

Business Case

We worked with a global pharmaceutical operation with disparate quality systems and limited quality culture across the organisation, and a complex IT quality governance structure.

We had to overcome some challenges including:

- Promoting operational effectiveness over regulatory compliance
- Integrated processes addressing GxP, SOX, Data Privacy and Security
- Different perceptions of regulatory expectations across regions and organisations
- Gaining commitment of resources to develop processes



Strategy

We needed to develop and establish:

- An understanding of industry practice and regulatory expectations (e.g. GAMP®, ITIL®, PIC/S, SOX) within the business
- Quality policies, standards and processes in response to business and IT strategy, external laws and regulation
- A simplified IT quality governance structure

Above all, we implemented effective and efficient processes that operate globally.

Execution

This project required excellent management, communication and training programmes.

- Management workshops to raise awareness of industry practice and regulatory expectation
- Technical training of IT personnel
- Gap analysis of existing QMS' to leverage current best practice
- Workshops defining new governance structure and IT processes
- Manage SME process development teams
- Gap analysis and remediation of quality records against implemented policies, standards and processes
- Manage Service Desk, EDMS, Training Management systems disciplines.

Outcome

The desired outcomes were achieved:

- Clarity of IT quality and business quality roles and relationships
- Common IT standards and processes across IT organisation
- Qualified IT infrastructure
- Implemented and validated support systems
- IT knowledge of industry standards and regulations increased

KPIs and Benefits

- Effective "global" IT processes through use of automated systems (e.g. Service Desk, EDMS, Training Management)
- Shorter infrastructure project timescales and fewer service calls
- Greater resource mobility
- Significantly improved outcome of compliance audits