



SmartLab™ Technical Brief

Customer Implementation: AstraZeneca

cGMP Informatics – Integrating Information Across Operations

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Abstract: *Data drives operations. It is the key to understanding and monitoring processes, defining efficiency opportunities, and justifying investment. All too often, the industry designs systems for a specific task, group, or site without thought to how others may utilize the information generated or how data from multiple systems could be used. How we define our data streams and their utilization is a key component of system design as is defining how systems are mapped to the tasks required. Two key concepts will be discussed during the presentation, globalization of systems, and utilization of systems across the organization.*

Key Presentation Points: Too often, “electronic solutions” are slotted into a very narrow section of the business and are selected independently by site or region. At AstraZeneca, through a defined “process definition and mapping” strategy, we are changing the way “systems” are designed and implemented. Key to this strategy is our focus on a Global Systems approach, Automation and System Integration.

Recent pharmaceutical “State of the industry” operations demands include:

- Pipeline challenges resulting in overcapacity of manufacturing capability
- Fluctuations in demand (patent expiry and competition issues) result in further capacity challenges
- Reduced costs of medication through manufacturing cost optimization
- Increased efficiency to maintain market share
- Maintain or improve quality

Within this industry perspective companies are moving to control resources, characterize processes and challenge the status quo. From a cGMP informatics perspective, our global quality operations team concluded that:

- Efficiency efforts based on continued use of manual systems will not provide the step change in efficiency required
- Implementation of technology, systems and equipment will provide a significant impact
- Integrated, well thought out implementations of technology will provide the greatest impact

Figure 1:

Quality Data Layers: Site Function and Quality Management Architecture

A multi-tiered architecture for cGMP informatics data management includes SmartLab GMP ELN at the method execution and instrument data collection level (lab analyst support) with LIMS (lab management support) and ERP (site management support).

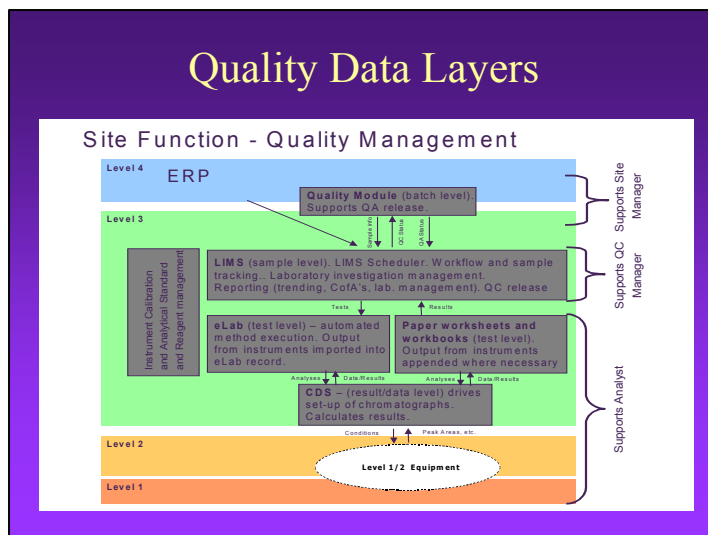


Figure 2: Process/Solution Architecture

The typical "paper-based" processes (manual transcription, calculations, data capture and review and approvals) are now automated with the SmartLab method execution GMP ELN.

Analyst test execution, equipment/instrument data capture, results, review and approvals are automated. Approved data is automatically transferred to the LIMS for final specification approval and lot release.

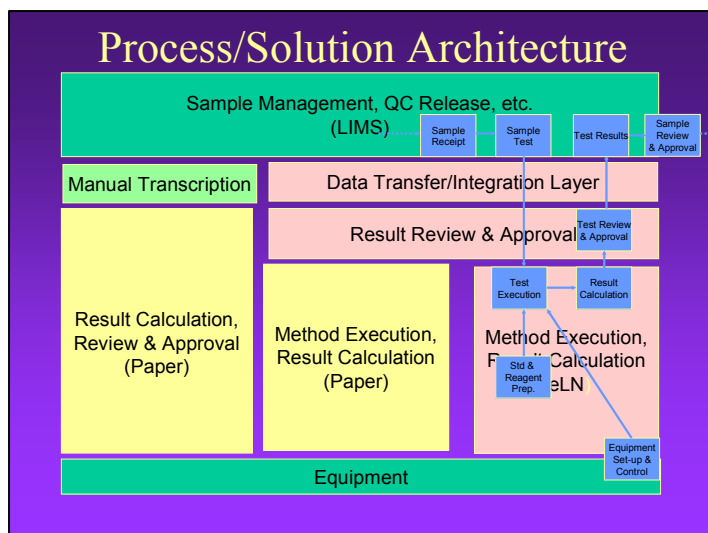


Figure 3: Automated cGMP Informatics Integration Across Operations Benefits

By utilizing a harmonized cGMP informatics architecture across plant operations significant operational, cost and compliance benefits are realized. Automating the manual lab processes and defining best-practice methods provides 30-50% improvements in resource costs and process cycle times.

What are the Benefits

- Reduce total cost of ownership
- Automate manual processes
- Standardization of Practice
- Data Utilization
- Resource Utilization
 - Published reports of 30 – 50% resource reductions/utilization