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CONFERENCE COMPENDIUM

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ELITE FACULTY WITH REPRESENTATION FROM



Arif Azad
Head of TechOps
Equipment and
Computer System
Validation
Pfizer



Chip Bennett, PMP
Senior Director
ProjectFarma
a PerkinElmer Company



Joscelyn Bowersock
Senior Director Quality
Assurance and
Regulatory
Precision for Medicine



Olivia Calder
Process Engineer
Kneat



Bob Castellucci
Principal Consultant
PQE Group



Jorge A. Cordero
Validation Manager
Bausch+Lomb



Adelberto Cordova
Head of Quality
Emerald Cloud Lab



David DeLuca
Director, Strategic
Consulting
Compliance Group



Cindy Duhigg
Senior Principal, Global
Manufacturing Science &
Technology Engineering
Alcon Laboratories



Parsa Famili
President & CEO
Novatek International



Jeff Felker
Deputy Director,
Cleaning SME
Sanofi



Joanne Goldberg
Sr. Principal
Business Analyst
Medtronic



Joachim Gutheil
Manager IT Quality
Abbott BTS
(Business &
Technology Services)



Dijana Hadziselimovic
Manager, Laboratory
Technical Services,
STERIS Corporation



Connie Hetzler
Global Validation Head
Alcon Laboratories



Leslie Lighton-Humphreys
Senior Manager
Compliance and Process
Management
Cencora



Kim Huynh-Ba, M.S.,
FAAPS, Managing Director,
Pharmalytik LLC and
Adjunct Faculty, RAQA,
Temple University



Rishabh Jain
Quality Assurance
Manager
Tetrapak

ELITE FACULTY WITH REPRESENTATION FROM



Reshma Kodumuru
Principal CSV
KBI BioPharma



Louie Rayal
VP of Governance
Risk and Compliance
GSK



Monica Manepalli
Sr.CSV/CSA Consultant
Compliance Group



Shreyans Shah
Director of Quality
Accumulus Synergy



Dawn Marshall (Tavalsky)
Global External
Manufacturing - Quality
Sanofi



Tara Scherder
Principal
SynoloStats



Shanna McGovern, Ed.D.,
President
Guide Star Consulting



Ken Shitamoto
Executive Director IT
Gilead Sciences



Giovana Mobiglia
Senior Process
Validation Engineer
Pfizer



Rohit Tyagi
President
Sagax Team



Ravi Moorthy
President
Quascenta



Gaurav Walia,
VP of CSV/CSA/DI & Digital
Governance, Head of
Chicago PQE Office & Sr.
Associate Partner,
PQE Group



Khaled Moussally
EVP, Corporate
Development &
Operations
Compliance Group



Jim Watson
Vice President
ProjectFarma
a PerkinElmer Company



Subhabrata Purakayastha
Associate Director and
Head of Enterprise
GxP IT Systems Quality
Incyte Corporation



Francisco Vicenty
(Former FDA)
Director of Continuous
Improvement
Getinge



Sarada Ramamoorthy
Head of Strategic
Consulting (India)
Compliance Group



Robert Yaffe
America Sales Manager
KAYE

7:20 - 8:20AM	Registration - Coffee & Tea
8:20 - 8:30 AM	Chairperson's Opening Remarks
  8:30 - 9:00 AM SYMPHONY	Keynote Presentation <u>Navigating Cost and Resource Constraints: Balancing Efficiency with Quality</u> Connie Hetzler, Global Validation Head, Alcon Laboratories
  9:00 - 10:00 AM SYMPHONY	Panel Discussion <u>Adopting Industry/Pharma 4.0: Integrating AI and Machine Learning into Validation</u> Moderator: Gaurav Walia, VP of CSV/CSA/DI & Digital Governance, Head of Chicago PQE Office & Sr. Associate Partner, PQE Group Panelists: Aldelberto Cordova, Head of Quality, Emerald Cloud Lab Connie Hetzler, Global Validation Head, Alcon Laboratories Louie Royal, VP of Governance Risk and Compliance, GSK Bob Castellucci, Principal Consultant, PQE Group
10:00 - 10:30 AM	Exhibitor Showroom and Refreshment Break
  10:30 - 11:00 AM SYMPHONY	Quality Risk Management (QRM): <u>Integrating ICH Q9 into Validation Processes</u> Chip Bennett, PMP, Senior Director, ProjectFarma , a PerkinElmer Company
  11:00 - 12:00 PM SYMPHONY	Panel Discussion <u>Modernizing Process Validation: Strategies for Stage 1-3 Compliance and Efficiency</u> Presenter: Jorge A. Cordero, Validation Manager, Bausch+Lomb Panelists: Joanne Goldberg, Sr. Principal Business Analyst, Medtronic Giovana Mobiglia, Senior Process Validation Engineer, Pfizer Ravi Moorthy, President, Quascenta
12:00 - 1:00 PM BALCONY	Roundtable Luncheon - Topics Include:
VMP	Validation Master Plans: Blueprinting Success for Compliance and Efficiency Leslie Lighton-Humphreys, Senior Manager Compliance and Process Management, Cencora
Single-Use	<u>Single-Use Systems in Validation: Balancing Flexibility and Compliance</u> Aldelberto Cordova, Head of Quality, Emerald Cloud Lab
Decommission	<u>Decommissioning with Confidence: Validation Strategies for Equipment Lifecycle Management</u> Joscelyn Bowersock, Senior Director Quality Assurance and Regulatory, Precision for Medicine

1:00 - 1:40 PM	Select Between Knowledge Exchange Sessions	
 Digitalization SYMPHONY		<u>Digital Validation Tools: Harnessing Data Analytics and Predictive Modeling for the Future</u> Moderator: Khaled Moussally, EVP, Corporate Development & Operations, Compliance Group Panelists: Francisco Vicenty (Former FDA), Director of Continuous Improvement, Getinge Parsa Famili, President & CEO, Novatek International
 CSV ARIA A		<u>CSV 4.0: Validating AI, SaaS, and Cloud-Based Systems</u> Subhabrata Purakayastha, Associate Director and Head of Enterprise GxP IT Systems Quality, Incyte Corporation
Industry Trends ARIA B		<u>Lean Validation: Driving Efficiency and Reducing Costs in Complex Projects</u> Joanne Goldberg, Sr. Principal Business Analyst, Medtronic
1:50 - 2:30 PM	Select Between Knowledge Exchange Sessions	
 Process SYMPHONY		<u>Redefining Medical Device Process Validation: Bridging Design, Risk, and Real-World Performance</u> Francisco Vicenty (Former FDA), Director of Continuous Improvement, Getinge
 CSV ARIA A		<u>Successfully Implementing CSA Company Wide Across Multiple Regulations: Case Study</u> Louie Royal, VP of Governance Risk and Compliance, GSK
Industry Trends ARIA B		<u>Validation in Continuous Manufacturing: Ensuring Compliance in Real-Time Processes</u> Giovana Mobiglia, Senior Process Validation Engineer, Pfizer
2:30 - 3:30 PM	Speed Networking	
3:30 - 4:10 PM	Select Between Knowledge Exchange Sessions	
 Statistics SYMPHONY		<u>Navigating Variability: Statistical Tools for Robust Process Validation</u> Tara Scherder, Principal, SynoloStats
 CSV ARIA A		<u>Risk-Based Approach to Computer Systems Validation: Simplifying Compliance</u> Ken Shitamoto, Executive Director, IT, Gilead Sciences
Industry Trends ARIA B		Automated Validation Systems: Reducing Human Error and Increasing Efficiency Joachim Gutheil, Manager IT Quality, Abbott BTS , (Business & Technology Services)

4:20 - 5:00 PM	Select Between Knowledge Exchange Sessions
 Data Integrity SYMPHONY 	<u>Strengthening Data Integrity: Regulatory Frameworks for Control and Security</u> Kim Huynh-Ba, M.S., FAAPS, Managing Director, Pharmalytik LLC and Adjunct Faculty, RAQA, Temple University
 Equipment ARIA A 	<u>Streamlining Equipment Qualification with Lean Validation Principles</u> Shanna McGovern, Ed.D., President, Guide Star Consulting
Statistics ARIA B	<u>Avoid Mistakes with Statistics: Sampling Plans, Process Capability and SPC</u> Tara Scherder, Principal, SynoloStats
5:00 PM	Networking Cocktail Reception

2025 Conference Schedule

 May 14-15 San Diego, CA 	Laboratory University Mastering Analytical Methods, Stability Testing, and QC Excellence
June 4-5 Dublin, Ireland	CSV & CSA University Dublin Ensuring Compliance and Integrity Across Traditional, Digital, and AI-Driven Systems Conference
 June 11-12 Philadelphia, PA 	Harness the Power of AI in GxP Use Cases, Process Optimization, and Validation
 August 5-6 Philadelphia, PA 	Advancing Sterility & Safety Summit Cleaning, Contamination Control & Microbiology
 September 18-19 Philadelphia, PA 	Medical Device Validation & Verification University Integrating Compliance, Design, and Post Market Success
 October 7 San Diego, CA 	GMP Bootcamp Building a Framework for GMP Success
 October 8-9 San Diego, CA 	GMP University Modernizing GMP Processes from Risk to Inspections
October 21-22 Philadelphia, PA	Pharmaceutical Engineering Summit Integrating Process, Automation, and Facility Excellence
November 19-20 Dublin, Ireland	Validation University Dublin Driving Excellence in Modern Validation & Qualification Processes
 December 9-10 San Diego, CA 	CSV & CSA University Ensuring Compliance and Integrity Across Traditional, Digital, and AI-Driven Systems

7:30 - 8:30 AM	Exhibitor Showroom Opens and Lite Breakfast
8:30 - 9:10 AM	Select Between Knowledge Exchange Sessions
 Process SYMPHONY 	Digital Tools to Improve Validation Management Ravi Moorthy, President, Quascenta
 Equipment ARIA A 	<u>Lifecycle Management of Equipment Qualification: Ensuring Continuous Compliance</u> Giovana Mobiglia, Senior Process Validation Engineer, Pfizer
Industry Trends ARIA B	<u>Real Life Industry Trends and Case Studies in AI/ML: Focus on Validation and Predictive Maintenance</u> Gaurav Walia, VP of CSV/CSA/DI & Digital Governance, Head of Chicago PQE Office & Sr. Associate Partner, PQE Group
9:20- 10:00 AM	Select Between Knowledge Exchange Sessions
Cleaning SYMPHONY 	<u>Paving the Way for AI: Establishing a Risk-Based Cleaning Validation and CCS Via Digitalization</u> Parsa Famili, President & CEO, Novatek International
 Equipment ARIA A 	<u>Breaking Down Equipment Qualification: From URS to PQ</u> Jim Watson, Vice President and Chip Bennett, PMP, Senior Director, PPProjectFarma , a PerkinElmer Company
Facility ARIA B	<u>Facility Qualification: Ensuring Regulatory Compliance Through Effective Design and Execution</u> Joscelyn Bowersock, Senior Director Quality Assurance and Regulatory, Precision for Medicine
10:00 - 10:30 AM	Exhibitor Showroom and Refreshment Break
10:30 - 11:10 AM	Select Between Knowledge Exchange Sessions
 Cleaning SYMPHONY 	<u>Driving Sustainability Through Cycle Optimization</u> Jeff Felker, Deputy Director, Cleaning SME, Sanofi Dijana Hadziselimovic, Manager, Laboratory Technical Services, STERIS Corporation
Facility ARIA A 	<u>Risk-Based Process Validation: Connecting CQAs, CPPs, and Control Strategies</u> Cindy Duhigg, Senior Principal, Global Manufacturing Science & Technology Engineering, Alcon Laboratories
Industry Trends ARIA B	IoT and Smart Sensors: Revolutionizing Validation and Monitoring Robert Yaffe, America Sales Manager, KAYE

11:20 - 12:00 PM	Select Between Knowledge Exchange Sessions
	<u>Cleaning Validation in Multi-Product Facilities: Managing Residues and Cross-Contamination</u> Cindy Duhigg, Senior Principal, Global Manufacturing Science & Technology Engineering, Alcon
	<u>Continuous Improvement in Facility Qualification Through Data-Driven Insights</u> Dawn Marshall (Tavalsky), Global External Manufacturing - Quality, Sanofi
CSA ARIA B	<u>Mastering CSA: Risk-Based Testing and Critical Thinking Workshop</u> David DeLuca, Director, Strategic Consulting, Compliance Group Monica Manepalli, Sr.CSV/CSA Consultant, Compliance Group Sarada Ramamoorthy, Head of Strategic Consulting (India), Compliance Group
12:00 - 1:00 PM BALCONY	Networking Luncheon - Topics Include:
FDA	FDA Warning Letters: Top Validation Issues and Industry Trends Ravi Moorthy, President, Quascenta
Requalifcaton	Aging Equipment Requalification: Ensuring Compliance Amidst Wear and Tear Jorge A. Cordero, Validation Manager, Bausch+Lomb
Cleaning	Leveraging Analytical Methods for Robust Cleaning Validation Results Cindy Duhigg, Senior Principal, Global Manufacturing Science & Technology Engineering, Alcon
1:00 - 1:40 PM	Select Between Knowledge Exchange Sessions
	<u>Audit Trails: Ensuring Data Integrity in a Digital Era</u> Reshma Kodumuru, Principal CSV, KBI BioPharma
Change Control ARIA A	<u>Mastering Change Control: Validation Strategies for Planned and Emergency Changes</u> Joscelyn Bowersock , Senior Director Quality Assurance and Regulatory, Precision for Medicine
Industry Trends ARIA B	<u>From Paper to Digital: Best Practices for Paperless Validation Programs</u> Jorge A. Cordero, Validation Manager, Bausch+Lomb

1:50 - 2:30 PM	Select Between Knowledge Exchange Sessions
 Utility SYMPHONY	<u>Ensuring Compliance: Utility Qualification for Water, HVAC, and Compressed Air Systems</u> Chip Bennett, PMP, Senior Director, ProjectFarma , a PerkinElmer Company
 Data Integrity ARIA A	 <u>Data Integrity Beyond ALCOA: Addressing Current Challenges in Validation</u> Subhabrata Purakayastha, Associate Director and Head of Enterprise GxP IT Systems Quality, Incyte Corporation
Industry Trends ARIA B	<u>Remote and Virtual Validation: Ensuring Quality in a Connected World</u> Leslie Lighton-Humphreys, Senior Manager Compliance and Process Management, Cencora
2:30 - 2:45 PM	Exhibitor Showroom and Refreshment Break
2:45 - 3:25 PM	Select Between Knowledge Exchange Sessions
 Utility SYMPHONY	 <u>Continuous Monitoring in Utility Systems: Ensuring Validation Integrity</u> Dawn Marshall (Tavalsky), Global External Manufacturing - Quality, Sanofi
Industry Trends ARIA A	 <u>Driving Collaboration: Standardization and Best Practices Through Information Sharing</u> Joanne Goldberg, Sr. Principal Business Analyst, Medtronic
Audit ARIA B	<u>Supplier Auditing and Quality Agreements: Ensuring Compliance and Efficiency</u> Olivia Calder, Process Engineer, Kneat
3:35 - 4:15 PM	Select Between Knowledge Exchange Sessions
 Inspections SYMPHONY	 <u>FDA Inspection Readiness: Preparing Your Validation Documentation for Success</u> Rishabh Jain, Quality Assurance Manager, Tetrapak
Industry Trends ARIA A	 <u>Validating Modern Enterprise Data Platforms: Balancing Agility with Compliance – Case Study</u> Shreyans Shah, Director of Quality, Accumulus Synergy Rohit Tyagi, President, Sagax Team
Cleaning ARIA B	<u>Next-Gen Cleaning Validation: Integrating Risk-Based Approaches and Visual Inspection</u> Jeff Felker, Deputy Director, Cleaning SME, Sanofi
	Close of Day Two

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