PDA
Parenteral Drug Association

PDA Global Headquarters
Suite 1500
3 Bethesda Metro Center
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Ref: INTERNATIONAL CONFERENCE on HARMONIZATION; DRAFT GUIDANCE on Q9 QUALITY RISK MANAGEMENT RELEASED FOR CONSULTATION ON MARCH 22, 2005; PUBLISHED AUGUST 8, 2005 [Docket No. 2005D-0288]

Dear Sir/Madam:

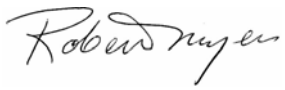
PDA is pleased to provide comments to FDA on ICH Q9 Quality Risk Management released for consultation on March 22, 2005. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological and device manufacturing and quality. The draft guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. The draft guidance is intended to enable regulators and industry to make more effective and consistent risk-based decisions. PDA wishes to thank the Agency for the opportunity to provide comments on this document.

PDA is optimistic that the publication of this document will provide industry with valuable resources and direction for managing a Quality Risk Management process. Detailed comments are provided in the attached Table. Topics are identified by topic or section number of the Draft Guidance. The following is a list of some of the major conclusions reached by the PDA review team.

1. We believe that a training program that includes case studies in the application of this document would benefit the industry as well as regulators.
2. PDA is concerned that, as written, this Guideline could lead to the practice of regulatory authorities wanting to audit results of internal risk management processes and procedures. As it is well accepted that one of the main goals of such processes is to allow industry to optimally strive for continual improvement, PDA recommends that the introductory language be revised to indicate that regulators will not audit all results of the Quality Risk Management process so that industry can use this process to work toward continual improvement.

PDA views this Guideline as a foundation document along with ICH Q8 and ICH Q10 (to be developed). Therefore, we believe it is of critical importance to ensure there is a clear and shared understanding between the regulatory authorities and industry of the concepts outlined in the Guideline and their practical application. We believe that all parties will benefit from continued dialogue around clarification, interpretation, and implementation of these concepts and we look forward to continuing to contribute to this discussion.

Sincerely,



Robert B. Myers
President, PDA