INTEGRITY PROJECT SOLUTIONS

Process Analytical Technology

Business Case

We were asked to implement and manage the deployment and validation of multiple PAT analysers, including the PAT analyser integration with Global PAT management tool.

The deployment was across world-wide manufacturing and R&D facilities including data management, integrity and security processes

We had to take account of:

- Integration with existing processing equipment
- QMS policies/standards/processes not designed to work with PAT
- Engagement of the business, IS/IT and quality leadership teams
- Relationship and conflicts with parallel business initiatives

Strategy

- Establishing cross functional/discipline teams
- Facilitate greater understanding of process design space through implementation of Quality by Design (QbD)
- Enhance process understanding, streamline technical transfer, increase production throughput and reduce off-line laboratory testing
- Meet regulatory expectations i.e. FDA's 21st Century GMP Guidance
- Ensure deployed technologies are validated and supported

Execution

We designed the integration of a PAT toolset with production processes which we then validated.

We facilitated the senior management commitment to PAT proposals and deployment of improvements.

QMS policies/standards/processes we updated to adopt PAT

Determine PAT techniques that yield maximum benefit.

Outcome

- Greater understanding of unit operations
- Increased manufacturing throughput
- Reduced reliance on laboratory confirmation testing
- Reduction in failed batches leading to an increase in OEE segregation of duties.

KPIs and Benefits

- The Product quality and performance are assured
- Product and process specifications are based on formulation process understanding
- PAT risk-based approach was accepted by regulators
- Continuous quality assurance with real time release possibilities