



Puerto Rico  
Section  
Excellence Through Quality®

# ASQ PUERTO RICO ANNUAL CONFERENCE

**TRANSFORMING EXCELLENCE:**

*Engaging People and Technology for  
Quality Improvement*

## CONFERENCE PROGRAM

November 14, 2024  
Salon Artaban, Ponce PR

Price: \$107.94  
Register in [www.eventbrite.com](http://www.eventbrite.com)  
<https://lnkd.in/gHDQy6MV>

CIAPR Technical Credits for Engineers & General for Surveyors: 4.0 hrs ASQ RU: 0.6



ASQ PR ANNUAL CONFERENCE 2024

## Engaging People and Technology for Quality Improvement



### Message from ASQ PR Section Chair

Welcome to this year's conference, **Transforming Excellence: Engaging People and Technology for Quality Improvement**, proudly hosted by ASQ Puerto Rico - Section 1500 in celebration of World Quality Month this November. We are thrilled to gather ASQ members, industry leaders, and professionals dedicated to advancing quality standards worldwide. This year's theme highlights the critical role of people and technology in shaping the future of quality management, aligning with our mission to empower individuals and communities to achieve excellence through quality.

Our agenda is filled with dynamic sessions and expert speakers who will share insights, experiences, and innovations to inform and inspire you. We hope these discussions energize your dedication to quality improvement and provide meaningful connections within our community. Also, individuals holding ASQ Certifications will earn 0.6 Recertification Units (RU) credits for participating in this event.

We extend our heartfelt gratitude to all participants, speakers, and sponsors for their invaluable contributions in making this conference an exceptional experience. Together, let us continue to elevate quality standards, working toward a better world.

Thank you for joining us—let's make this World Quality Month an inspiring celebration of excellence!

Eileen Serrano, ASQ CQE, CSSBB, CMQ/OE  
ASQ PR - Section 1500  
Chair 2024 - 2025



ASQ PR ANNUAL CONFERENCE 2024

Engaging People and Technology for Quality  
Improvement

## Event Agenda

NOV 14, 2025 12PM TO 6PM - SALON ARTABAN, PONCE PR

<b>12:00pm</b>	<b>Registration and Lunch</b>
<b>1:00pm</b>	<b>Welcome Message &amp; Conference Kickoff</b> Eileen Serrano, ASQ PR Chair 2024 - 2025
<b>1:30pm</b>	<b>FDA Inspection Readiness: Before, During, and After</b> Ariel Cruz, Retired FDA Consumer Safety Officer
<b>2:30pm</b>	<b>Quality Directors Discussion Panel</b> Mabel Andujar - Zimmer Biomet, Gilberto Lopez - Medtronic Ponce, Glenda Quinones - Baxter Aibonito
<b>3:30pm</b>	<b>COFFEE BREAK</b>
<b>3:45pm</b>	<b>E-Quality: Digitize to Optimize</b> Jesus Berrios Portela, Vice-President & Co-founder SOLTECHPR
<b>4:45pm</b>	<b>Leadership in Quality: Engaging People in the Digital Landscape</b> Mayra Lopez, Associate Director Human Resources - Zimmer Biomet
<b>5:30pm</b>	<b>Closing Remarks</b> Eileen Serrano, ASQ PR Chair 2024 - 2025
<b>5:45pm</b>	<b>Networking cocktail</b>





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# Presentation Briefs

### FDA INSPECTION: BEFORE, DURING, AND AFTER

Ariel Cruz - Retired FDA Consumer Safety Officer

This session will provide a comprehensive perspective on preparing for and managing FDA Good Manufacturing Practices (CGMP) inspections, drawing from a former investigator with the Food and Drug Administration, including best practices in preparing for an inspection based on CGMP standards, expected conduct during the inspection, including recommended behaviors and key insights on what to anticipate from the investigator and essential post-inspection activities to support compliance and continuous improvement.

Session key takeaways:

- Equip attendees with actionable strategies to enhance their inspection readiness.
- Offer insights into effective engagement and best practices during an inspection.
- Provide guidance on closing an inspection, with an emphasis on responding to observations and identifying lessons learned for ongoing improvement.

### DISCUSSION PANEL

### THE FUTURE OF QUALITY MANAGEMENT IN A DIGITAL WORLD

Mabel Andujar - Zimmer Biomet, Gilberto Lopez - Medtronic Ponce, Glenda Quinones - Baxter Aibonito

This panel discussion will bring together Quality Directors to share insights into the impact of digitization on quality management in the coming years. Panelists will discuss the challenges and strategies associated with implementing digital tools, the integration of these tools with established systems, and the opportunities digitization offers for enhancing quality metrics. Additionally, they will explore how to prepare teams for digital adaptation and foster a culture ready for continuous improvement. Panel key takeaways:

- Understand the anticipated impact of digitization on quality management practices over the next 3-5 years.
- Gain insight into the challenges and solutions related to integrating digital tools with existing quality systems and processes.
- Explore strategies to prepare and support teams in adapting to digital tools for improved quality performance.

### E-QUALITY: DIGITIZE TO OPTIMIZE

Jesus Berríos Portela, Vice-President & Co-founder SOLTECHPR

This session will explore how digital tools can transform quality processes in the industry. It will discuss a variety of digital solutions available, their application in quality improvement and how these tools can benefit both users and the business. Session key takeaways:

- Learn about the digital tools available to optimize quality management.
- Identify the solutions these tools are pursuing in the industry.
- Understand how these tools help both the user and the business to improve efficiency and become more agile.
- Evaluate the impact of digitization on continuous improvement of quality processes.
- Develop strategies for the successful implementation of digital tools in quality systems.

### LEADERSHIP IN QUALITY: ENGAGING PEOPLE IN THE DIGITAL LANDSCAPE

Mayra Lopez, Associate Director Human Resources - Zimmer Biomet

In today's rapidly evolving digital environment, quality leaders are called to develop new skills and strategies to guide their teams through technological transformation. This session will focus on essential leadership competencies for the digital era, emphasizing how quality leadership can foster engagement, innovation, and continuous learning. Attendees will gain insights on cultivating a digitally adept workforce, fostering cross-functional collaboration, and embedding a culture of agility and innovation. Session key takeaways:

- Identify key leadership skills essential for guiding quality teams through digital transformation and fostering a culture of innovation.
- Explore strategies to upskill and prepare employees for future digital trends, enhancing readiness for technology-driven roles.
- Understand methods for encouraging cross-functional teamwork and agile collaboration within a tech-driven quality framework.





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# Keynote Speakers



### **ARIEL CRUZ** **RETIRED FDA CONSUMER SAFETY OFFICER**

Born in Peñuelas, Ariel Cruz earned a Bachelor of Science in Chemistry from the University of Puerto Rico, Río Piedras. With a career spanning over four decades in the pharmaceutical industry, Ariel held key roles beginning as an Analytical Chemist at AH Robins in 1980, followed by various supervisory and management positions at Bristol Myers, Whitehall, Warner Lambert, Searle, Pfizer, MOVA Pharmaceutical, and Patheon. In 2007, he achieved certification as a Lean Six Sigma Black Belt with the American Society for Quality, furthering his expertise in operational excellence. In 2014, he joined the U.S. Food and Drug Administration as a Consumer Safety Officer, serving until his retirement in December 2023.



### **JESUS BERRIOS** **VICE PRESIDENT & CO-FOUNDER SOLTECHPR**

Jesus Berrios is an industrial Engineer, graduated from the University of Puerto Rico in Mayagüez, with a Master's Degree in Marketing from the University of Turabo. He has over 18 years of experience in the medical device and biotechnology industry. As Co-Founder of SOLTECHPR, Jesús is passionate about continuous improvement and digitalization, focusing his career on driving innovation and efficiency in these sectors.



### **MAYRA LOPEZ** **ASSOCIATE DIRECTOR HUMAN RESOURCES ZIMMER BIOMET**

Mayra D. López Alvarez, MPA, is a seasoned Human Resources Executive with over 30 years of experience in strategic HR and operational leadership. Known for her passion for life, family, and mentoring others, she brings a deep commitment to personal and professional development. Mayra holds a Master of Public Administration from Syracuse University and a Bachelor of Arts in Economics from the University of Puerto Rico, Mayagüez. Her professional career includes her current role as Associate Director of Human Resources at Zimmer Biomet, along with previous leadership positions at CPM Puerto Rico, Rovira Biscuit Corporation, and at Roche Operations Ltd. A dedicated SHRM Puerto Rico member, she has served as both Past President and Board Director.



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### Panelists



#### **MABEL ANDUJAR** **QA DIRECTOR - ZIMMER BIOMET**

With over 23 years of experience in the medical device industry, Mabel Andújar leads Quality Operations across Zimmer Biomet sites in Puerto Rico, Delaware, and Virginia. Known for building high-performing teams, Mabel's leadership has led to the promotion of all her Quality Assurance staff over the past four years. Certified in Six Sigma, CAPA, and auditing, Mabel specializes in FDA Warning Letter remediation and regulatory compliance, maintaining strong ties with the Regulatory Agencies to ensure Zimmer Biomet's ongoing success.



#### **GILBERTO LOPEZ-ARROYO** **MFG OPERATIONS QA DIRECTOR – MEDTRONIC PONCE CAMPUS**

With 20+ years of experience in the medical device industry, Gilberto has held various different roles within quality at leading companies including Johnson & Johnson, Abbott and Medtronic. He earned his bachelor's degree in Industrial Engineering from the Mayagüez Campus of the UPR and is a subject matter expert in Process Validation and Design Transfer. Currently, as Quality Leader of the Medtronic Ponce Campus Medtronic Ponce Campus, he is dedicated to improve the quality and compliance in the manufacturing of medical devices through the implementation of efficient and robust processes, always prioritizing patient safety.



#### **GLEND A QUIÑONES** **QUALITY DIRECTOR - BAXTER AIBONITO**

Glenda Quiñones is a seasoned quality management and operations professional with over 26 years of experience in the medical device and pharmaceutical industries. Glenda's career journey includes roles from Solution Formulation Technician to Senior Regional Quality Manager, with achievements in implementing Quality Management Systems (QMS), managing FDA audits, and supporting manufacturing transfers. She holds a B.S. in Biology with a concentration in Microbiology and a minor in Chemistry from the University of Puerto Rico. Known for her inspirational leadership and dedication to excellence, Glenda remains committed to advancing quality and public health standards across the industry.





## **BECOME A MEMBER TODAY!**

Calling all champions of quality, change-makers, visionaries of progress and masterminds in the pursuit of excellence. The future of quality and continuous improvement needs you.



## **ASQ PUERTO RICO LEARNING COURSES!**

Learn from the best. Certification preparation courses delivered by recognized, quality-focused instructors with more than 20 years of experience.



## **BECOME A SPEAKER!**

Are you using quality concepts and tools in new or unique ways? How are your quality efforts driving bottom line results? Are you and your team exploring and developing new quality procedures? Submit your proposal and come share how you are taking quality to the next level.