

PDA

AN INTERNATIONAL ASSOCIATION FOR
PHARMACEUTICAL SCIENCE AND TECHNOLOGY



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

Chair:

Nikki V. Mehringer
Eli Lilly and Company

Chair-elect:

Richard V. Levy, Ph.D.
PAREXEL Consulting

President:

Neal G. Koller

Secretary:

Stephanie R. Gray

Treasurer:

Georg L. Roessling, Ph.D.
Schering AG

Immediate Past Chair:

Floyd Benjamin
Keystone Pharmaceuticals, Inc.

Directors:

Jennie K. H. Allewell
Wyeth Research

Vince R. Anicetti
Genentech, Inc.

Robert L. Dana
Elkhorn Associates, Inc.

Rebecca A. Devine, Ph.D.
Independent Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corp.

Yoshihito Hashimoto, M.Sc.
Chiyoda Corporation

Maik W. Jornitz
Sartorius Corporation

Suzanne Levesque
Sabex, Inc

Tim R. Marten, D.Phil.
AstraZeneca

John G. Shabushnig, Ph.D.
Pfizer, Inc

Lisa M. Skeens, Ph.D.
Baxter Healthcare Corporation

Anders Vinther, Ph.D.
CMC Biopharmaceuticals A/S

General Counsel:

Jerome Schaefer, Esq.
O'Brien, Butler, McConihe &
Schaefer, P.L.L.C.

**Editor, PDA Journal of
Pharmaceutical Science
and Technology:**

Lee E. Kirsch, Ph.D.
University of Iowa
College of Pharmacy

November 23, 2004

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

Ref.: FDA White Paper: "Defining the Customer in a Regulatory Agency" submitted to Docket #2003N-0059 - Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

PDA is pleased to provide comments on the recently issued white paper: *Defining the Customer in a Regulatory Agency*. PDA is an international professional association of more than 10,000 individual member scientists having interest and expertise in pharmaceutical and biopharmaceutical manufacturing and quality. A committee of interested industry representatives prepared the comments that follow.

PDA is encouraged and applauds FDA for issuing this white paper presenting a mechanism to define and characterize internal and external customer relationships. Defining customer relationships is a complex undertaking by FDA and at times can be "uncomfortable" given the many different roles, responsibilities and relationships FDA has with the identified customer base. We believe FDA's effort and the ultimate benefit of this white paper will support other FDA initiatives including, but not limited to:

- First and foremost, the use of a "quality system" approach to FDA operations that defines procedures that may guide these FDA customer relationships going forward.
- International Harmonization
- Promotion of the use of scientific principles that clarify and provide a common platform to discuss the execution of FDA's roles and responsibilities with its variety of customers (i.e. ranging from other governmental agencies to *compelled customers*).
- Setting the context for dialog regarding the application of risk management principles to assure that safe and efficacious drugs are available in support of the FDA's public welfare mandate.

PDA supports discussion and further development of this white paper and offers these comments in a constructive manner.

2003N-0059

C6

General Comments:

- We recommend FDA clarify the term *Industry* by evaluating their roles, responsibilities and relationships for each *Industry* segment. Within the document, FDA has stated the term *Industry* may encompass "industry groups or associations as well as individual firms." PDA as a member based organization (e.g. individuals not their respective firms join PDA) sees itself in a unique role separate from *Industry* as defined in this document. Specifically,
 - Industry as a *compelled customer*, FDA's interaction includes enforcement activities with industry.
 - Industry as a *technology provider*¹ to a *compelled customer*, FDA's interaction depending on the specific technological tool or service may or may not warrant enforcement activities.
 - Industry as a *collaborating customer*, FDA may engage Academia or Scientific Associations such as PQRI or PDA to help support new FDA initiatives by collecting the best available scientific positions; to develop FDA training programs; or solicit input to new or revised guidance documents.
- Another FDA customer segment includes the International Regulatory Agencies such as ICH, EMEA & PIC/S. We recommend FDA explicitly define such organizations as a customer segment within the scope of this white paper given FDA's commitment to achieving harmonization.
- This white paper states (Section 3, page 5 of 5) the regulated industry should receive:
 - professional treatment in resolving disputes;
 - fair application of laws and regulations in enforcement activities; and
 - fair and consistent inspections.....

Based on these statements, industry expects and anticipates that scientific data and evaluation should rule when FDA approaches industry during inspections as well as when resolving technical disputes and thereby underscores the importance of the Technical Dispute mechanism for resolving differences between the agency and its various customers. Please amend these bullet points to include:

- scientific evaluation in resolving technical disputes
- fair and consistent application of laws and regulations in enforcement activities.

¹ Technology Providers represent an FDA industry segment that provides technology, tools and services (i.e., process development & validation) for development through production of new therapies and drugs manufactured on a worldwide basis.

- We recommend the following image-related characteristics or changes be considered for inclusion in the *Quality Attributes (Section III page 4 of 5)*:

Insert	Replace
<u>Innovation</u> : Continuously looks for new and better ways to do things. (additional Quality Attribute)	
<u>Reliability & Integrity</u> : Dependable, confidence in character, abilities and acts in an honorable and trustworthy way.	Reliability and Trustworthiness

- Having identified one's customers, it is important to truly understand their needs (whether they be internal or external). PDA encourages including references in the white paper to establish appropriate techniques (such as surveys, focus groups, etc.) for gathering and assessing customer (internal and external) needs and expectations. It is important FDA has a clear, factual understanding of customer needs incorporated into an Agency plan outlining appropriate customer interactions. Implementing such techniques provides a more rigorous and reproducible methodology for characterizing customers needs and expectations (especially when industry is a "compelled customers").

Corrections &/or Clarification Requested:

- Corrections: (Section IV, page 5 of 5), second bullet
 . . . Correction in red.efficiency **without** compromising the work product.
- Clarification: (Appendix B- Enforcement page 2 of 3)
 However the *FDA all-customer service?* standard includes "participation in the agency's decision-making process. Does an "all-customer service standard" exist? PDA is unclear as to the meaning or intent of this statement.

Yours sincerely,



Victoria Ann Dedrick
 Vice President, Quality and Regulatory Affairs
 PDA