PAT in the Age of AI/Machine Learning: Navigating a Regulatory Framework in Transition

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Process Analytical Technology has significantly impacted pharmaceutical manufacturing by enabling real-time testing and data-driven quality decisions. Yet the regulatory framework governing PAT tools – how they are approved, how model changes are managed, and how new algorithmic approaches are governed – is itself undergoing a transition.

This talk traces the evolution of PAT regulation from its foundations in the FDA PAT guidance and the ICH quality framework, through the maturation of lifecycle expectations in the FDA's 2021 NIR guidance, USP <1039>, and ICH Q14, to the current regulatory frontier. As PAT evolves beyond classical PLS calibration toward machine learning approaches including ensemble methods and neural networks, health authorities are actively defining their position: the FDA's January 2025 draft guidance on AI for regulatory decision-making and the EMA's September 2024 AI Reflection Paper both signal a risk-based, credibility-driven approach.

For process engineers and quality professionals planning the next generation of PAT implementations, integrating this regulatory transition is required.

Samd Guizani is a Data Scientist and Process Engineer with over 20 years of experience in pharmaceutical development and manufacturing, gained across Pierre Fabre, Bayer Healthcare, Ferring Pharmaceuticals and Sanofi, Montpellier, France. Holding degrees in Pharmacy, Chemical Engineering, and Applied AI, he has led PAT and chemometric modelling initiatives delivering measurable efficiency gains through QbD, multivariate NIR spectroscopic methods, and machine learning. A published author and Six Sigma Black Belt, he has presented at ISPE and global pharma industry forums on continuous manufacturing and process analytical technology.

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