

PQRI PQTC 2025 Webinar

Understanding Complete Response Letters: Key Findings and Strategic Resolutions in Regulatory Affairs



October 30, 2025

Agenda

- Welcome and Overview of Webinar (5 min)
 - Cat Vicente, Johnson & Johnson, PQRI PQTC Chair
- Presentations (15 minutes each)
 - ***Review of the FDA CRL Issue Facing Pharma Manufacturing***
 - Glenn E. Wright, President & CEO, Parenteral Drug Association (PDA)
 - ***The Evolving Landscape of CRL Interpretation***
 - Fidelle Jarmon, Vice President of Customer Engagement & Quality Partnerships, Minaris Advanced Therapies
- Open Q&A /Moderated Discussion (55 min)

All above plus Stelios C. Tsinontides, PhD, FAIChE, Vice President, Global Quality, Quality Management Systems, Transformation & External Advocacy, Merck & Co., Inc.

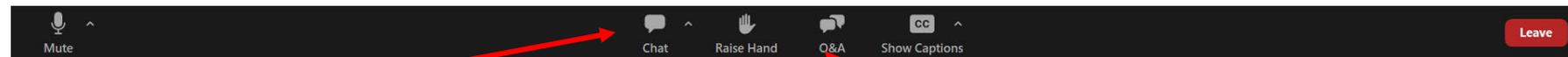
Housekeeping

- All Attendees are on mute.
- Webinar is recorded and will be posted on the PQRI website.

Understanding Complete Response Letters: Key Findings and Strategic Resolutions in Regulatory Affairs



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- The Chat function has been disabled for Attendees.

Type your question in the Q&A box.

Raise hand to ask a verbal question.



Product Quality Research Institute (PQRI)

What is PQRI? *A neutral form for regulators and industry to advance pharmaceutical regulations, standards and science.*

Mission:

PQRI is a non-profit consortium of organizations, including standard setting and regulatory agencies working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation.



Health
Canada

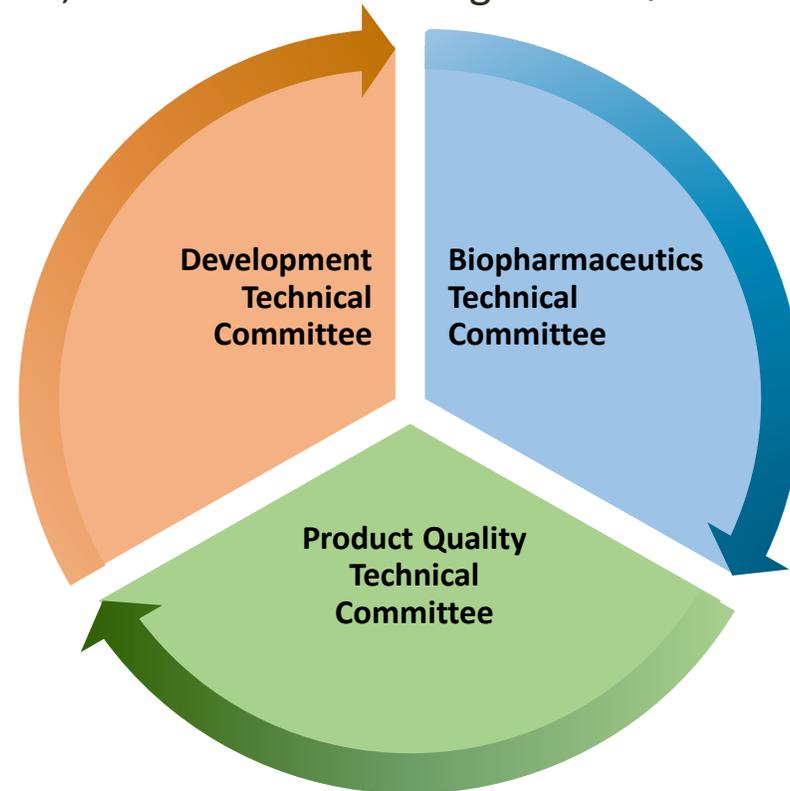


What Does PQRI Do ?

- 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 common understandings of current scientific, technical and regulatory challenges among a diverse collection of industry organizations, FDA, and other 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 **PQTC**.
 - You can find out more information about the TCs on the PQRI website: <https://pqri.org/about-pqri/>



Review of the FDA CRL Issue Facing Pharma Manufacturing

Glenn E. Wright, MA, Parenteral Drug Association

Glenn Wright is currently the President and CEO, PDA. Glenn has more than 30 years of experience in the pharmaceutical industry. Previously, he served in various technical and senior leadership positions at Exelead, Eli Lilly, Amgen, and Pfizer. He has extensive technical, regulatory, and quality expertise in both small molecule and biologic drug substance manufacturing as well as sterile injectable drug product manufacturing. Glenn has served on the PDA Board of Directors, Science Advisory Board, and Program Advisory Board. In addition, he has chaired numerous PDA meetings, Task Forces, and Steering Committees. Glenn is a frequent speaker at PDA and industry events. He received his BS and MS degrees in Microbiology from Southern Illinois University.



The Evolving Landscape of CRL Interpretation



Fidelle Jarmon, Vice President of Customer Engagement & Quality Partnerships, Minaris Advanced Therapies

Fidelle Jarmon is currently the Vice President of Customer Engagement & Quality Partnerships at Minaris Advanced Therapies. In this role, Fidelle serves as the strategic link between clients and contract manufacturing quality operations, ensuring every customer interaction is grounded in compliance, transparency, and operational agility. She is the trusted Quality partner who collaborates with Business Development, Regulatory Affairs, and Technical Operations to facilitate new product introductions, technology transfers, and market expansion.

Prior to joining Minaris Advanced Therapies, Fidelle was the Head of External Manufacturing Regulatory Compliance at Johnson & Johnson Innovative Medicines. In this role she partnered with J&J Supply Chain to enhance compliance profiles at contract manufacturing sites, maintained strategic regulatory compliance programs for the external supply chain, and provided GXP compliance oversight for health authority regulated activities and overall commercial readiness.

Fidelle has over 20 + years of pharmaceutical expertise providing quality compliance and GMP support for the life-cycle management and manufacture of sterile drugs, OTCs, biologics, and advanced therapy products. She has extensive experience building alliance partnerships to support complex contract manufacturing supply chains, compliance remediation, tech transfers, and commercial launch from a global perspective.

Fidelle has held quality management positions of increasing responsibility at Merck, Wyeth, and Novartis. She holds a Bachelor of Arts degree in Biology from Arcadia University and a Master of Science degree in Quality Assurance/Regulatory Affairs from Temple University School of Pharmacy.



Open Q&A

Moderator: Cat Vicente, Johnson & Johnson

Panelists: Glenn Wright, PDA

Fidelle Jarmon, Minaris Advanced Therapies

Stelios Tsinontides, Merck & Co., Inc.



Product Quality Research Institute

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Stelios Tsinontides PhD, FAIChE, Merck & Co., Inc., Vice President, Global Quality, Quality Management Systems, Transformation & External Advocacy

Dr. Stelios Tsinontides is Vice President of Global Quality, Merck & Co., Inc. He is the Head of Quality Management Systems, Transformation and External Advocacy for Merck Manufacturing Division globally. Prior to joining Merck & Co., Dr. Stelios Tsinontides served as Director of the Office of Pharmaceutical Manufacturing Assessment (OPMA) under the Office of Pharmaceutical Quality (OPQ) in CDER from October 2019 to March 2025. OPMA evaluates facilities, process design, and control strategies to assess capabilities of manufacturers to produce quality pharmaceutical and biotechnology products at commercial scale and provides leadership and technical expertise to Agency components internal and external to the Office of Pharmaceutical Quality regarding manufacturing quality issues. Prior to joining the FDA, Dr. Tsinontides served in senior-level positions in the pharmaceutical industry - most recently as Shire's Head of Small Molecule Drug Product Technical Services. His group was responsible for providing scientific and technical expertise for SM Drug Product scale-up and commercial manufacturing activities worldwide, to ensure the establishment of commercial robust manufacturing processes and a continuous supply of products to patients. Dr. Tsinontides holds a B.E. in Chemical Engineering from City College of CUNY and an M.A. and Ph.D. in Chemical Engineering from Princeton University. He also attended the Wharton Management Program at the University of Pennsylvania. Dr. Tsinontides was elected Fellow at the American Institute of Chemical Engineering (AIChE) in 2016.



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 (ELSIE, FDA, Health Canada, IPEC-Americas, IPAC-RS, 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.

