EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ICH guideline Q9 on quality risk management

Step 5

Transmission to CHMP	June 2005
Transmission to interested parties	June 2005
Deadline for comments	October 2005
Final adoption by CHMP	November 2005
Date for coming into effect	January 2006

Scope:

This guideline provides principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality. These aspects include development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substances, drug (medicinal) products, biological and biotechnological products (including the use of raw materials, solvents, excipients, packaging and labelling materials in drug (medicinal) products, biological and biotechnological products).

Link to: Quality guidelines

Link to: ICH Q8/Q9/Q10 Training material

Link to: ICH Q8/Q9/Q10 Points to consider

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