



# ABBOTT

## Corporate Regulatory and Quality Science

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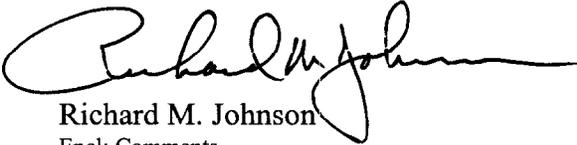
**Ref: Docket No 2005D-0288 – International Conference on Harmonisation;  
Draft Guidance on Q9 Quality Risk Management**

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the International Conference on Harmonisation; Draft Guidance on Q9 Quality Risk Management published on August 8, 2005 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,



Richard M. Johnson  
Encl: Comments

2005D-0288

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September 20, 2005

**ABBOTT COMMENTS TO FDA ON**

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International Conference on Harmonisation; Draft Guidance on  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

**COMMENTS**

**General Comments:**

Abbott supports the progression of Q9 as an ICH guideline and incorporation as a FDA Guidance for Industry

**Specific Comments:**

**Section 1. INTRODUCTION:**

Comment: Provide a statement on how risk management would apply to quality systems.

Proposed New Wording: Add the following statement at the end of the last paragraph in this section:

“Risk management may be an effective tool in determining the level of resources or degree of checks and balances put in place to address specific GMP requirements to assure the tolerable risk is not exceeded.”



## ABBOTT COMMENTS TO FDA ON

### Docket No 2005D-0288 International Conference on Harmonisation; Draft Guidance on Q9 - Quality Risk Management

#### Section 3. PRINCIPLES OF QUALITY RISK MANAGEMENT:

Comment: This section was rewritten as:

“Two primary principles of quality risk management are:

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

The underlined section doesn't make sense, level of effort is not based on scientific knowledge. The addition of this statement was in a previous round of comments and was intended to be added to the first bullet point after "protection of the patient".

Proposed New Wording: Correct to:

“Two primary principles of quality risk management are:

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

#### Section 4.3 Risk Assessment

Comment: The 3 questions were rewritten as:

1. What might go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)? (previously version stated "What is your ability to detect them")

The text in **Risk analysis** was not reworded to be in-line with the change to question #3 to “What are the consequences”. It was rewritten as:

**“Risk analysis** is the estimation of the risk associated with the identified hazards. It is the process that focuses on the second and third questions, seeking the likelihood that risks identified in risk identification might occur and an ability to detect them.”

Proposed New Wording: Correct to:

**“Risk analysis** is the estimation of the risk associated with the identified hazards. It is the process that focuses on the second and third questions, seeking the likelihood that risks identified in risk identification might occur and ~~an ability to detect them.~~ what are the consequences if they occur.”



## ABBOTT COMMENTS TO FDA ON

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

#### Section 4.4 Risk Control

Comment: Clarification is needed to ensure assessments are not repeatedly made without an end point.

Proposed New Wording: Revise the last sentence in the *Risk Reduction* section by adding underlined text as noted:

“Hence, it might be appropriate to revisit the risk assessment to identify and evaluate any possible change in risk until an acceptable risk tolerance is determined.”

#### Section 5.2 Informal Risk Management

Comment: Enhance the example by stating existing documented systems may meet the requirement of informal risk management

Proposed New Wording: Add the following statement at the end of the **Informal Risk Management** section:

“In these types of applications documentation to comply with GMP requirements is adequate”

#### Section 6. INTEGRATION OF QUALITY RISK MANAGEMENT INTO INDUSTRY AND REGULATORY OPERATIONS

Comment: These statements on training may be interpreted as an expectation or requirement. Also, this concept is redundant with Section 4.1, which is more appropriately stated as: “... individuals who are knowledgeable of the quality risk management process.”

Proposed New Wording: Delete the following paragraph

~~Training of both industry and regulatory personnel in quality risk management provides for greater understanding of decision making processes and builds confidence in quality risk management outcomes.~~