

## Introduction- Laboratory Quality Management System

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## Standards Organizations

<b>ISO</b> International Organization for Standardization
Guidance for quality in manufacturing and service industries
Broad applicability; used by many kinds of organizations
Uses consensus process in developing standards

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## CONFORMITY ASSESSMENT STRUCTURE

```
graph TD
    subgraph Level1 [1]
        A([ISO/IEC]) <--> B([IAF/ILAC  
Regional Accred.])
        B <--> C([IPC, IQNET])
    end
    subgraph Level2 [2]
        D[Accreditation Bodies]
        E[ISO/IEC 17025, ISO/IEC 17020, ISO 15189, ISO/IEC 17065]
        F[ISO/IEC 17021]
        G[ISO/IEC 17024]
    end
    subgraph Level3 [3]
        H[Laboratories, Testing & Calibration]
        I[CB's Inspection & Product Cert.]
        J[CB's Management Systems Cert.]
        K[PCB's Personnel Certification]
    end
    L[End Users - Consumers - Industry - Professionals]

    B --> D
    E --> H
    E --> I
    F --> J
    G --> K
    H --> L
    I --> L
    J --> L
    K --> L
```

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Achieving a **99%** level of quality  
means  
accepting a **1%** error rate

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In France a **1% error rate** would mean **everyday**

- 14 minutes without water or electricity
- 50,000 parcels lost by postal services
- 22 newborns falling from midwives' hands
- 600,000 lunches contaminated by bacteria
- 3 bad landings at Orly Paris airport



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Result: **1%** failure



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Essential to all aspects of industry are **laboratory results** that are

- **accurate,**
- **reliable,** and
- **timely**



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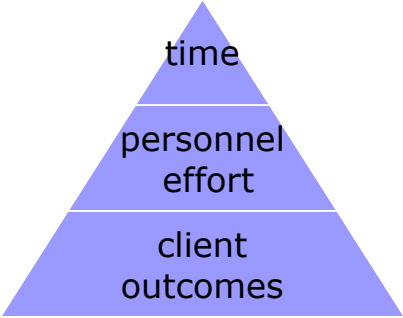
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Laboratory errors cost in



time  
personnel effort  
client outcomes

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How do we achieve excellent performance in the laboratory?



Organization	Personnel	Equipment
Purchasing & Inventory	Process Control	Information Management
Documents & Records	Occurrence Management	Assessment
Process Improvement	Customer Service	Facilities & Safety

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Quality Management System Definition

Coordinated activities to direct and control an organization with regard to quality.

**All aspects of the laboratory operation need to be addressed to assure quality; this constitutes a quality management system.**

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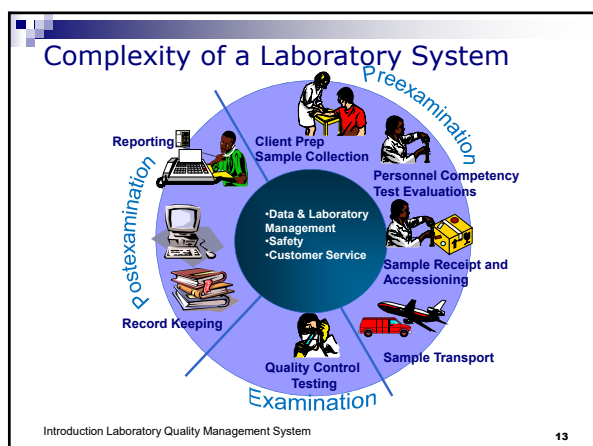
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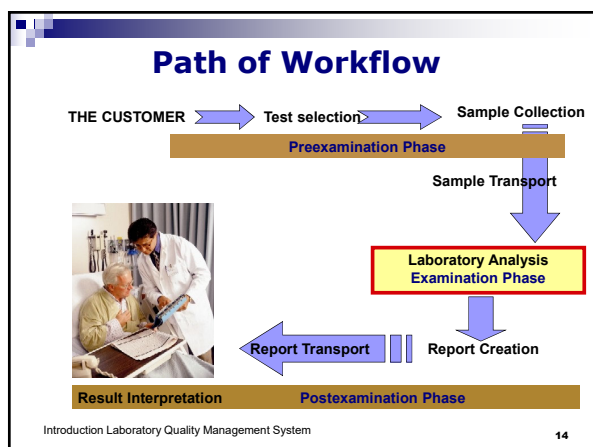
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### WHY is the Path of Workflow essential to consider in laboratories?

The **entire process** of managing a sample must be considered:

- the beginning: sample collection
- the end: reporting and saving of results
- all processes in between.

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### Laboratory tests are influenced by

- laboratory environment
- knowledgeable staff
- competent staff
- reagents and equipment
- quality control
- communications
- process management
- occurrence management
- record keeping



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### Twelve Quality System Essentials

set of coordinated activities that function as building blocks for quality management



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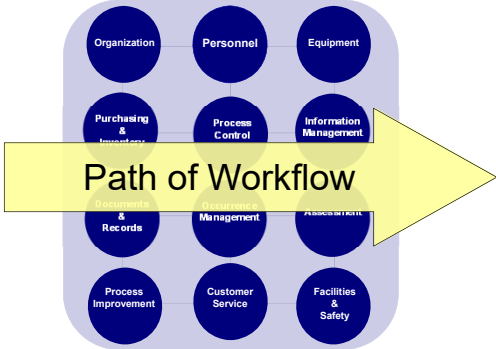
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### Path of Workflow

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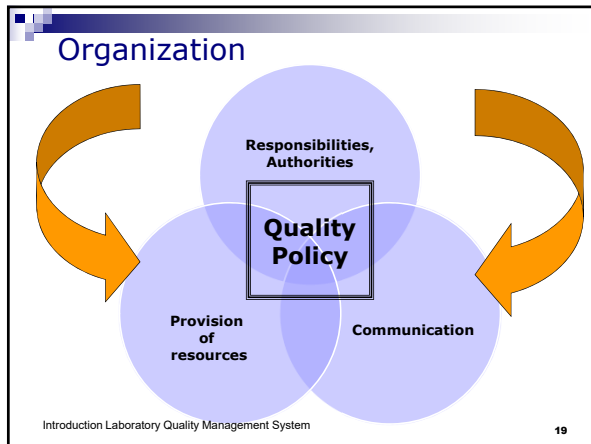
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### Personnel

- human resources
- job qualifications
- job descriptions
- orientation
- training
- competency assessment
- professional development
- continuing education

The top right of the slide features a row of blue silhouettes of people in various poses. Below this, on the right side, is a photograph of two laboratory technicians in white lab coats working at a piece of equipment.

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### Equipment

- acquisition
- installation
- validation
- maintenance
- calibration
- troubleshooting
- service and repair
- records

A photograph of a laboratory technician in a white lab coat and safety glasses, operating a piece of laboratory equipment.

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## Purchasing and Inventory

- vendor qualifications
- supplies and reagents
- critical services
- contract review
- inventory management



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## Process Control

- quality control
- sample management
- method validation
- method verification



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## Information Management

- confidentiality
- requisitions
- logs and records
- reports
- computerized laboratory information systems (LIS)



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Documents	Records
creation	collection
revisions and review	review
control and distribution	storage
	retention

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### Occurrence Management

- complaints
- mistakes and problems
- documentation
- root cause analysis
- immediate actions
- corrective actions
- preventive actions



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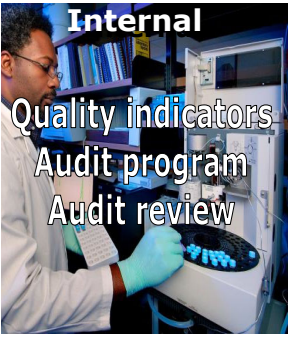
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### Laboratory Assessment

<b>Internal</b>  <p>Quality indicators Audit program Audit review</p>	<b>External</b>  <b>Proficiency testing (EQA)</b>  <b>Inspections</b>  <b>Accreditations</b>
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## Process Improvement

- opportunities for improvement (OFIs)
- stakeholder feedback
- problem resolution
- risk assessment
- preventive actions
- corrective actions



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## Customer Service

- customer group identification
- customer needs
- customer feedback



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## Facilities and Safety

- safe working environment
- transport management
- security
- containment
- waste management
- laboratory safety
- ergonomics



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Implementing Quality Management **does not** guarantee an **ERROR-FREE** Laboratory

But it detects errors that may occur and prevents them from recurring

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Personnel  
Inventory  
Documentation  
Customer Service

**Laboratories *not* implementing a quality management system guarantees UNDETECTED ERRORS**

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Laboratory Quality Management System

Coordinated activities to direct and control an organization with regard to quality.

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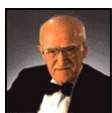
## Innovators of Quality



**Walter Shewhart**  
1891-1967



**W. Edwards Deming**  
1900-1993



**Joseph Juran**  
1904-2008 (103 years)



**Philip Crosby**  
1926-2001



**Robert Galvin**  
b. 1922

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## A Brief History of Quality Management

**Quality Management is not new.**

Innovator	Date	Cycle
Walter A. Shewhart	<b>1920s</b>	Statistical Process Control
W. Edwards Deming	<b>1940s</b>	Continual Improvement
Joseph M. Juran	<b>1950s</b>	Quality Toolbox
Philip B. Crosby	<b>1970s</b>	Quality by Requirement
Robert W. Galvin	<b>1980s</b>	Micro Scale Error Reduction

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## ISO Documents - Laboratory

**ISO/IEC 15189:2012** General requirements for the competence of medical laboratories

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### In summary

- Quality management is not new.
- Quality management grew from the good works of innovators who defined quality over a span of 80 years.
- Quality management is as applicable for the medical laboratory as it is for manufacturing and industry.

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### Key Messages

- A laboratory is a complex system and all aspects must function properly to achieve quality.
- Approaches to implementation will vary with local situation.
- Start with the easiest, implement in stepwise process.
- Ultimately, all quality management system elements must be addressed.

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Questions?

Comments?

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