

# Importance of Quality System

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# Why We Implemented Quality System

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- ❑ We were a small laboratory started in 1990 competing with large labs
  - ❑ Approximately 10 Employees
  - ❑ We did not want to look small since we had the same technical capabilities as large labs
  - ❑ Implemented a formal quality system in 1999
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# Benefits of Quality System

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What We Gained

# Quality System Provides a Business Model

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- ❑ Uniform Standards
  - ❑ Provides an “industry standard” to reference
  - ❑ Serves as a “guide”
  - ❑ Removes guesswork from identifying “What is good enough?”
  - ❑ Enhances credibility for small labs
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# Are there Significant Differences in the Chemistry Used by Different Labs?

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- ❑ Usually not – there is no magic bullet
  - ❑ Most labs are using the same technologies, same methods, and same quality control practices
  - ❑ There is not really anything unique or innovative about following the directions in a method
  - ❑ What is unique and beneficial, is a lab's ability to implement an effective Quality System
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# What Do Labs Want?

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- ❑ Profitability
  - ❑ Customer satisfaction
  - ❑ Minimize mistakes reported to client
  - ❑ Competent, experienced employees and smooth transition with employee turnover
  - ❑ A system that works smoothly with few interruptions
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# Quality System Helps Achieve Goals

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- ❑ Developing and implementing a sound quality system is a good step to achieving business goals
  - ❑ The quality system provides the framework that guides decision making, training, transition, and management of changes
  - ❑ Quality system assures consistency
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# Customer Satisfaction

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- ❑ Suitable precision, accuracy, and sensitivity for its intended use
  - ❑ Meeting the Data Quality Objectives
  - ❑ To determine suitability, quality of data must be known
  - ❑ Having a quality system in place will allow a lab to achieve the goal of known quality
  - ❑ Should also assure that that information is “shared” with the customer so they can know too - Traceability
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# Efficiency Profitability

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- ❑ Nobody wants to be done any quicker than the analyst who does the test
  - ❑ Quality system provides a framework of rules for the analysts so they know what is expected and what actions to follow during adverse events
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# Quality System Elements Can Improve Speed and Efficiency

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- ❑ Thorough documentation of procedures so everybody know what, and how, to do tasks
  - ❑ Training requirements and tracking for easy identification of who knows what
  - ❑ Includes Sample Check-In Process
  - ❑ Actually begins Prior to Sample Collection
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# Cost

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- ❑ Labs know that the lower price they can offer, the more customers they can probably get
  - ❑ Consistent quality systems create a level playing field beneficial to the lab and the customer
  - ❑ An effective quality system should prevent labs from “cutting corners” to offer lower prices
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# Cost vs. Profitability

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- ❑ Assume the lab's profit is 10%
  - ❑ That means that for a \$100 test, it cost the lab \$90 to produce
  - ❑ If the lab has to repeat the test, then the lab has "spent" \$180 to generate that \$100 invoice
  - ❑ Lab just "lost" \$80
  - ❑ An effective quality system can help minimize the number of repeat analysis
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# What are Some of the Elements of a Quality System that Prevent Reanalysis?

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- ☐ Second source standard verification
  - ☐ Calibration requirements of support equipment
  - ☐ SOP requirements
  - ☐ Training
  - ☐ Demonstration of Capability
  - ☐ Preventive Maintenance
  - ☐ Corrective Action (And Follow-Up)
  - ☐ Internal Audits
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# What is the Most Common Error Made in the Lab?

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- ❑ Usually not chemistry error
  - ❑ Most labs use methods from EPA or other sources such as ASTM, Standard Methods, USGS
  - ❑ Techniques for preventing and detecting chemistry errors are built into these methods
  - ❑ The most common cause of mistakes in labs is human error.
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# Causes of Human Error

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- ❑ Labs generate a massive amount of data that must be evaluated
  - ❑ Environmental testing often has tight deadlines to be met (holding times, turnaround times)
  - ❑ Not every sample is identical in composition
  - ❑ Not every sample is identical in testing requirements
  - ❑ Irregular workloads throughout a year
  - ❑ Business profitability objectives dictate that most labs cannot continuously staff at a level of the maximum expected volume
  - ❑ People get tired and distracted
  - ❑ Some are incompetent, and some just don't care
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# How Can a Quality System Prevent Human Error?

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- ❑ It can't -but it can reduce the chance of it happening
  - ❑ A Quality system can also improve the chances of the lab detecting human errors before data are reported
  - ❑ The lab must have specific procedures in place that work for their business process and people to help prevent human errors
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# How Labs Can Prevent Human Error Using Quality System

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- ❑ Correctly identifying resources needed, including but not limited to, adequate personnel, facility, and equipment
  - ❑ Operate with integrity to employees and clients
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# Summary of Benefits of a Quality System for Labs

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## ☐ Control

- Documentation of Processes
- Documentation of Changes to Process
- Notification to Management of Changes

## ☐ Credibility

## ☐ Clarity

## ☐ Peace of Mind

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# Benefits of Quality System for Customers

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- ❑ Allows client to determine if data are consistent with their DQOs
  - ❑ Determines usability of data
  - ❑ Should improve communication between client and lab
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# Cost to Implement Quality System

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- ❑ Additional resources allocated to QA activities
  - ❑ Increased documentation requirements at bench may require increase in analytical staffing
  - ❑ Lab Supply costs could increase if changes to QC processes are necessary
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# Greatest Difficulties with Implementation of Quality System

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- ❑ Resistance from experienced employees because of perceived redundancies in Quality System
  - ❑ Frustration with additional documentation and traceability elements that make data more defensible, without perceived improvement in precision and accuracy
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# CONCLUSION

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- ❑ Overall purpose of testing is to help assure protection of human health and the environment
  - ❑ Implementation and following an effective Quality System helps achieve that goal
  - ❑ The benefits of implementing a Quality System more than justified the cost in my laboratory
  - ❑ An effective quality system helped achieve business success
  - ❑ A Quality System is a guide to successful business operation on a day to day basis, not an additional requirement
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