

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
	P1: AI: Lets Get Down to Basics Moderator: Peter J. Makowskyj MEng , Senior Director of Design Consulting, G-CON
16:00 – 17:30	Welcome Remarks from the Workshop Co-Chairs <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 <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
	P2: Discover AI! Moderator: Kir Henrici , President, <i>The Henrici Group</i>
08:00 – 09:30	AI in Pharma <ul style="list-style-type: none">• Presenter: Robert Repetto BE, MS, MBA, Consultant, <i>Repetto Consulting</i>
	AI and You <ul style="list-style-type: none">• Presenter: Gokhul Srinivasan , Sr Partner Solution Architect, <i>Amazon Web Services</i>
	Discovering AI: An Interactive Experience <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	
P3: AI Strategy in Biomanufacturing: Building Digitally Mature, Audit-Ready Solutions		
Moderator: Sara Cook PhD, President and Founder, <i>IliaCook Consulting</i>		
09:45 – 11:15	09:45 – 10:05	Regulatory Considerations for a Drug Product Process Control Digital Twin <ul style="list-style-type: none">• Presenter: Ben Stevens PhD, MPH, Director of CMC Policy and Advocacy, <i>GSK</i>
	10:05 – 10:55	Interactive Case Study: Connecting the Example to Maintenance and Lifecycle Management <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	
P4: Demystifying AI: Hands-On Learning for GxP Beginners		
Moderator: Peter J. Makowskyj MEng, Senior Director of Design Consulting, <i>G-CON</i>		
12:15 – 14:00	12:15 – 12:35	AI – The Most Misunderstood Mystery: Foundations, Facts, and Forward Steps <ul style="list-style-type: none">• Presenter: Sara Cook PhD, President and Founder, <i>IliaCook Consulting</i>
	12:35 – 12:45	Introduction to the Hands-On Activity <ul style="list-style-type: none">• Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
	12:45 – 14:00	Table Activity: Build a Simple AI Model <ul style="list-style-type: none">• Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
14:00 – 14:15	Networking Break	
P5: AI in Pharma – Validation and Oversight		
Moderator: Andrew C. Chang PhD, Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, <i>Novo Nordisk</i>		
Moderator: Kir Henrici President <i>The Henrici Group</i>		
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
		Closing Remarks from Workshop Co-Chairs

15:55 – 16:00

- **Co-Chair: Peter J. Makowskyj MEng**, Senior Director of Design Consulting, *G-CON*
- **Co-Chair: Toni Manzano PhD**, CSO and Compliance Officer, *Aizon*