Deploying PAT Across a CDMO: From Feasibility to Routine cGMP Release

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Process Analytical Technology (PAT) is widely recognized as a framework to improve process understanding and assure product quality through timely measurements. In routine GMP operations, and particularly in a CDMO setting with diverse processes and customers, making PAT actually work requires considerably more than selecting the right sensor. This presentation shares an industrial perspective on translating PAT from feasibility work into scalable, compliant routine use.

We first describe a "PAT-by-default" entry gate for early-stage projects. This approach de-risks scale-up and supports right-first-time process integration at large scale by ensuring that PAT is considered systematically. We then focus on spectroscopy and probe-based systems, where plant integration realities often dominate success: representative sampling points (e.g., loops, bottom valves, flow cells), probe and hardware integration constraints, and maintainability considerations. In practice, plant integration topics such as probe location, fouling and cleaning, fiber routing, and ATEX constraints frequently determine whether PAT becomes an integral part of manufacturing or remains on the side.

Building on these learnings, we describe a pragmatic lifecycle approach covering feasibility, model building and validation, method verification, and routine implementation. This includes how to standardize deployment, assure instrument readiness and spectral quality, manage model drift, and ensure robust process control.

Finally, we discuss value creation beyond automated release: yield improvement, deviation reduction and prevention, faster troubleshooting, better comparability through historical process "fingerprints," and earlier fault detection. These benefits must be balanced against the reality that attractive PAT business cases are not always straightforward to build, given plant-to-plant throughput, product pricing, ownership, compliance, and architecture/cost considerations. Everyone likes real-time analytics; few projects succeed at routine GMP deployment.

Born in Geneva, Selim Agrebi is a PAT Team Leader at Lonza (Visp, Switzerland), where he drives the industrial deployment of PAT from development into routine GMP operations. His team specializes in spectroscopic PAT implementation (at-/on-/in-line), chemometrics and multivariate analysis, and the practical aspects of plant integration, method verification, and lifecycle management. Prior to his current role, he supported chemical process development and optimization as well as analytical development, including troubleshooting during manufacturing and technology transfer. He began his career as an apprentice in the QC laboratory of the internal pharmacy at CHUV Lausanne, which shaped his strong interest in chemistry.