at:  
PQRISecretariat@pqri.org

Call for Volunteers
If you or your company is a member of a PQRI member organization (CHPA, FDA, Health Canada, IPEC-Americas, PDA or USP) and you would like to participate in any of the PQRI Technical Committees, please contact the PQRI Secretariat (PQRISecretariat@pqri.org) for further information.