IS QMS And Audit Services

The regulatory landscape changes constantly. New regulations are issued, industry standards change, guidelines and good practices are constantly updated. Likewise, the requirements of any business change over time, as does the organizational structure required to support that business.

To support such changes the GAMP Guide recommends that Life Sciences organizations should have a formalized IS/IT Quality Management System (QMS).

While most Information Technology (IT) or Information Systems (IS) departments will have some or most of the required policies and procedures in place, these may not be formalized as a single QMS. In other companies, changes such as internal reorganization, mergers or acquisitions may have made the scope of the IT QMS unclear or the existence of multiple procedures may lead to ambiguity or inefficiencies.

In many cases, organizations are looking to leverage GAMP5 Key Concepts and recent Good Practice Guides in support of cost reduction exercises.

Evidence shows that even the best IT QMS becomes out-of-date, leading to inefficiencies in IS/IT process or to regulatory observations when organizations fail to follow their own procedures or have not established appropriate processes.

01 How can qointa help?

Following an established and cost effective process, qointa assists clients in the establishment of an efficient and compliant IT QM.

- IT QMS Review
  As either a standalone exercise or as part of a Lean IS Compliance Program, we assesses client's existing policies, processes and procedures for internal alignment and external compliance against applicable regulations, standards and guidelines.

This includes a process -based audit designed to assess compliance with existing policies and procedures, and also to:

- Identify the outdated documents;
- Review the content and scope of existing procedures and work instructions against current regulatory expectations and industry best practices (e.g. ITIL and CobiT);
- Identify opportunities for process improvements and cost savings.

- IT QMS Development

Using the tools and accelerators from our unique Document Accelerator Kit, our consultants then assist clients in the development of a comprehensive, consistent and up-to-date set of policies, procedures and work instructions as part of an integrated IT QMS.

These are combined with client's existing documents and content to produce an appropriately scaled IT Quality Management System. The framework of the complete IT QMS will be defined and agreed, but work on specific processes and procedures will be prioritized in accordance with business priorities.

Rather than develop specific IT policies and processes for the life sciences industry, we fully endorse the use of IT best practice, modified to meet specific regulatory expectations. This minimizes issues working with outsourced IT service providers and minimizes the training burden when hiring new members of IT staff or recruiting contractors.

Our Document Kit includes accelerators designed to allow Life Sciences organizations to align their IT processes with IT standard frameworks such as CobiT (Control Objectives for Information and related technology) and ITIL (The IT Infrastructure Library), and industry standards such as IEEE and ISO. This is part of our unique multi-domain approach to IS compliance, ensuring that Life Sciences clients not only benefit from efficient IS/IT processes designed to meet prioritized business objectives, but that compliance with regulatory expectations is built-in. We also ensures that the client's documented IT Quality Management System meets regulatory expectations with respect to.

- All key life sciences guidance (e.g. FDA, PIC/S and GAMP);
- Effective and efficient periodic review;
- Appropriate, independent QA oversight.

Depending upon the client's requirements, we will either develop policies, procedures and work instructions alongside technical and quality stakeholders or will provide review, support and guidance to document authors within the client's organization.

- IT QMS Training

Our training services are one of the most efficient and effective ways to train users in the roles and responsibilities of the IT QMS. Because processes and procedures are largely based upon IT industry standards, the training of IT staff is more meaningful, knowledge transfer is easier to achieve and new skills are more likely to be retained.

Combining a number of techniques, we develop a variety of training materials and where required, are able to provide training materials either for remote staff members or to allow new staff

members to undertake induction or refresher training at their own pace. Education can be combined with guidance and support to ensure that training has been effectively delivered and that staff and/or contractors are confident and competent in the requirements of the IT QMS.

- Periodic Review, Audit and Update

  As part of a Service Level Agreement (CSLA), we provide a number of risk-based IT QMS audit, periodic review and update services. We undertake the periodic review of the IT QMS. This is designed to encourage ongoing compliance with the IT QMS and identify any training issues. We can also audit the IT QMS, to identify opportunities for continuous process improvement and ensure that the IT QMS remains aligned with industry best practice and regulatory expectations. For those clients wishing to immediately identify any gaps in their IT QMS, we provide an update service designed to alert selected clients to updates in applicable regulations and guidance, which may then trigger a review and/or update of their IT QMS.

All of these IS QMS and Audit services are designed to allow clients to focus on core IT and Quality Assurance activities, and be confident that their IS/IT processes are not only cost effective and efficient, but safe in the hands of knowledgeable experts.