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

Reference: Draft Guideline entitled *Q10 Pharmaceutical Quality Systems*; FR Notice July 13, 2007; Vol. 72, No. 134; Docket No. 2007D-0266

Dear Sir/Madam,

PDA is pleased to offer comments on the Draft Guidance entitled *Q10 Pharmaceutical Quality* Systems, as published in the Federal Register on July 13, 2007. 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. Our comments were prepared by a global group of PDA quality system experts and are attached in a spreadsheet with specific detail. PDA appreciates the opportunity to offer comments on this important document and wishes to thank the FDA for the opportunity to do so

PDA strongly supports the concepts of life cycle thinking that are evident throughout the document and believes that companies embracing these concepts will facilitate the creation, seamless transfer, and maintenance of product and process knowledge. We also salute the articulation of management responsibility as well as escalation expectations—a quality system cannot be successful without the full endorsement and engagement of management. And finally, PDA appreciates that the document facilitates the concepts of continual improvement of the product, processes, and quality systems to assure capable and controlled operations.

Broadly speaking, and to further strengthen the document, we offer the following general comments. More detailed comments and suggestions for rewording are included in the attached spreadsheet which accompanies this letter. For ease of reference, we have attached a Word version of the original Guideline with line numbers added, and have referenced our comments by Section and line number.

1. While PDA enthusiastically endorses the concepts of life cycle thinking, we believe the tables could be improved with more meaningful examples. We have provided detailed comments for the tables in the attached spreadsheet.

2. The document provides commentary on the alignment of quality objectives with a company's strategic plans as well as the development and review of key performance indicators. We strongly support the development of quality objectives but find guidance on the alignment of those objectives to a company's "strategic plans" too prescriptive given the diversity in size and management approaches across the companies to which this guidance will apply. We are proposing the same intent with different language, replacing the words "strategic plans" with "company's corporate strategy and

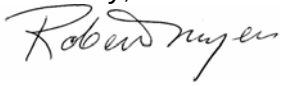
direction". We also find the terminology of "key performance indicators" to be less appropriate than the use of "performance metrics". For many companies key performance indicators are synonymous with financial results.

3. Finally, we have added wording throughout to emphasize the importance of defining roles and responsibilities as well as decision making processes.

Again, PDA appreciates the opportunity to comment and offers these suggestions for your consideration. We believe that these comments will serve to streamline and strengthen the guidance and will create a document that will better serve the needs of both regulators and industry.

We would welcome the opportunity to participate in a public discussion of these and other comments which FDA may receive on the draft guidance, and would be happy to discuss the details of such a meeting and contribute to the planning process, should you wish to pursue that concept.
If you need further clarification, please do not hesitate to contact me.

Sincerely,



Robert B. Myers
President, PDA

Enc: Detailed Comment Spreadsheet

H: ICHQ10cover letter
10/9/07