Defining the Customer in a Regulatory Agency

A white paper from the FDA Quality Resource and Development Team
Version 2.0

I. Introduction

This document supports the implementation of quality systems within FDA components by clarifying the concept of "customer" of a regulatory agency.

When an FDA component develops a quality system, the FDA Quality Systems Framework *(reference #1)* requires the component to do an analysis of customers and customer needs. Section 1.3 of the Framework outlines the requirements for identifying customers of the products or services that are provided by FDA. A customer is defined in the Framework as "a person or organization (internal or external) that receives a product or service anywhere along the product's life cycle."

> *Regulators must adopt a broader vocabulary, so they can think not only in terms of customers, but also of stakeholders, citizens, obligates, objects or targets of enforcement, beneficiaries, taxpayers, and society."*
> Reference #2, p. 63

In carrying out our public health mission (reference #3), we at FDA clearly understand that the American public is our primary customer and that we are to serve the public good by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. However, many other groups are considered customers as well: Congress, the Department of Health and Human Services and other government agencies, healthcare groups, and healthcare providers. The industries that we regulate are also customers of FDA regulatory activities, processes, or work products.

Identifying specific customers of an organizational unit or activity can be complex. The Customer Identification Exercise in Appendix A provides a consistent methodology for FDA components to follow when identifying their customers. The exercise will help

1) identify both internal and external customers, and
2) prepare to analyze the relationship between the unit's customers and the unit's work products as a quality system is developed.

Once customers have been identified, quality metrics can be determined for a particular interaction or process and linked to the metrics of the component's quality objectives. Appendix B will aid the organizational unit in terms of better understanding the role of industry as a "customer."

II. Types of Customers

A. Internal customers

> *Customer - a person or organization (internal or external) that receives a product or service anywhere along the product's life cycle.*
> Ref. #1, Glossary

Quality expert W. Edwards Deming taught that everyone in an organization has a customer; if that is not understood, then they do not understand their job. Internal customers are persons or units within an organization that receive another unit's products, services, or information[1]. Many times immediate customers will be part of the same organization, component, or even unit rather than a party external to FDA (see section B below). Internal customers within a work unit may be referred to as "process partners."

Some examples of internal customers:

- Product review team members (including Regulatory Project Managers), Regulatory Information Specialists and consult/collaborative reviewers are internal customers working in a collaborative process to assure both maximum review efficiency and a complete administrative record.
- Inter- and intra-center consultation
- Functional branches frequently have an internal customer relationship such as when they provide an investigative report to a compliance branch for enforcement evaluation.
- The Office of Shared Services (OSS) provides services to FDA offices and individual FDA employees. For example, when a Center, ORA, or Office of the Commissioner employee contacts the Employee Resource and Information Center (ERIC) requesting service, then OSS views that employee as an internal customer.
- When an investigator needs information while on an inspection and contacts an application reviewer, employees should treat one another as internal customers.

B. External customers

Any customers outside of FDA are called external customers. Although many FDA employees do not interact directly with external customers, they nevertheless need to be aware how their work products or services may be related to external customers' requirements downstream in the work process.

The FDA serves four primary external customer groups:

[1] Note: This paper does not intend internal customer relationships to be applied to the chain-of-command or supervisory relationships.

(1) the general public (consumers)

(2) health professionals

(3) other Federal, state, local and international government agencies, and

(4) regulated industry.

These four broad categories encompass the populations served and worked with most often. There may also be involvement with other customers such as academia, legal firms, trade associations, or the media. Unlike in some private sector contexts, FDA's definition of an external customer does not relate to an exchange of money, a purchase, or a buying decision.

Some examples of external customers:

- The general public is almost always the ultimate customer of our services and products, albeit frequently in an indirect fashion, through our mission to protect and advance the public health *(reference #2)*. However, the public may be the direct customer when a Public Affairs Specialist is presenting information to an interest group or when an investigator is responding to a consumer complaint.,

> *"Merits of customer service have not only to be balanced with mission accomplishment but, integrated within it. All the tools- from the gentlest persuasion to the harshest enforcement campaigns – should be melded within the coherent strategies for producing broad compliance.*
> Reference #2, p. 64

- Health professionals and patient advocacy groups are generally indirect customers. For some FDA employees, they may be direct customers: the recipients of training or information programs, or users of the consumer and health professional complaint reporting processes in the agency. Patient representation on Advisory Committees.
- Relationships with other government agencies may be complicated. A state agency could be a recipient of an FDA analysis, a partner in embargoing regulated products with suspected violations, or a sub-contractor receiving payment to perform inspections on behalf of FDA.
- FDA has previously, in the context of Executive Orders in the 1990's, referred to regulated industry as a customer, "compelled customer," or stakeholder. The idea of regulated industry as a customer has been an awkward one for FDA because all of the traditional "customer" roles and expectations do not necessarily apply or may even seem to conflict with FDA's regulatory or enforcement duties (see Appendix B). Regulated firms may be direct customers—receiving an Inspectional Observations Form *FDA 483 (483)* from an investigator, or indirect customer—an industry member who analyses other companies' 483s for their own benefit. The term 'industry' may encompass industry groups or associations as well as individual firms.

III. Customer Interactions

A. Developing standards

The standards described below represent the agency's effort to identify the needs and concerns of customers. The standards are based on measured performance attributes—a set of criteria that expresses customer requirements and expectations. Performance attributes are organized into two categories.

(1) Process Attributes—transaction-related characteristics represented by internal operations, such as procedures, policies, and functions.

- *Consistency in policies and procedures* – holding to the same principles or practices across the organization.
- *Convenient feedback mechanisms* – feedback (output that is responsive to input) arrangements that are easy to use or get to.
- *Frequent communication, including follow-up* – any form of communication on a regular basis, where the effectiveness of that communication is enhanced by taking action following that communication.
- *Optimal resource management* – careful control and use of resources, human, as well as fiscal, to maximize their impact and effectiveness.
- *Problem solving/troubleshooting* – proposed solutions or considerations to resolve something that is an obstruction or prevents progress.
- *Prompt and thorough handling of complaints* – immediate or quick investigations and appropriate handling of charges of dissatisfaction and their resolution.

Communication Is Key to Our Success - Developing effective tools to open lines of communication with our customers will help us do our jobs better. By developing more effective ways to direct information to our customers and by providing clearer paths to receive feedback, our agency will be in a better position to address customer needs and concerns.
Reference #4

(2) Quality Attributes—characteristics that describe the value of the contact between the customer and the organization.

- *Accessibility* – ability or freedom to approach, communicate with, or make use of.
- *Courteousness* – respect or consideration.
- *Flexibility* – capability to adapt to or change requirements.
- *Knowledgeable* – familiarity with or understanding of facts and/or conditions.
- *Active listener* – gives attention and/or careful consideration to what is said.
- *Reliability and Trustworthiness* – dependable, confidence in character, abilities, truth and confidentiality
- *Timeliness* – information and/or responses are provided early or on time. Customers will be notified of any delays.

B. FDA Customer-interaction Standards

The following FDA standards were developed by FDA in the 1990's and apply to the major customer groups.

All FDA Customers should receive:

- Fair, courteous and professional treatment;
- Information that is accurate and current;
- Timely responses to requests;
- Reasonable access to appropriate staff;
- Confidence that efforts are made to assure that regulated products in the marketplace are in compliance with FDA laws and regulations;
- Two-way communication;
- Opportunities for collaboration and partnerships, as appropriate;
- Participation in the agency's decision-making process; and
- Consideration of their opinions and concerns by the agency.

In addition,

- Consumers should receive accurate and timely health information about regulated products.
- Health Professionals should receive timely information that will assist them in advancing and protecting the public health.
- Other Government Agencies should receive:
  - cooperation from the FDA in maximizing efficient use of resources, eliminating duplication of efforts, and carrying out collaborative efforts.
  - technical assistance, training and guidance.
- Regulated Industry should receive:
  - timely review of product applications;
  - professional treatment in resolving disputes;
  - fair application of laws and regulations in all FDA activities;
  - fair and consistent inspections and product application reviews; and
  - respect in the agency's performance of duties and responsibilities.

IV. Next Steps

After identifying a unit's customers, the next task in developing a quality system is to determine customers' needs in relation to the products or services the unit provides to them. Because FDA work products and services may have many internal and external customers, conflicts between customers' needs may be perceived. For example:

- internal customers may desire process attributes such as speed, low cost, or efficient use of resources. These demands may impact the *product* attributes needed by the ultimate (internal or external) user of the product.

- user fees may be provided with the requirement to provide pre-market reviews in an agreed upon time frame. Some contend that a faster review process occurs at the expense of the public health. FDA's goal should be to improve review efficiency without compromising the work product—the review decision.
- External health care providers may request information from FDA, that is, by law, required to be kept confidential.

When a unit begins the needs-identification step, the unit manager is the primary resource for accounting for and explaining different customer needs.

References

1. FDA Staff Manual Guide: FDA Quality System Framework for Internal Activities, version. 1.0., September 2004.
2. Malcolm K. Sparrow, The Regulatory Craft (Brookings Institution Press, 2000)
3. FDA Mission Statement: http://www.fda.gov/opacom/morechoices/mission.html
4. FDA Customer Service Standards: http://www.fda.gov/comments/standard.html
5. U.S. Food and Drug Administration Customer Service Plan, 1998?
6. Mark Moore, Creating Public Value: Strategic Management in Government (Harvard University Press, 1995)

[end paper, v2, 07 Mar 2007]
[attached: Appendices A & B]

Appendix A - Customer Identification Exercise

1. Purpose of Exercise

Under the FDA Quality System Framework for Internal Activities, FDA units identify their customers and their customer's requirements in order to design and implement a quality system. This exercise is designed to help FDA units successfully accomplish that task. The goal of a quality system is to ensure that customers receive quality services and/or products from the organization, so it is critical that the customer(s) be clearly defined and that the employees understand the link between their work and their customers' needs.

As a regulatory agency, FDA also interacts directly and indirectly with the regulated industry. As part of completing a customer analysis, FDA units will explore their relationship to the regulated industry (FDA SMG 2020, (5)(a)(§1.3)).

> *"Identify the organization's customers and, when applicable, the organization's relationship(s) with regulated industry"*
>
> (FDA Quality System Framework for Internal Activities, Section 5 Quality System Framework, (a) Requirements, §1.3(a))

Once customer identification is accomplished, the unit will also need to solicit and understand the customers' needs; confirm that product/service characteristics meet the customers' needs; develop appropriate metrics; and ensure that personnel understand the impact of their activities on the product/service and the customer. This exercise sets up the foundation for these additional activities.

2. Responsibilities for presenting the exercise

(a) Unit manager

Prior to the exercise, the manager should:

- identify quality concerns
- address the benefits of the exercise to the organization and the individual participants
- choose a facilitator, and
- assist the facilitator in identifying general categories of work products and customers, especially if quality problems exist.

During the exercise, the manager should

- explain to participants why the exercise is being done and what, if any, quality issues have been noted. Any problem discussions should be factual and blame-free.
- share any known priorities concerning work products/services, or customers and explain the program information or management directives that establish priorities consideration, i.e. FDA Strategic Plan or management concerns, and
- participate in the discussion as needed to identify any significant customers, products, and /or services that were not identified by the group, or if new information is available.

After the exercise and in a timely fashion, the manager should follow-up on or oversee any action items agreed upon during the exercise.

(b) Facilitator

Prior to the exercise, the facilitator should prepare an evaluation form for the participants.

During the exercise and utilizing the exercise outline in the available MS PowerPoint presentation (see §4.), the facilitator should:

- lead participants in a brainstorming exercise and capture ideas on flipcharts or other visual format,
- instruct and facilitate participants in how to categorize ideas,
- provide a forum for opposing views, and
- lead discussions.

3. Outline of exercise

(a) Techniques - Group participation techniques of brainstorming, categorization, prioritization, and discussion should be used in the exercise.

Balancing and integrating customer service with mission accomplishment is one of the central challenges of the regulatory art…
Paying insufficient attention to customer satisfaction may result in heavy-handed, unresponsive, and low-quality service…
Overemphasizing customer service can lead to those on the receiving end of the regulatory encounters to feel entitled to be pleased; and they will use every avenue open to them to retaliate against inspectors or enforcement agents who displease them by taking a firm stance.
Malcolm K. Sparrow, *The Regulatory Craft*, p. 64

(b) Objectives – The following objectives are to be met by completing the exercise:

- identify products and services,
- identify immediate, secondary, and indirect recipients (customers) by examining work processes, process inputs, and who provides feedback,
- note relationships to and between various customers identified (including industry), and
- identify any conflicts between customers or between FDA's mission and that of a customer

(c) Outputs - Outputs of the exercise should include

- list of customers for various products and services (note: customers and/or customer relationships may vary during a product's life cycle)
- statement(s) on relationship to industry, if any, for those products and services
- priorities for processes, products or services, and/or customers to be addressed by the quality system, and
- action items identified as needed.

Although the focus of this discussion is to identify the customer, the unit may also have notes on the value of products to the customer, initial ideas of customer needs or information on how the customers' requirements are obtained, etc. These ideas should be retained for determining the Framework requirements concerning identifying customer needs.

4. Supporting tools

Available from QRGT via e-mail FDA-QTIPS.INBOX@EROOM.FDA.GOV, or the "QTIPS eRoom" at HTTP://EROOM.FDA.GOV/EROOM/OC/FDA-QTIPS.

- *"Customer Identification Exercise"* (Appendix A) & PowerPoint presentation
- QRGT white paper: *"Defining the Customer in a Regulatory Agency"*
- Information on brainstorming, process mapping, *etc*.

[end appendix A, v2, 07Mar07]

Appendix B - Industry as a Customer

This document is designed to be used as part of an FDA customer identification exercise. It should not be used outside the context of identifying the multiple customers of FDA.

For regulatory agencies, defining the regulated industry as a customer can be problematic. Traditional notions of customer service, *e.g.* "the customer is always right," may conflict, or seem to conflict, with FDA's regulatory responsibilities or enforcement duties. However, FDA meets its regulatory responsibilities while providing guidance and assistance. This document discusses FDA's relationship with industry as a spectrum of customer interactions. Regardless of the customer definition, FDA treats all customers, including regulated industry, in a fair, courteous, and professional manner[2]..

Identify the organization's customers and, when applicable, the organization's relationship(s) with regulated industry

(FDA Quality System Framework for Internal Activities, Section 5 Quality System Framework,(a) Requirements, §1.3(a))

1. Providing Services – FDA's customer relationship with industry will differ depending on the transaction involved. At one end of the spectrum, industry clearly is a direct customer of FDA's products or services. For example, when FDA develops guidance documents representing the agency's current thinking on a particular subject, we provide clarity and understanding to firms that manufacture FDA regulated products. With this information, industry has a better understanding of the agency's expectations about their products, and this may enable companies to manufacture products more efficiently or approach regulatory milestones with greater certainty.

In addition to guidance, FDA provides training to help companies understand the regulatory processes and requirements. In some cases, we tailor presentations to companies that have had little or no previous contact with FDA. In other cases, we target audiences seeking an advanced understanding in a specific regulatory area. We may even offer suggestions that assist industry with solving a specific technical problem in their research, application, or product.

[Regulatory] organizations meet individual clients not as service providers but as representatives of the state obliging clients to absorb a loss on behalf of society at large.

Mark Moore, *Creating Public Value: Strategic Management in Government*, p. 37

During the last decade, FDA began using regulatory strategies based on a mix of traditional and nontraditional tools. This strategy included outreach programs that encouraged communication between the agency and industry about FDA's new compliance initiatives. These strategies help the agency leverage its scarce inspectional and enforcement resources by improving the dialogue between the agency and industry, and helping

[2] See discussion in main paper, section III.B.

industry customers achieve voluntary compliance with the Federal Food, Drug, and Cosmetic Act and agency regulations. Thus, industry clearly is a customer of the guidance documents and educational programs that we develop.

Other activities at FDA may have less obvious, but no less important significance to the regulated industry. For example, we conduct internal training in many regulatory areas to promote increased competency and greater review consistency among our review staff. Although this training is targeted at FDA reviewers, the regulated industry is also one of the beneficiaries. Likewise, when we conduct research to develop industry standards and methods, industry is a customer of this activity since this research assists them during the product development or agency review phase. In addition to guidance, FDA provides training to assist companies to understand our regulatory processes and requirements. In some cases, we tailor presentations to companies that have had little or no previous contact with FDA. In other cases, we target audiences seeking an advanced understanding in a specific regulatory area. We may even offer suggestions that assist industry with solving a specific technical problem in their research, application, or product.

2. Enforcement – Enforcement actions occupy the other end of the industry-as-a-customer spectrum. Here, industry is not viewed as a customer in the traditional sense. For example, when FDA conducts a civil or criminal enforcement action against a firm for violating a law or regulation, the firm bears little resemblance to a customer. In such cases, we sometimes refer to industry as a "compelled customer." Yet even when FDA conducts an enforcement action, we nonetheless should meet certain customer service standards, such as communicating clearly in a professional and timely manner. Moreover, we need to be aware of indirect customers who benefit from the information generated by our enforcement actions. For example, when we issue a Form FDA 483 or regulatory letter, or publish the details of an enforcement action, we are also publicizing how we intend to apply our regulatory standards. This information may, in turn, be used by a much larger audience that relies on this information to improve their processes, procedures, or methods.

When FDA operates in an enforcement mode, there are limits to the scope of customer service that we should provide.

> *To understand the merits and limits of customer service for regulatory and enforcement functions, practitioners should pass the idea through a number of filters… First they should not assume that emulating the private sector's treatment of customers will automatically improve government… Second, in most regulatory contexts, the person or party the regulator encounters directly is not paying for the service, often does not want it, and will not be pleased by it.*
>
> *Third, regulators should not permit a customer orientation to lead to exclusion or neglect of enforcement capacities…Failure to enforce the law swiftly and effectively against deliberate or persistent offenders undermines the incentives for compliance in the rest of the community and may bring a regulatory regime into disrepute.*
>
> *"Fourth, regulators should understand that corporate behavior moves quickly to take advantage of any perceived softening*
>
> Malcolm K. Sparrow, *The Regulatory Craft*, p. 62-63

We have already mentioned that "the customer is always right" concept may at times be inappropriate, particularly in regard to enforcement issues. However the FDA Customer Service Standard includes "participation in the agency's decision-making process." Although we provide opportunities for discussion during an inspection, for formal dispute resolution, and for replies to FDA actions, FDA does not extend this customer-service standard to industry in enforcement matters. The importance of these limits is illustrated by the experiences of two Federal agencies responsible for criminal enforcement of their laws. During the mid-1990s the U.S. Customs Service (now the Bureau of Customs and Border Patrol) and the Internal Revenue Service instituted policies to promote customer service, customer satisfaction, and partnering with customers. Although these initiatives yielded important benefits, enforcement officers and criminal investigators viewed these initiatives as an effort to downplay enforcement as an agency priority, which, in turn, triggered a decline in enforcement efforts by these agencies. As Dr. Malcolm Sparrow warns in *The Regulatory Craft*, regulatory agencies "should not permit a customer orientation to lead to exclusion or neglect of enforcement capabilities."(*reference #1, p.63*)

3. The Middle Ground – FDA also conducts activities in which our relationship with industry falls somewhere between the traditional concept of a customer and the enforcement mode. Examples of activities that lie in this broad middle ground include vaccine lot release or alternative to lot release decisions, letters placing a product application on clinical hold, application reviews, and requests for information, labeling negotiations, and pre-launch review of advertising. In some cases, our relationship to industry will vary depending on the nature of the regulatory interaction; we will strive to consider appropriately the needs of regulated customers while fulfilling our agency mandate.

[end appendix B, v2, 07Mar07]