

PDA/PQRI Advancing Artificial Intelligence in the Pharmaceutical Industry Workshop 2025

Agenda

Wednesday, 10 September

EDT Daylight Time (UTC -4:00)

15:00 – 18:30	Registration Open
16:00 – 17:30	P1: AI: Lets Get Down to Basics This interactive session will set the stage for the workshop by introducing key objectives and exploring the foundational concepts of Artificial Intelligence. Participants will gain a shared understanding of AI's background and relevance to the pharmaceutical industry before engaging in a collaborative case study that examines how AI tools might be thoughtfully integrated into real-world company scenarios. Moderator: Peter J. Makowskyj MEng , Senior Director of Design Consulting, G-CON
	Welcome Remarks from the Workshop Co-Chairs
	16:00 – 16:10 <ul style="list-style-type: none">• Co-Chair: Peter J. Makowskyj MEng, Senior Director of Design Consulting, G-CON• Co-Chair: Toni Manzano PhD, CSO and Compliance Officer, Aizon
	Applied Artificial Intelligence Essentials
	16:10 – 16:30 <ul style="list-style-type: none">• Presenter: Toni Manzano PhD, CSO and Compliance Officer, Aizon
16:30 – 17:10	Balancing Challenges and Rewards: A Team-Based Strategy Experience
17:10 – 17:30	Report Out and Discussion
17:30 – 18:30	Networking Reception

Thursday, 11 September

EDT Daylight Time (UTC -4:00)

07:00 – 08:00	Continental Breakfast
07:00 – 16:00	Registration Open
08:00 – 09:30	P2: Discover AI! Begin your journey as an AI Explorer in the dynamic and rapidly evolving world of pharmaceutical innovation. This session sets the stage with an overview of current trends, real-world applications, and future possibilities for leveraging artificial intelligence across the product development lifecycle. Designed as your first stop on the roadmap to success, it offers an interactive opportunity to apply your expertise and creativity to identify potential projects that address business challenges and unlock new opportunities through AI-driven solutions. Moderator: Kir Henrici , President, <i>The Henrici Group</i>
	AI in Pharma
08:00 – 08:10	<ul style="list-style-type: none">• Presenter: Robert Repetto BE, MS, MBA, Consultant, <i>Repetto Consulting</i>
	AI and You

	08:10 – 08:20	<ul style="list-style-type: none"> • Presenter: Gokhul Srinivasan , Sr Partner Solution Architect, <i>Amazon Web Services</i>
		Discovering AI: An Interactive Experience
	08:20 – 09:10	<ul style="list-style-type: none"> • Presenter: Robert Repetto BE, MS, MBA, Consultant, <i>Repetto Consulting</i> • Presenter: Gokhul Srinivasan , Sr Partner Solution Architect, <i>Amazon Web Services</i>
	09:10 – 09:30	Report Out and Discussion
09:30 – 09:45	Networking Break	
	<p>P3: AI Strategy in Biomanufacturing: Building Digitally Mature, Audit-Ready Solutions</p> <p>This session will explore the practical realities of implementing AI in GxP-regulated biomanufacturing environments. Using industry case studies and live input from the audience, we'll examine common challenges, from fragmented infrastructure and governance gaps to the complexities of regulatory alignment. The session will introduce frameworks for scalable AI deployment, covering strategy definition, data readiness, risk assessment, model development, and lifecycle management. Participants will gather key insights, identify implementation barriers and enabling factors, and contribute to a shared resource that promotes actionable knowledge-sharing, strategic alignment, and ongoing refinement.</p> <p>Moderator: Sara Cook PhD, President and Founder, <i>IliaCook Consulting</i></p>	
09:45 – 11:15	09:45 – 10:05	<p>Regulatory Considerations for a Drug Product Process Control Digital Twin</p> <ul style="list-style-type: none"> • Presenter: Ben Stevens PhD, MPH, Director of CMC Policy and Advocacy, <i>GSK</i>
	10:05 – 10:55	<p>Interactive Case Study: Connecting the Example to Maintenance and Lifecycle Management</p> <ul style="list-style-type: none"> • Presenter: Ben Stevens PhD, MPH, Director of CMC Policy and Advocacy, <i>GSK</i>
	10:55 – 11:15	Report Out and Discussion
11:15 – 12:15	Networking Lunch	
	<p>P4: Demystifying AI: Hands-On Learning for GxP Beginners</p> <p>This session will introduce core AI concepts tailored to GxP-regulated environments, clarifying key terms and addressing common misconceptions. Participants will engage in a low-code activity to build a simple Machine Learning model, followed by a reporting exercise and group discussion to reinforce understanding and explore practical, compliant AI applications.</p> <p>Moderator: Peter J. Makowskyj MEng, Senior Director of Design Consulting, <i>G-CON</i></p>	
12:15 – 14:00	12:15 – 12:35	<p>AI – The Most Misunderstood Mystery: Foundations, Facts, and Forward Steps</p> <ul style="list-style-type: none"> • Presenter: Sara Cook PhD, President and Founder, <i>IliaCook Consulting</i>
	12:35 – 12:45	<p>Introduction to the Hands-On Activity</p> <ul style="list-style-type: none"> • Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
	12:45 – 14:00	<p>Table Activity: Build a Simple AI Model</p> <ul style="list-style-type: none"> • Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
14:00 – 14:15	Networking Break	
	<p>P5: AI in Pharma – Validation and Oversight</p> <p>This session will explore the distinctions between AI validation and traditional system validation, focusing on regulatory, cybersecurity, and quality aspects. Using models created by attendees as examples, participants will be guided through a validation process specifically designed for AI applications in the pharmaceutical industry. Additionally, the session will detail the FDA's credibility framework, explain how to implement it, and highlight key questions to consider before deploying an AI model, as well as common challenges in AI model validation.</p>	

Moderator: Andrew C. Chang PhD, Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, *Novo Nordisk*

Moderator: Kir Henrici President *The Henrici Group*

14:15 – 16:00

14:15 – 16:00	14:15 – 15:05	Validation in Pharma vs. AI <ul style="list-style-type: none">• Presenter: Stephen Ferrell , Chief Product Officer, <i>Valkit.ai</i>
	14:35 – 14:55	Oversight, Verifications, and Governance of AI Models in Drug Manufacturing <ul style="list-style-type: none">• Presenter: Krishnakali Ghosh PhD, President, <i>VERITAS COMPLIANCE LLC</i>
	14:55 – 15:25	Reflection and Validation of Your AI Model <ul style="list-style-type: none">• Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
	15:25 – 15:55	Q&A
	15:55 – 16:00	Closing Remarks from Workshop Co-Chairs <ul style="list-style-type: none">• Co-Chair: Peter J. Makowskyj MEng, Senior Director of Design Consulting, <i>G-CON</i>• Co-Chair: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>