Understanding Why “PROCESS” is the Essential Key for Lean and Other Quality Tools to Continually Improve Your Lab’s Efficiency, Cost Effectiveness, and Profitability

Lucia Berte

Laboratories Made Better

Broomfield, Colorado
Has your lab “Leaned” anything?

If so, which process(es)?

Why that one (those)?
Replication?

- Has your lab replicated Lean to other processes?
- If so, why?
- If not, why not?
Why This One Word?

PROCESS
Reasons Why “Process”

- All work is sequential processes
- ISO 9001 and CLSI QSEs process-based QMSs
- Lean: Reduce process waste
- Six Sigma: Reduce process variation
- Engaging with practitioners: Through the test ordering and results interpretation processes
- Change leadership: Process and cost thinking
Understand

Train to, Assess

Measure, Monitor

Document

Improve
“Everyone doing his best is not the answer. It is first necessary that people know what to do.”

W. Edwards Deming
Understand

“Seek first to understand…”

Stephen Covey
Understand

The sequence of “Who does what, and when”

All preexamination, examination, post-examination processes

All management (ie, QMS) processes

The role of persons outside the laboratory

Who is the process owner

Process versus Procedure as concepts
“…then to be understood”

Stephen Covey
Difference between process and procedure as documents
Banishment of lengthy, incomplete SOPs
Use of flow charts, process maps, tables

Responsibility assigned for each process activity
Connections (ie, “handoffs”) between processes
“Training turns good intentions into good results.”

Thomas Berry
Train to, Assess

- Process-based training ("Telling Ain’t Training")
- Train to the process flow chart and work instructions (ie, work does not happen in alphabetical order)
- The way the work happens – people work the process!
- Assess how people perform the process and what they do when it doesn’t work
Measure, Monitor

“To manage quality, you must measure it.”

Steven George
Measure, Monitor

- Quality Assurance (QA) = *process* performance

- What aspect of this process can be measured to show it is working – or not?

*NOTE:* QC measures only **method performance**!

- Collect raw data and turn it into information

- What is the information revealing?
“The people don’t need to change; the process needs to be changed.”

A. Donald Stratton
Improve

- All processes can be improved
- Find and remove the redundancies, dead ends, and bottlenecks in every technical and management process
- Personnel know and can point out process problems
- Automate where possible
A 17 year old patient was to receive a heart and lung transplant at a prestigious hospital. The organs were blood group A. The patient was blood group O. The patient is transplanted and had a massive rejection.

Group O organs are obtained and transplanted. The patient dies anyway. 2 sets of organs were wasted.

What went wrong???
Everyone thought he/she knew what to do
No one knew what the others were doing
We were not trained to think “process”
The Joint Commission said the root cause was “lack of communication”
“Medical error is a failure of process.”

US-IOM *To Err is Human*...1999
“If the process is right, the results will take care of themselves.”

Takashi Asada
Quality is Lack of Variation

Where most laboratories are (including yours) due to lack of a process approach

Where your laboratory needs to be to survive
- Documented Lean processes
- Effective instructions
- Quality cost management
- “Lab 2.0” thinking
“To succeed we must disturb the present.”

Roberto Goizueta
Look at Old Things in a New Way
Old Things                New Way

“SOPs”                         Process flow charts
Example: Analyzer Set-Up and Run Process

Samples arrive

Readiness assessed

No

Analyzer ready?

Yes

Patient samples loaded and tested

Did analyzer work properly?

Yes

Function troubleshooting performed

No

Control troubleshooting performed

In control?

Yes

No

Repeat patient testing?

Yes

Patient results reviewed for flags, delta, absurd, etc.

No

Patient results released

Critical values?

Yes

No

Critical values communicated

End

No

Repeat patient testing?

Yes

Patient results released

Critical values?

Yes

No

Critical values communicated

End

Readiness performed; eg, maint, reagts, QC, waste

No

Yes

Yes
Old Things               New Way

“SOPs”                   Process flow charts

One SOP per analyte     Analyte Attribute Tables
### Analyte Attribute Table(s) for Automated Processes

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<td>Critical values…</td>
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Old Things — New Way

“SOPs” — Process flow charts

One SOP per analyte — Analyte Attribute Tables

Procedures in alpha order — Instructions in process order
Suggested Table of Contents for Procedures Manuals for Automated Instruments

For paper or electronic manuals:

- Process flowchart
- Operations Procedures
- Analyte Attribute Table(s), where needed
- Quality Control Plan section
- Calibration section
- Maintenance section
- Troubleshooting section
- Examples of properly completed forms
- Other? As needed
A Quality Process Approach

- Work processes are designed such that requirements are met *while doing the job*
  - Regulatory and accreditation
  - Customer

- Work processes are
  - Controlled
  - Measured and monitored
  - Improved
“It is always, only, and ever about money.”

Luci B
Quality, Cost, and Profitability 1.

Charge

Actual Cost

Real cost of production

Cost of failure

Margin or profit

Waste

Potential savings or profit
Charge more for margin or profit

Actual Cost

Reduced when process is improved

Real cost of production

Margin or profit when waste is removed

Charge less to beat the competition
Why This One Word?

PROCESS
“If we don’t change our direction we’re going to wind up where we’re headed.”

Native American proverb