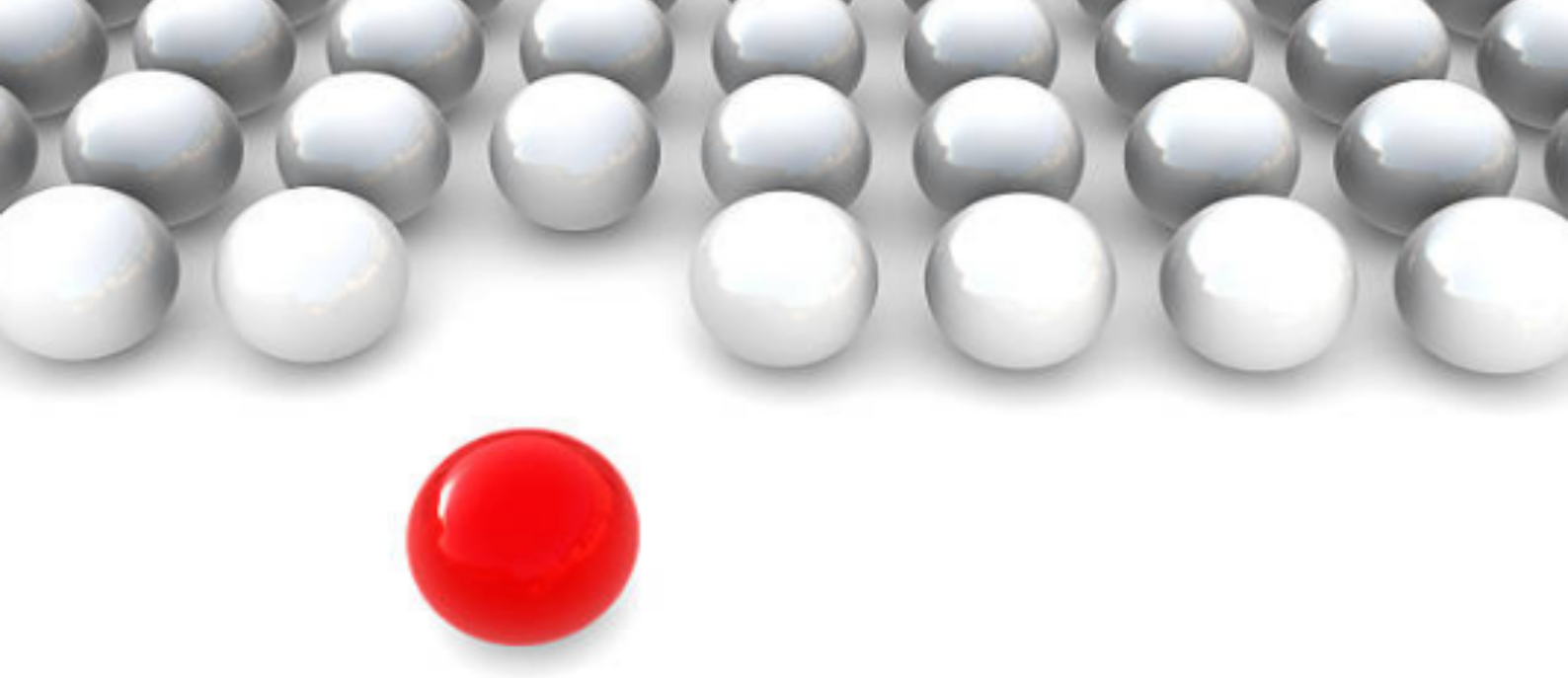

Computer System Validation Services

Throughout initial enforcement actions in the late 1980's, the development of regulatory and industry guidance in the early 1990's, focus on electronic records and signatures in the early 21st Century, and up to the current 'risk-based' approach, the last twenty years have seen a great deal of change in the field of computer systems validation.

01 Why is Validation Still an Issue?

Following initial focus in areas of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP), regulatory authorities now understand that most business areas pose a potential risk to product quality and patient safety.

Important business processes are supported by increasingly complex 'mission critical' software applications. In many cases, these systems contain functionality that has a direct or indirect impact on product quality and patient safety. Regulatory authorities expect all such systems to be appropriately validated and the underlying IT infrastructure qualified.

Whereas validating a manufacturing or laboratory system with direct impact on product quality is highly critical and relatively well understood, the validation of complex business applications with an indirect impact on patient safety is more complicated.

This is an area where many Life Sciences organizations are struggling to balance the need for appropriate validation against the requirement to deliver business applications on-time and on-budget. The lack of appropriate validation of such systems is one reason for increasing regulatory focus in these areas.

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02 Computer System Validation Services.

qointa has specialized in the risk-based validation and provides a number of services to help ensure that clients' computerized systems are appropriately validated. These are delivered as a one-off consulting engagement or included as part of a client specific Services Agreement. These services include:

- Validation Framework Development

  As a standalone set of policies and procedures, or as part of a wider IT Quality Management System, we have helped both small and large Life Sciences organizations to develop flexible, scalable validation models.

  These are based upon our extensive experience in the application of risk-based validation and allow clients to use the framework to validate everything from simple spreadsheets to large complex enterprise level systems. The result is intelligent, risk-based computer systems validation, scaled appropriately to the size and complexity of the application and is always cost effective.

- Computer System Validation

  Operating at either a strategic or tactical level, qointa is the trusted partner for the validation of critical computerized and business systems across all areas of the life sciences organization.

  Our consultants are not only experts in the field of computer systems validation, but also have a detailed understanding of the regulatory critical business processes and the underlying supporting applications and technology.

  Mission critical applications that we specialize include:

  - Laboratory Data Acquisition and Information Systems
  - Clinical Trial and Data Management Systems
  - Manufacturing Process Control Systems
  - Manufacturing Execution Systems
  - Quality Workflow and Document Management Systems
  - ERP Systems
  - Cloud computing; Software-as-a-Service Systems
  - Medical Device Software
  - SOA and Middleware
  - Custom-developed Software
  - IT Infrastructure

  At a strategic level, our consultants assist clients to plan the validation of large, complex applications. This includes integrating validation activities into project planning, ensuring a balance between cost, on-time delivery and appropriate validation. In all cases, our risk-based approach is used to scale verification tasks, integrate such activities as part of the existing project activities, minimize the validation overhead and ensure 'least cost compliance'.

At a tactical level, our consultants develop key validation documentation and help clients (and/or other third parties) to execute verification tasks in the most cost effective way possible.

- Project Leadership

  Maintaining the balance between regulatory compliance, validation and on-time / on-budget delivery is a complicated task. Relatively few organizations have a good track record in this area and relatively few Project or Program Managers have the necessary experience to balance validation tasks against more easily understood dates and budgets.

  As a specialist in the Life Sciences industry, qointa has a strong track record of balancing such tactical constraints. Using this experience, our consultants provide on-going input to large complex projects to help ensure appropriate focus.

  Working alongside the client's Program Manager or as a member of the Project Steering Group, our experience is also used to facilitate difficult decision making, provide acceptable regulatory guidance and rationale, and help ensure that complex, often conflicting program priorities are met.

03 The Document Accelerator Kit.

All of these works are underpinned by our unique Document Kit. Unlike most 'off-the-shelf' template sets, the constantly updated Document Kit provides our consultants with the necessary background on current regulatory guidance and industry good practice to ensure that risk-based principles can be applied in practice

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