Defining the Customer in a Regulatory Agency

A white paper from the FDA Quality Resource and Development Team
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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 their needs. Section 1.3 of the Framework outlines the requirements for identifying customers of the products or services that you provide. 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."

In carrying out its public health mission *(reference #3)*, FDA clearly understands that the American public is the primary customer of the agency's work and the products we regulate. However, we also see many other groups as customers: Congress, the Department of Health and Human Services

> *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

or other government agencies, healthcare groups, and healthcare providers. The industries that we regulate may also be customers of FDA regulatory activities, processes, or work products.

Identifying specific customers of an organizational unit or activity can be a complex process. The Customer Identification Exercise in Appendix A provides a consistent methodology for FDA components to follow when identifying their customers. The exercise will help you
        1) identify both your internal and external customers, and
        2) prepare to analyze the relationship between your customers and your work products as you develop your quality system.

Once you identify your customers, you will be able to determine quality metrics for a particular interaction or process and link the metrics to your component's quality objectives. Appendix B will aid you in coming to terms with the role of industry as a "customer."

II. Types of Customers

A. Internal customers

Quality expert W. Edwards Deming says 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

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

receive your products, services, or information[*]. Many times you will find your immediate customers to be part of your organization, component, or even unit rather than a party external to FDA (see section B below). Internal customers within your own 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.
- Functional branches frequently have an internal customer relationship such as when an investigative report is handed over to a compliance branch for enforcement evaluation.
- The Office of Shared Services (OSS) provides services to its customers, in this instance to an internal customer. When a Center, ORA or Office of the Commissioner employee contacts ERIC (the Employee Resource and Information Center) requesting some sort of service, for example, a computer password change or a request for building and maintenance service such as a leaky ceiling, then OSS views that employee as a customer.
- When an investigator needs information while on an inspection and contacts an application reviewer, the reviewer needs to treat the investigator as an internal customer.

B. External customers

Any customers outside of FDA are called external customers. Many FDA employees do not interact directly with external customers, but they must know how their work products or services may be related to external customers' requirements downstream in the work process.

The Food and Drug Administration serves four primary customer groups – (1) the general public (consumers), (2) health professionals, (3) other Federal, State and local government agencies, and (4) regulated industry. These four broad categories encompass the populations that we serve and work with most often. You may be involved with other customers such as academia, legal firms, trade associations, or the media. Unlike in some private sector contexts, FDA's definition of customer does not relate to an exchange of money or a purchase, a buying decision, to define a group as an external customer.

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

Some examples of external customers:

- The general public is almost always the ultimate customer of our services and product, 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.

- 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.

> *"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

- 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 by 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 uncomfortable one for FDA but as our understanding of quality systems grows, we may be able to expand our vocabulary to adopt more fitting references to industry. Regulated firms may be direct customers—receiving an Inspectional Observations Form 483 from an investigator, or indirect—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.
- *Manages resources well* – careful control and use of resources, human as well as fiscal, to maximize their impact and effectiveness.
- *Problem solving and attempts to remove barriers* – proposed solutions or considerations to resolve something that is an obstruction or prevents progress.
- *Prompt handling of complaints* – immediate or quick management of charges of dissatisfaction.

> *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—image-related characteristics that describe 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.
- *Listens well* – gives attention and/or careful consideration to what is said.
- *Reliability and Trustworthiness* – dependable, confidence in character, abilities, and truth
- *Timeliness* – information and/or responses are provided early or on time.

B. FDA Customer-interaction Standards
The following FDA standards were developed by FDA in the 1990's and apply to the major customer groups.

<u>All FDA Customers</u> 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,

- <u>Consumers</u> should receive accurate and timely health information about regulated products.
- <u>Health Professionals</u> should receive timely information that will assist them in advancing and protecting the public health.

- <u>Other Government Agencies</u> should receive:
  - o cooperation from the FDA in maximizing efficient use of resources, eliminating duplication of efforts and carrying out collaborative efforts.
  - o technical assistance, training and guidance.
- <u>Regulated Industry</u> should receive:
  - o timely review of product applications;
  - o professional treatment in resolving disputes;
  - o fair application of laws and regulations in enforcement activities;
  - o fair and consistent inspections and product application reviews; and
  - o respect in the agency's performance of duties and responsibilities.

IV. Next Steps

After identifying their customers, your unit's next task in developing a quality system is to determine customers' needs in relation to the products or services you provide to them. Because FDA work products and services may have many internal and external customers, you may have or perceive conflicts between your customers' needs. For example:
  - o 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 your products.
  - o user fees may be provided with the requirement to provide pre-market reviews in a agreed upon time frame. Some contend that a more efficient review process occurs at the expense of the public health. However, it is possible for FDA to improve our review efficiency with compromising the work product—the review decision.

When your unit begins the needs-identification step, your manager is your 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)

[Appendices A & B]

Appendix A - Customer Identification Exercise

1. Purpose of Exercise

Under the FDA Quality System Framework for Internal Activities, as part of the design and implementation of a quality system, FDA units identify their customers and their requirements. 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 your organization, so it is critical that the customer be defined and that the employees understand the link between their work and the customers' needs.

As a regulatory agency, FDA also interacts directly and indirectly with the regulated industry. As part of a customer analysis, FDA units will explore their relationship to the regulated industry.

Once customer identification is accomplished, the unit will solicit and understand the customers' needs; confirm that product/service characteristics meet the customers' needs; develop appropriate metrics; and ensure that personnel understand

> *"Identify the organization's customers and, when applicable, the organization's relationship(s) with regulated industry"*
> (FDA Quality System Framework for Internal Activities (version. 1.0), Section 5 Quality System Framework, (a) Requirements, §1.3(a))

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) <u>Unit manager</u>

　　Prior to the exercise, the manager should
- o choose a facilitator, and
- o assist facilitator in identifying general categories of work products/customers, especially if quality problems exist.

　　During the exercise, the manager should
- o 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.
- o share program information and management directives that establish priority consideration, i.e. why a particular category is important, and
- o add comments if significant customers, products and /or services were not identified, especially if they have information that may not have been communicated but should have been.

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

(b) <u>Facilitator</u>

　　Prior to the exercise, the facilitator should prepare an evaluation form for the participants. During the exercise and following the exercise outline in the available PowerPoint presentation (see §4.), the facilitator should,

o   lead participants in brainstorming exercise and capture ideas on flipcharts or other visual format
o   instruct and facilitate participants in how to categorize ideas, and
o   lead discussions.

3. Outline of exercise

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

(b) <u>Objectives</u> – The following objectives are met by the exercise:
o   identify products and services,
o   identify immediate, secondary, and indirect recipients (customers) by examining work processes, process inputs, and from whom you receive feedback, and
o   Note relationships to and between various customers identified (including industry)
o   Identify any conflicts between your customers

(c) <u>Outputs</u> - Outputs of the exercise should include
o   list of customers for various products and services (customers and/or customer relationships may vary during a product's life cycle).
o   statement(s) on relationship to industry, if any, for those products and services
o   priorities for processes, products or services, and/or customers to be addressed by the quality system
o   action items as needed

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

You may also have notes on value of products to the customer, initial ideas of customer needs or how they are obtained, etc. These ideas should be retained for determining the Framework requirements concerning identifying customer needs.

4. Supporting tools
•   PowerPoint presentation (available from QRGT contacts)
•   QRGT white paper: "*Defining the Customer in a Regulatory Agency*"
•   Information on brainstorming, process mapping, *etc.* (available from QRGT contacts)

[end]

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[†].

> *Identify the organization's customers and, when applicable, the organization's relationship(s) with regulated industry*
> (FDA Quality System Framework for Internal Activities (version. 1.0), 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 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.

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

> *[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

between the agency and industry, and helping 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.

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

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.

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 none-theless 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. We have already mentioned that "the customer is always right" concept is inappropriate. However the FDA all-customers service standard includes "participation in the agency's decision-making process." Although we 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

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, 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]