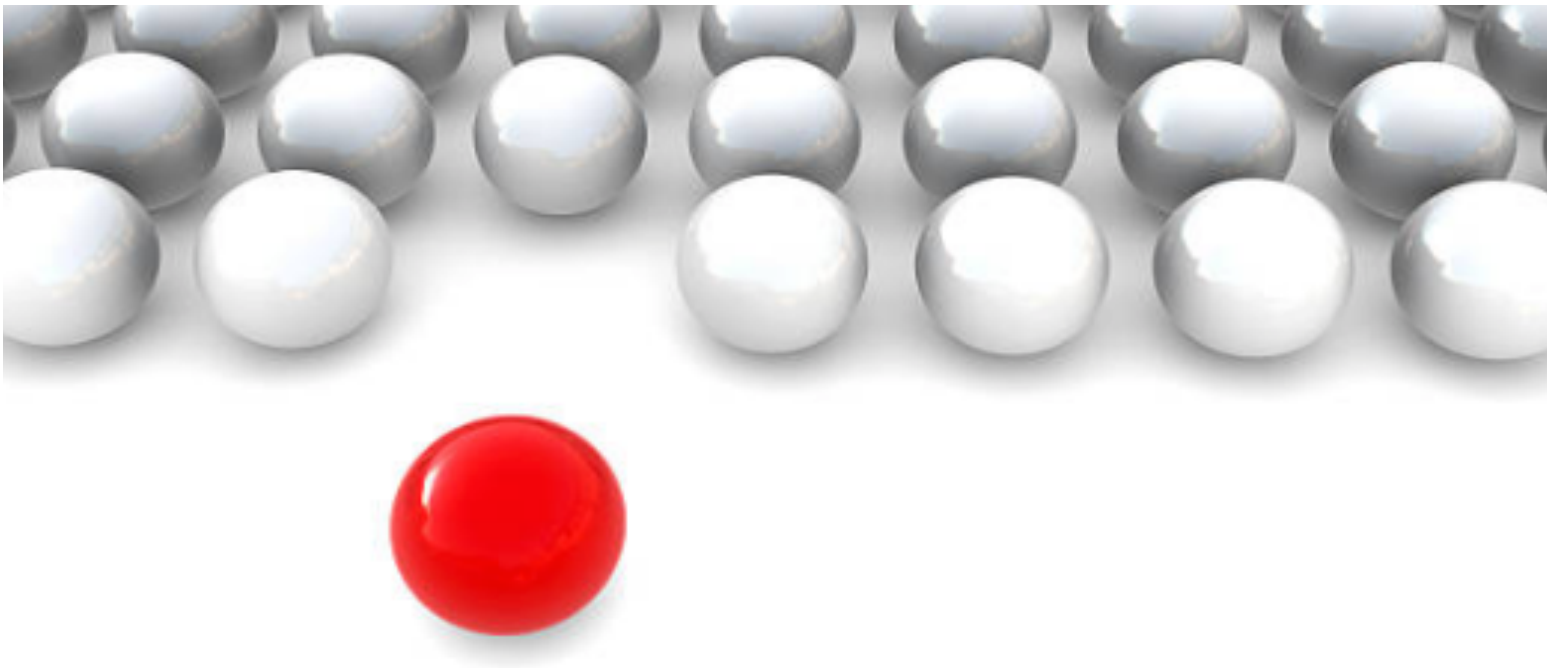

Data Integrity Services

Data integrity is a prerequisite for the regulated healthcare industry due to a direct impact on **product quality and patient safety**. Electronic data and computerized systems have introduced new challenges to maintaining data integrity, as it is much easier to change electronic data and records than it is to change a paper or other physical record.

FDA mandates the electronic data integrity through 21 CFR Part 11 and 21 CFR Part 820 regulations. Health Canada has adopted Pharmaceutical Inspection Cooperation Scheme's (PIC/S) good guidance for computerized systems in regulated GXP environments, while the European Commission details electronic data integrity requirements in EU EudraLex Annex 11.

As the life sciences industry is focused on leveraging its computerized systems to significantly improve and expand its resources, the regulatory authorities such as FDA, EMA, MHRA, Health Canada have put much emphasis on data integrity in recent years, because they uncovered serious cases of data integrity breaches. For example, FDA recently announced that they would be regularly conducting inspections focusing on 21 CFR Part 11 requirements. UK MHRA also set an expectation that the aspect of the data integrity and traceability would be covered during inspections from the start of 2014.

The integrity of regulated data relies upon the compliance of the computer systems responsible for managing regulated data. Due to increasing complexity of computerized systems landscape and lack of a balance between cost, schedule and appropriate level of compliance, the regulated organizations and its vendors often struggle to implement the most effective and defendable compliance standards, and, as a result, are at a disadvantage when it comes to data integrity.

qointa allows customers to achieve compliance and the data integrity, which is integral to a fully functional Quality System. As a proven leader on this topic, qointa can support customers in the implementation of a cost effective and feasible compliance strategy. This results in the assurance of the systems validation life cycle, which in turn enhances and improves product quality, patient safety and data integrity. qointa's integrated approach enables client's data integrity and validation requirements through a scalable and fully regulatory compliant delivery model, based on a robust risk analysis. qointa's solutions are robust enough to stand up to audit scrutiny by any regulatory agency or group.

qointa

01 qdata Integrity Services.

qointa's services in the Data Integrity space include:

- **Computer Systems & Software Validation**
  - Risk-based framework (GMAP5)
  - CSV planning, training and support
  - Technology and Vendor evaluation
  - Periodic Review of validated state

- **ICT/IT/IS Quality System and Audits**
  - GAMP5 and FDA QSR-based QMS
  - Easy-to-follow SOPs and policies
  - Scalable "As-Needed" approach
  - Integration with current quality system
  - Periodic Audits/Assessments

- **FDA 21 CFR Part 11 & EU Annex 11 Compliance**
  - Gap analysis and Remediation
  - Technical & procedural controls Integration with current quality system
  - Data Integrity controls across the record lifecycle
  - Training ("As-Needed" details)
  - Mock inspections

- **Infrastructure Qualification**
  - Infrastructure compliance assessments
  - Prospective/retrospective qualification
  - Maintaining Control
  - ASTM E2500 and GAMP principle
  - Mock inspections