

Quality Risk Management ICH Q9 Briefing Pack

Introduction

ICH Q9 together with ICH Q8 and Q10 is one of the ICH Q-topics that encourage further development science based and risk based approaches to quality. The intention of ICH Q9 is to focus the behaviours of industry and regulatory authorities on the two primary principles of Quality Risk Management, which are:

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and
- The level of effort, formality and documentation of the Quality Risk Management process should be commensurate with the level of risk.

To support the implementation of Quality Risk Management into daily operations for Regulators and Industry some members of the ICH Q9 Expert Working Group have prepared a set of slides, which are intended to be used for information purposes in industry, regulators and other facilitators such as consultants. When using these slides it should be remembered that:

- **One purpose is to provide general guidance and references for some of the primary tools as well examples that might be used in quality risk management by industry and regulators.**
- **The slides are provided for illustrative purposes and suggest possible interpretations of the ICH Q9 guideline. It must be remembered that the selection of particular risk management methodology / tools is completely dependent upon specific facts and circumstances related to the risk being managed.**
- **Many of the slides contain animations. Viewing the slides in PowerPoint as a slide show will help the reader to understand the context in which the particular slide was derived.**
- **The slides are not intended to create any new expectations beyond the current regulatory requirements.**
- **The slides include the authors' views on the theory and practice of Quality Risk Management and do not represent official guidance or policy for either regulators or industry.**
- **The slides are placed in the public domain and should not be copied or republished for purposes of financial gain.**



Briefing Pack

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Disclaimer:

The Q9 briefing pack is offered as a supplementary explanation of the material in ICH Q9. It was prepared by some members of the ICH Q9 EWG for example only. It has not gone through any ICH formal process. It does not represent an official policy/guidance.