

Docket No. 2005D-0288.
International Conference on Harmonisation;
Draft Guidance on Q9 Quality Risk Management

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Page and position in March 2005 version	Current text	Suggested change	Comment/rationale for change
Page 1, paragraph 2	... achieving a shared understanding of the application of risk management...is difficult because...		It would be useful for ICH to discuss how Q9 could make risk management less difficult by helping to standardize the language and techniques used for QRM. What benefits will be seen by using Q9?
Page 1, paragraph 5	Appropriate use of QRM...	Use of QRM in situations where (add more detail)	It would be useful to have a clearer, more specific description of where and when QRM could be appropriate. Are there some criteria that can be used?
Page 2, section 4	...review of risks to quality of the drug...	Review of risks to the safety, identity, strength (potency), purity, quality, or efficacy of the drug	This makes the description of when to use QRM more specific to drugs/biologicals by mentioning the characteristics of a GMP-compliant product. (This also applies to the definitions.)
Page 2	Figure 1		The process flow diagram shown is different from that used by other risk management systems, particularly with regard to communication. The diagram implies that communication is done at only place point in the process. Other models (e.g., the Canadian standard, CAN/CSA-850-97, <i>Risk Management Guideline for Decision Makers</i>) have communication occurring throughout the risk management process. More communication between stakeholders <i>throughout</i> the process is valuable.

Other diagrams of risk management have monitoring and re-evaluation as a step; this is in keeping with the quality monitoring/product quality reviews that are standard practice in the pharma industry.

Another diagram that is an amalgam of other accepted is included in these comments.

Page 3, section 4.1	...teams dedicated to the task	...focused team...	The term “dedicated” implies that this is all the team is doing; they may have other responsibilities. “Focused” (or some other term) helps indicate that the team may have the analysis as a high priority but that it isn’t their sole job.
Page 3, section 4.3	Risk identification...to identify hazards	Hazard identification is...to identify those real or potential conditions, situations, or agents that could cause immediate or long term harm.	What is talked about here is hazard; when probability and impact are considered it is <i>risk</i> .
Page 3	Risk identification addresses...	Hazard identification addresses...	(See above.)
Page 4	Risk analysis is the estimation of the risk associated with the identified hazard.	Risk analysis includes the estimation...	Usually risk analysis incorporates system (or product or process) definition, hazard identification, and risk estimation. [“The systematic use of information to identify hazards and to estimate the chance for, and severity of, injury or loss...” CSA; “Systematic use of available information to identify hazards and to estimate the risk.” ICH 14971]
Page 4	Risk evaluation...		Risk evaluation examines if the risk is acceptable as it is or if it needs to be mitigated in some way. [“The process

by which risks are examined in terms of costs and benefits, and evaluated in terms of acceptability...” CSA; “Judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context...” ISO14971]

Page 5	Risk control	Risk evaluation	See above; control would be applying mitigation strategies
Page 5, section 5.1	Basic risk management facilitation methods	Defining systems, processes and products	Facilitation tends to imply that a person is helping or “facilitating” a discussion or discovery process. The emphasis in this section is on tool and techniques that can be used to better understand the system, process, products, facilities, etc. where hazards may be present.
Page 6, section 5.5	HACCP		HACCP is more than just a method for risk assessment – it is a more complicated <i>process</i> for managing risks. “Preliminary Tasks” (which are not listed in the document) and the 7 HACCP steps can be easily mapped back to most risk management schemes. While line #346 mentions this, it should be given more prominence. Is there a suggested reference for this tool?
Page 9, section 5.9	Risk ranking and filtering		
Page 11, section 7	Quality: Formalized system that...	Quality: Formalized, integrated system that...	Adding “integrated” incorporates the concept that the quality system elements (e.g., validation, change management, etc.) are connected
Page 13, section 8	References		It would be a benefit if ICH could somehow create a package of these references that would be available at low or no cost. For example, some of the IEC documents cost \$150-200, for each copy.
N/A			It would be useful if ICH could provide a description of the documentation

needed/appropriate for various “intensities” of a risk assessment and risk management program. The frequent questions are, “what should I document?” and “how much stuff should I keep?”

N/A

Another frequent question that should be considered by regulatory agencies is, “what QRM information is subject to review by regulatory investigators or inspectors?” Firms may be reluctant to include details that an investigator might use against a firm.

N/A

It would be useful if ICH could take a product or process example and show how the different tools would be used throughout the lifecycle of the process.

Example of an alternative diagram for risk management (shown in Draft as “Figure 1”).

The risk management process

