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RISK MANAGEMENT & ITS PROCESS

**PRODUCED BY:
OUR SUBJECT MATTER EXPERTS.**

RISK MANAGEMENT & ITS PROCESS

COMMUNICATION
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BUSINESS
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SUCCESS
ENTERPRISE
COLLABORATION
PARTNER
OFFICE
SERVICE
EXCELLENCE
INTERNATIONAL

Enterprises must be proactive when deploying risk management strategies. Risk management and its process is a mission-critical component of software validation best practices, which encompass the entire product lifecycle from conception to post-production monitoring. Establishing a documented risk management process is specifically suggested by regulations such as cGMP, GAMP, FDA 21 CFR part 11 and FDA 21 CFR part 820, yet regulatory pressures merely lay the foundation for the process of risk management; enterprises must develop their own risk management strategies. To provide FDA-regulated enterprises with a means to improve upon the benefits of a risk management-based approach, IQS's software validation service assists enterprises in identifying, evaluating and mitigating risks associated with the implementation of new or updated software.

RISK MANAGEMENT AND SOFTWARE VALIDATION REQUIREMENTS

Concerning software validation, the FDA broadly defines risk management as the iterative discipline of

assessing risks relating to software use and intervening proactively by deploying strategies to minimize such risks. From this general framework, FDA-regulated enterprises must create their own risk management process to satisfy regulatory requirements to validate software consistently.

Utilizing the medical device manufacturing industry as an example, FDA regulations suggest that manufacturers formalize risk management policies. Manufacturers should not underestimate the importance of risk management when alleviating FDA regulatory pressures. The challenge facing enterprises today relates to the process of performing and, more importantly, continually improving upon the results of risk management policies. For manufacturers in particular, the development and execution of risk management strategies must not lose sight of the challenge of satisfying regulatory requirements.

With respect to software validation, the process of risk management hinges on deploying the right services to better identify, analyze, evaluate and mitigate the inherent risks of a particular FDA-regulated enterprise. The FDA received over 80,000 reports of medical device problems in 2010 alone. More worrisome, over

the last decade, the number of problems reported by consumers is on the rise. This example illustrates the importance of alleviating regulatory pressures through a successful risk management-based approach.

THE PROCESS OF RISK MANAGEMENT

To overcome regulatory pressures, enterprises have established best practices for documenting the results of continually improving risk management in conjunction with software validation. Essentially, this process encompasses:

- Pinpointing risks
- Analyzing risks
- Evaluating risks
- Executing proactive steps to intervene

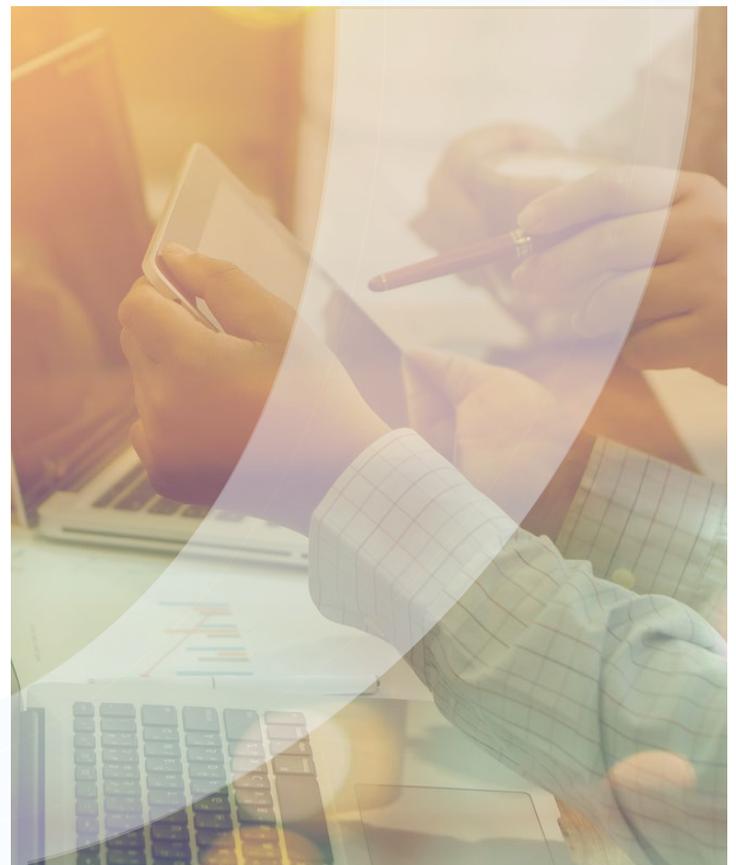
For instance, when manufacturers seek to validate software, risk management plays a critical role in pinpointing the sources of potential risks or non-conformances and their adverse consequences. Risk analysis then seeks to calculate the likelihood of such adverse events; and likewise, risk evaluation allows enterprises to prioritize risks according to this analysis. Once enterprises complete these steps in the risk management process, they can then take the necessary steps to intervene in the most cost effective manner.

IQS'S ROLE IN THE PROCESS OF RISK MANAGEMENT

IQS's software validation service affords enterprises the ability to improve upon the efficiency of the process of risk management. For instance, IQS's software

validation service provides a means to audit the efficiency of an enterprise's proprietary risk management policies and to institute recommendations accordingly. IQS's software validation service provides FDA-regulated enterprises with the increased agility necessary to deploy appropriate resources in concert with IQS's risk management-based approach.

The process of risk management incorporates the entire business. From conception to post-production monitoring, deploying the right consulting service is key to an efficient risk management process. Of the many services offered by IQS, software validation allows FDA-regulated enterprises to alleviate regulatory pressures through a sound methodology of risk management.





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