

# Essentials of a Quality Management System and How to Use Them to Improve Your Laboratory

Lucia Berte  
*Laboratories Made Better! P.C.*  
Broomfield, CO


1

"We can't solve today's problems by using the same kind of thinking we used when we created them."

Albert Einstein


2

<b>Today's problems 1.</b>	<b>Thinking that created them</b>
Continued use of 32-year old document template that doesn't work	"One size fits all" for all laboratory documents
"Continue to monitor" on lab quality reports	Reporting data constitutes QA




3

<b>Today's problems 2.</b>	<b>Thinking that created them</b>
Repeated external inspection findings	Respond – and carry on
Unseen failure costs	"Cut the budget"



4

Today's problems 3.	Thinking that created them
Ineffective new staff training	Training by telling process and memorizing details
Some management, little leadership	Focusing on CLIA, QC, QA technical details



5

**Take home message #1...**

More QC, QA, and SOPs  
will not solve  
today's problems!

6

Today's solution?

**Think differently**

....a *system*  
to organize and manage  
all aspects of quality  
in the laboratory.

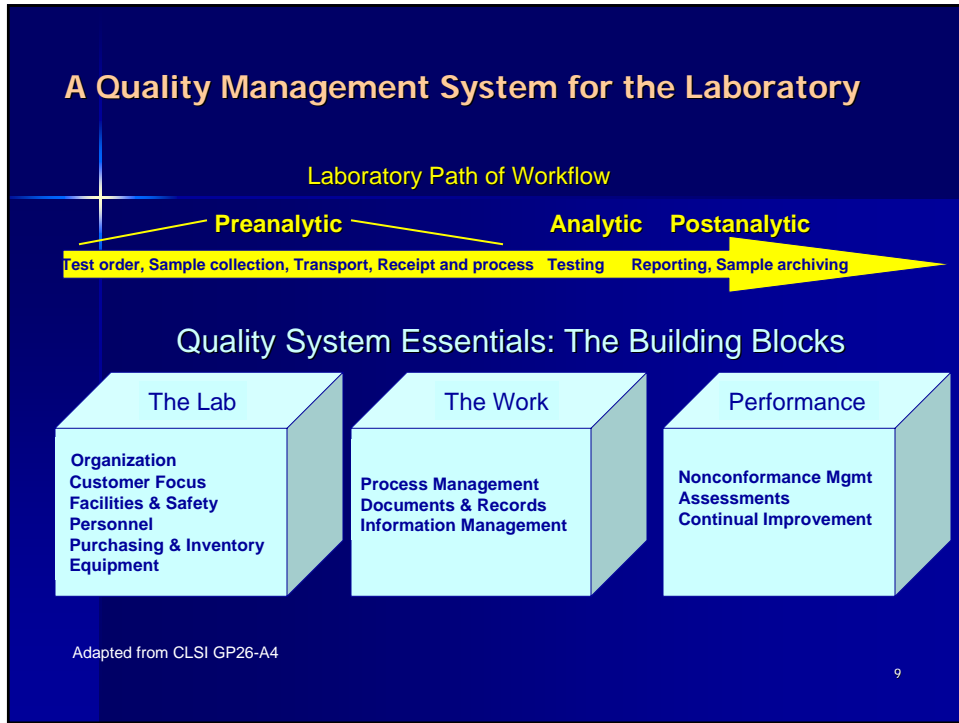
7

Definition of "system"

Set of interrelated or  
interacting elements

ISO 9000:2005, 3.2.1

8



**Why a quality system  
makes your lab better**

10

## QSE Organization

“Plans are nothing.  
Planning is everything.”

Dwight Eisenhower

11

## QSE Organization

“Good things only happen  
when planned –  
bad things happen on their own.”

Crosby

12



## QSE Customer Focus

"The person into whose 'In' basket you empty your 'Out' basket is the customer."

Townsend and Gebhardt

14

## QSE Customer Focus

*Knowing what the next process in the lab's PoW  
needs from YOU  
enables designing a better process for delivering it.*

15

## QSE Facilities and Safety

"The price for ignoring  
the impact of design on service  
can be staggering."

Davidow and Uttal

16



## QSE Facilities and Safety

- Study your given space
- Design for unidirectional workflow
- Move stuff around as best you can



17

## QSE Personnel

“One thing worse than training employees and losing them... is not training them and keeping them.”

Ed Metcalf

18

## QSE Personnel

"Training, training,  
and then more training.

And if I have to say it again,  
then you just don't get it."

Tom Peters

19

## QSE Personnel

- All work happens in process
- Train to properly documented processes
- Assess competence in performing processes
- Train supervisors in quality management



20

## QSE Purchasing and Inventory

“The most difficult problem to solve is employee indifference. People closing their eyes and choosing to do nothing.”

Katsuyoshi Ishihara

21

## QSE Purchasing and Inventory

- Find ways to buy less
- Find ways to use less
- Find ways to reduce supply waste
- Make inventory management easier



22

## QSE Equipment

“The time to repair the roof  
is when the sun is shining.”

John F. Kennedy

23

## QSE Equipment

- Don't skip or fudge
  - preventive maintenance
  - calibration
  - regular cleaning
- Analyze information in downtime logs
- Don't let the computer system be the tail that wags the dog



24

## QSE Process Management

"Change is what makes the world go round, not love.

Love only keeps it populated."

Charles Brower

25

## QSE Process Management

"Bad processes beat good people every time."

Unknown

26

## QSE Process Management

- Flowchart work processes
- Listen to your people about how it *really* happens
- Apply Lean thinking wherever possible
- Build process controls into the work



27

## QSE Documents and Records

“The palest ink is clearer  
than the best memory.”

Chinese proverb

28

## QSE Documents and Records

“Nothing has really happened until it has been recorded.”

Virginia Woolf

29

## QSE Documents and Records

- Document all of the following
  - Quality policy and QSE policies
  - Quality procedures
  - Pre-exam, exam, post-exam processes
  - Pre-exam, exam, post-exam procedures
  - Forms/screens for capturing information
- Record results concurrently with doing the work



30

## QSE Information Management

“A fact in itself is nothing. It is valuable only for the idea attached to it, or for the proof which it furnishes.”

Claude Bernard

31

## QSE Information Management

- Maintain confidentiality of patient data, results, and information
- Protect information from access through other means or computer systems
- Apply ethics in charging and billing



32



## QSE Nonconforming Event Management

“Condemn the fault,  
and not the actor of it.”

William Shakespeare

33

## QSE Nonconforming Event Management

“The way we see the problem  
is the problem.”

Stephen Covey

34

## QSE Nonconforming Event Management

- Make it easy to report NCEs
- Practice a “just culture”
  - Unintended error – console, review process
  - At-risk behavior – counsel and observe
  - Reckless behavior – discipline
- Analyze NCEs to ID problem processes



35

## QSE Assessments

“What gets measured gets attention.”

Ian Littman

36

## QSE Assessments

- External assessments
  - Licensure/accreditation inspections, assessments, surveys
  - Proficiency testing
- Internal assessments
  - Quality indicators
  - Internal audits



37

## QSE Continual Improvement

“It’s easy to sit up and take notice.  
What’s difficult is getting up  
and taking action”

Al Batt

38

## QSE Continual Improvement

- Identify OFIs through management review
- Prioritize OFIs and select
- Generate solution(s)
- Implement solution(s)
- Evaluate effect of solution(s)
- Integrate and sustain improvement(s)



39

## Is there a QMS Body of Knowledge for laboratories?

# CLSI Guidelines



40

## CLSI QMS Guidelines



- **OR** – GP38 in process
- **CU** –
- **FS** – GP05, GP17
- **PE** – GP21, GP 40 in process
- **PU** – GP09 update in process
- **EQ** – GP31, GP37 (new)
- **PR** – most other
- **DR** – GP02 update
- **IN** – Auto series
- **NC** – GP32
- **AS**
  - GP27, GP29 for PT
  - GP35 Indicators
  - GP39 Audits – in process
- **CI** – GP22 update

41

“Never mistake motion  
for action.”

Ernest Hemingway

42

## Today's Needed Actions

### 1.

- Formalize problem identification
  - Nonconforming event management program
  - Laboratory sample and record tracing audits
- Prioritize problems
  - Patient safety
  - Customer service
  - Financial
  - Regulatory

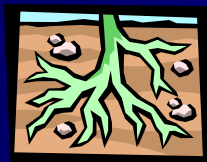


43

## Today's Needed Actions

### 2.

- Improve processes
  - Root cause analysis
  - Change management
- Process and procedure documents
  - Process flowcharts
  - Accurate, complete procedures



44



## Take home message #2...

"If you always do what you've always done, you'll always get what you've already got!"

