



1st Edition

# QMS19

## Customer Focus in a Quality Management System



This guideline provides useful information for how laboratories can develop and maintain a customer focus and meet the regulatory and accreditation requirements for managing external and internal customers.

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A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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### Abstract

Clinical and Laboratory Standards Institute guideline QMS19—*Customer Focus in a Quality Management System* defines the laboratory's external and internal customers; outlines the fundamentals of identifying customer expectations, defining shared expectations, and communicating performance outcomes; and provides useful tools to help the laboratory focus on providing quality examination results, products, and services to its customers. The processes described in this guideline will also help laboratories meet regulatory and accreditation requirements related to managing laboratory customers.

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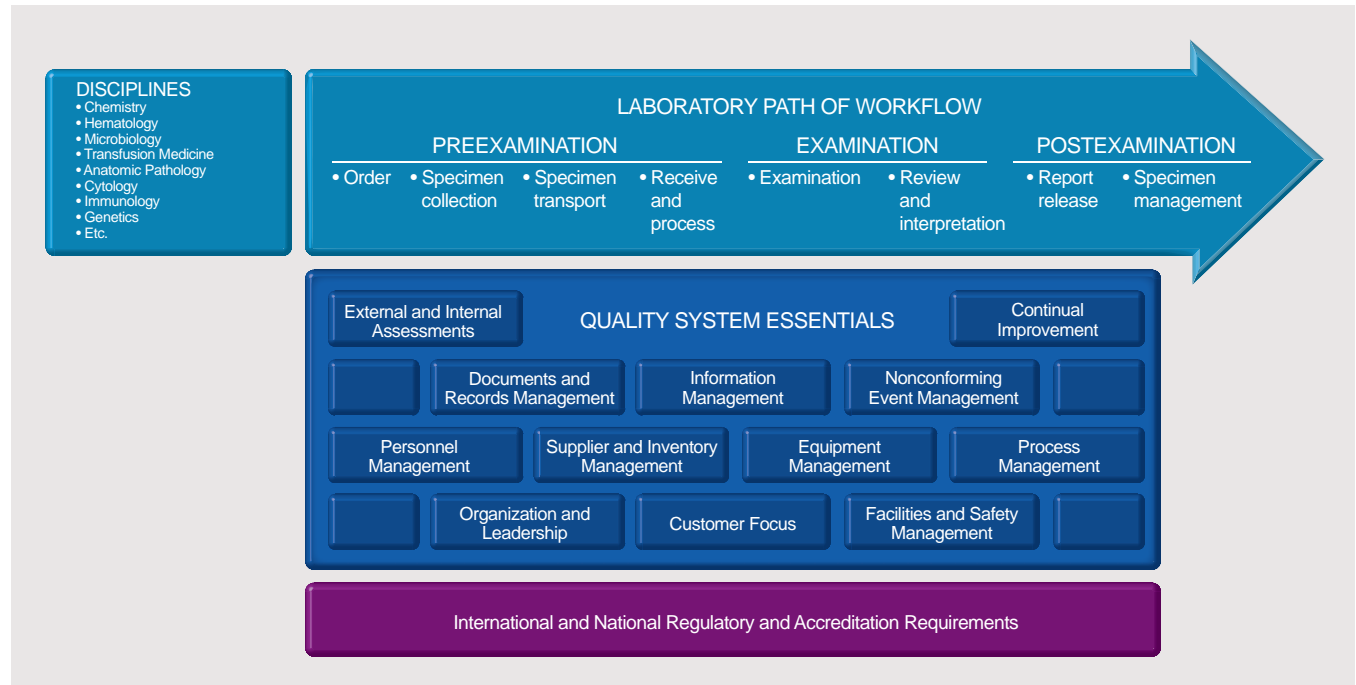
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## Foreword

Quality system essential (QSE) Customer Focus is one of the 12 QSEs described in CLSI document QMS01<sup>1</sup> and CLSI product *The Key to Quality*<sup>TM,2</sup> which provide the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE, such as Customer Focus, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.



**Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01<sup>1</sup>).** The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory processes. For example, when the laboratory lacks defined processes and procedures for properly installing, calibrating, and maintaining its analyzers so they work effectively, problems in examination processes could cause a failure to meet customer expectations.

International guidance related to the QSEs and the laboratory's path of workflow is available. Topics include:

- ▶ A process-based model for quality that any business should use to manage its operations, with information relating directly to the QSEs<sup>3</sup>
- ▶ Requirements for both quality management and technical operations of testing and calibration laboratories<sup>4</sup>
- ▶ Standards for quality management and technical operations in the medical laboratory environment<sup>5</sup>

QMS19 is a **guideline** for how to implement requirements established by customers, regulators, and accreditation organizations.<sup>3-14</sup> **QMS19 is not a standard**, ie, this guideline **does not set requirements** for customer focus. Instead, this guideline describes what laboratories need to do to meet applicable regulatory and accreditation requirements for customer focus and provides suggestions and examples for fulfilling the requirements.

A new paradigm is developing in which the patient is the direct user of laboratory examination results and reports. International standards and recent legislation allow patients to view their own reports without a physician interpretation. This practice creates new opportunities for the laboratory to serve as the patient's educational and informational partner. As a result, when establishing postexamination expectations, the laboratory should evaluate the patient's expectations for reviewing the results.

**NOTE:** The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

## KEY WORDS

Customer

External customer

Satisfaction survey

Customer satisfaction

Internal customer

Voice of the customer

# Chapter 1

## Introduction

### This chapter includes:

- ▶ Guideline's scope and applicable exclusions
- ▶ Background information pertinent to the guideline's content
- ▶ "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- ▶ Terms and definitions used in the guideline
- ▶ Abbreviations and acronyms used in the guideline



# Customer Focus in a Quality Management System

 **NOTE:**

This guideline discusses areas in which the laboratory should focus to provide appropriate outputs, products, and customer services.

## 1 Introduction

### 1.1 Scope

This guideline is intended to assist laboratories in meeting customer-based requirements for their QMS as represented by quality system essential (QSE) Customer Focus. This guideline does not review the theory of good customer relations or service but instead discusses areas in which the laboratory should focus in order to provide appropriate outputs (such as examination results and reports), products (such as blood and tissue), and customer services (such as courier retrieval of collected specimens from physicians' offices).

This guideline is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing. However, because the concepts of customer service and satisfaction are generic, this guideline can be used by other types of laboratories, such as public health, research, food, environmental, and veterinary laboratories. It can be used by all levels of personnel to develop and support a customer-focused laboratory.

This guideline does not apply to patients who use test devices and kits at home, because they are customers of the test kit manufacturer and not the laboratory.

 **NOTE:**

QSE Customer Focus describes the requirements for identifying customer expectations and establishing the capability to meet them, agreeing upon the deliverables, measuring customer satisfaction, and recording and managing complaints.

### 1.2 Background

QSE Customer Focus describes the requirements for identifying customer expectations, establishing the capability to meet the customer's expectations, agreeing upon the deliverables, measuring customer satisfaction, and recording and managing complaints.

The laboratory's decisions and actions can profoundly affect its internal and external customers. Laboratory decision makers should identify and understand their customers' expectations and impart that knowledge and understanding to personnel through education, communication, and appropriate direction to ensure customer focus is paramount to the operational model. Acquiring and keeping customers is critical to financial success. Increasing competition among laboratory service providers means that, in some situations, customers who feel their expectations are unmet have options to seek these services elsewhere.

Customer focus is ongoing. Once feedback has been received, it is often necessary to cycle through again, identifying current and future customers, determining their current and changing expectations, ensuring those expectations are being met, receiving feedback, and resolving any issues.