

August 8, 2019



Sheraton Convention Center
Hotel, San Juan PR

7:30 AM	Registration	
8:30 AM	Welcoming Remarks	Wendy Perry President Pharmaceutical Industry Association (PIA) Gloria Martínez , Chairperson PIA Quality Committee
9:00 AM	Update FDA Trends	Alonza Cruse , Director Office of Pharmaceutical Quality Operations
9:30 AM	Update FDA Trends for Combination Products	Nydia Colón , Investigator Medical Devices, FDA
10:00 AM	Leading Change in a Changing Environment	Steve Greer , Corporate External Engagement, Procter & Gamble
10:30 AM	Morning Break	
11:00 AM	Uses of Artificial Intelligence in Pharma Applications	Daniel L. Weese , Executive Director Quality, Amgen; Mark DiMartino , Director Data Sciences, Amgen; Jorge Delgado , Sr. Manager Process Development, Amgen
12:00 PM	Q&A Morning Session	Morning Speakers
12:30 PM	Lunch	San Juan 6-8 Ballrooms
1:30 PM	New Regulations in Nutritional Products	Ramón Hernández , Director Investigations Branch San Juan District, FDA
2:00 PM	Innovation in Combination Products	Adaliz Santaliz , Medical Device Specialist, FDA
2:30 PM	Panel: Approaches to Human Error Reduction	Anthony Mire-Sluis, PhD , Head of Global Quality, AstraZeneca Pharmaceuticals; Adaliz Santaliz , Medical Devices Specialist, FDA; Sonia Soto , Quality Control Consultant, Lilly; Iveliz Kock, PhD , Director Regulatory Compliance, J&J
3:45 PM	Afternoon Break	
4:00 PM	One Compliance Culture	Tia Bush , Sr. Vice President of Quality, Amgen
4:30 PM	Effective Organization and Talent Management of Quality Resources in the Global Setting	Esther M. Alegría, PhD Senior Advisor, CatalystExcel & Advance
5:00 PM	Q&A Afternoon Session	Afternoon Speakers
5:30 PM	Networking Activity	

Regulations

Compliance