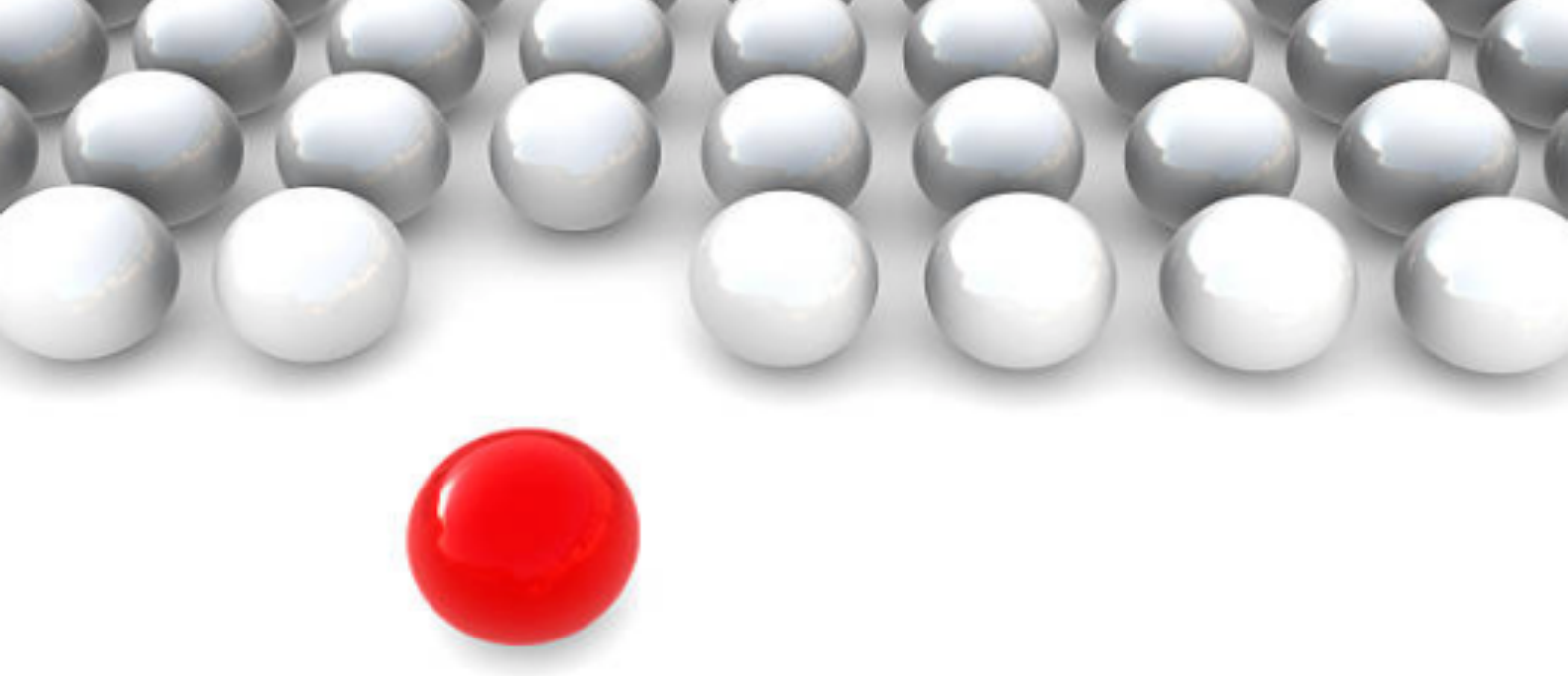

CVS Maintenance Services

Regulations change on a continuing basis, Interpretation of the regulations change and industry standards and good practice constantly improve. This is intended to guarantee product quality and patient safety and computerized systems must remain in a compliant state during ongoing operations.

With more Life Sciences organizations focusing on core business activities, there is an increasing need to maintain the validated status of regulatory significant systems in a cost-effective manner.

The increasing importance of this is recognized in the GAMP Maintaining Control in Operation Good Practices Guide.

01 What is Ongoing Compliance?

Compliant computerized systems must:

- Remain appropriately qualified and validated,
- Be appropriately maintained and supported,
- Support business processes that comply with the appropriate predicate rules

In a changing organizational and regulatory landscape it is necessary to periodically review systems to ensure that they remain compliant. This is a challenge for Life Sciences organizations who cannot dedicate full-time resources to such activities or who may lack the necessary specialist skills. For an increasing number of companies, these are also seen as non-core activities.

Just as Life Sciences organizations are looking to outsource IT services, there is a growing realization that it is still possible to be accountable for the compliant status of IS infrastructure and software while at the same time outsourcing the day-to-day responsibility to trustworthy organizations.

02 Validation Maintenance Services.

qointa provides a number of services to help ensure that clients computerized systems remain compliant. These services include:

- Post-implementation Compliance Assessment
  In a number of cases, the initial qualified state of IT infrastructure or the validated state of a system may not have been maintained. There may be an element of regulatory risk if such deficiencies are discovered during regulatory inspection.

  As either a standalone exercise or as part of a more comprehensive IS Compliance Program, we can assess such systems, identify any deficiencies and correct any problems as part of a program of corrective actions.

- Development of Maintenance and Support Processes
  In cases where the compliant state is undermined by a lack of appropriate maintenance and support processes, we will use our unique Validation Accelerator Kit to quickly develop appropriate processes and procedures as part of a controlled IT Quality Management System.

- Revalidation Services
  Either through change of use or a failure to maintain a qualified/validated state, it is sometimes necessary to re-qualify or revalidate computerized systems. We are able to efficiently undertake revalidation exercises, limiting validation and verification activities to regulatory significant change-in-use, thereby speeding up the revalidation process, minimizing upgrade costs and maximizing return on investment.

  Using a risk-based approach, we are able to cost-effectively bring legacy infrastructure and applications into a defined and documented state of compliance.

  By using existing documentation, empirical evidence of past operation and by using statistical sampling of historical performance data, we are able to re-establish a state of compliance without undertaking a full-cycle validation exercise.

- Periodic Review
  Once established, it is important that a compliant status is maintained. This is achieved through the use of periodic review. Routine checks should be made to ensure that computerized systems remain compliant and that:

  - The IS Quality System is being followed,
  - No previously undetected incidents have occurred,
  - Changes in the organizational or regulatory landscape have not overtaken or undermined the validated state,
  - Systems remain ready for regulatory inspection.

Unlike many other organizations, we work with clients to establish a risk-based approach to periodic review rather than a fixed cyclical basis. This ensures that compliance risks are effectively mitigated but that reviews are not conducted where they add little or no value.

Reviews will be conducted with varying frequency, based on the outcome of a post-implementation risk assessment. These risk assessments will also be reviewed as part of the periodic review, allowing the review frequency to be changed to reflect not only the risk impact but also the actual risk likelihood and probability of detection.

- Third Party Oversight

  As many organizations have found, it is necessary to provide appropriate oversight of outsourced IT services. This is often a challenge where IT Quality teams have been downsized or where small quality organizations may lack the skills to oversee their IT service providers.

  While Life Sciences companies must maintain final accountability for the compliant state of their computerized systems, we also undertake the responsibility for this day-to-day oversight as part of an overall Service Level Agreement.

  Such oversight services can be applied to internal IT groups as well as outsourced service providers and may include ongoing periodic reviews and audits as well as day-to-day review and/or approval of documentation.

03 Services Level Agreement.

All of the above services can be included in a client specific Service Level Agreement. This will define the specific accountabilities retained by the client, as well as activities to be performed by qointa.

Under such an SLA, we provide a degree of resource flexibility and expertise that is unavailable to many small-to-medium sized Life Sciences organizations.

For larger companies the opportunity to scale computerized systems validation requirements is a key part of focusing on core activities and reducing costs.