



Risk-based Computer Systems Validation and IT-Infrastructure Qualification for SAP using a novel approach involving outsourced systems



Medical Devices



Pharmaceuticals



Health Care

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expertise



Introduction

- Computer systems used in the pharmaceutical, medical device and biotechnology industries today are all subject to strict regulatory scrutiny.
- Many such systems have been outsourced to ‘hosting’ partners, who provide the infrastructure required to run many different applications, such as:
 - SAP
 - Document Management Systems
 - Laboratory Information Management Systems
 - diverse laboratory applications, e.g. ChemStation, ChemLMS, CAD-Systems etc.



IQC Methodology

- The choice of hosting partner requires:
 - Careful planning of all outsourcing project activities e.g.:
 - Requirements of both parties
 - Agreement on SLAs and the level of service to be provided
 - Methodology of implementation (with regard to laws & regulations)
 - A specialist knowledge of the laws and requirements for
 - Europe, Middle East
 - United States of America
 - Pacific Region
 - Experience and knowledge of the implementation of those laws
 - For example, FDA requires a risk-based approach to validation and qualification as stated in the *Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach*



IQC Methodology

- IQC (International Quality Consulting) is in the position to offer its clients both experience and specialist knowledge in the aforementioned industries
 - IQC was founded in 1996 and has worked successfully with the health industries since that time
 - IQC has specialist consultants, each with a minimum of 15 to 20 years in the industry

Laws, Regulations and Guidances

Laws and Regulations:

21 CFR 210, 211 (Pharmaceutical Industry)

21 CFR 820 (Medical Device Industry)

21 CFR Part 11 (E-records & signatures regulation)

FDA CPG 7132a.11 (requirement to qualify hardware)

EU GMP Annex 11 (Computerised systems directive)

Guidances:

FDA Guide to General Principles of Software Validation

FDA Guidance – Computerised Systems used in Clinical Trials

GAMP 5 & GAMP Good Practice Guides



Implementation

- Implementation of the life-cycle for hardware
 - Installation and operational qualification of infrastructure components
 - Configuration management and change control of infrastructure components
 - Management of risks to IT-infrastructure
 - Involvement of service providers in critical infrastructure processes
 - Security management, backup, restore and disaster recovery
- Installation Qualification for the software applications to be installed
- Close coordination of all activities between medical device / pharmaceutical / biotechnology company and the outsourcing partner
- These activities must be carried out with close regard to the appropriate laws, regulations and guidelines



IQC as Implementation Partners

- IQC uses an approach which not only takes the appropriate laws, regulations and guidelines into account but also uses a novel approach to the interpretation of the laws and the qualification of IT-infrastructure components based on our vast knowledge of the medical device, pharmaceutical and biotechnology industries.