



IS Compliance Services

Life Sciences organizations increasingly rely on industry specific and general business applications for GxP critical tasks. They are increasingly looking to leverage new IT/Information solutions to deliver business improvements and reduce operational costs.

In recent years regulatory expectations have become more pragmatic, a fact recognized by the latest GAMP Guide (GAMP 5 – A Risk- Based Approach to Compliant GxP Computerized Systems).

With input and review by US and European regulatory agencies, GAMP 5 provides guidance on achieving IS compliance efficiency improvements.

Recognizing that accountability for maintaining compliance rests with the regulated company, GAMP 5 identifies an appropriate oversight role for the regulated company's QA organization and highlights the role of suppliers in supporting life sciences organizations to achieve these objectives.

Based upon significant experience applying the key concepts of GAMP5, qointa has developed a Lean IS Compliance program to support Life Sciences organizations in achieving a cost effective and sustainable state of compliance.

01 Program Scope.

Tailored for each individual client, qointa's Lean IS Compliance Program consists of a number of defined stages, each of which uses predefined models, tools and templates. This accelerates program activities, minimizes costs and allows clients to assess and assure return on investment at each.

- **Assessment**
Preceded by a one-day health check, the assessment stage confirms the Program scope, provides a high-level view of the current state of IS compliance, identifies any gaps, inefficiencies and opportunities for costs savings.

The assessment encompasses a 360 degree view of IS compliance, focusing on areas such as:

- IS Quality Management System
- Computer systems validation processes and practices
- On-going maintenance and support processes (maintaining the validated state)
- IT infrastructure qualification Training and education
- Training and education

Assessments are benchmarked against industry specific regulatory expectations, but also leverage IT industry good practice such as ITIL and ISO 12207, as recommended in GAMP 5.

□ Strategy and Roadmap Definition

Based upon the outputs from the Assessment stage, the Strategy and Roadmap Definition stage provides an IS Compliance Strategy and a transition model.

These provide a set of realistic and achievable goals against which the client's progress towards achieving a cost effective level of IS compliance can be measured.

Leveraging appropriate IS/IT standards and guidance, the roadmap streamlines IS operations, helps clients to leverage organizational change management opportunities and ensures that acceptable levels of compliance are maintained.

□ Education and Knowledge Transfer

Education and informed decision making is at the heart of cost effective IS compliance. Without such knowledge it is difficult to successfully adopt a cost effective and consistent approach to risk-based IS compliance across the organization.

During the Education and Knowledge Transfer Stage, qointa's consultants ensure that the client's staff is appropriately educated to be able to fulfill agreed responsibilities

□ Sustain and improve

Following the completion of the Program, and using the knowledge transferred in the Education and Knowledge Transfer Stage, clients are responsible for sustaining and improving their state of IS Compliance. Where applicable, qointa may continue to provide strategic or tactical support