Lab Quality Confab 2011

Overcoming the 5 Major Roadblocks that Prevent Continual Improvement in Your Laboratory

Presenter: Anne T. Daley
November 2011



©2011 Chi Solutions Inc Proprietary and Confidential

Purpose of Presentation

This session will share the collective wisdom of many quality professionals on the most common roadblocks that prevent continual improvement in a medical laboratory. Each roadblock discussion will include real life examples and strategies organizations have taken to overcome them.

Note: The PowerPoint on the Quality Confab website is a participant worksheet. The complete set of slides are available after the presentation on the Confab website or at www.chisolutionsinc.com.

Key Learning Objectives

- 1. To learn the most common major roadblocks that derail continual improvement efforts within medical laboratories.
- 2. To assess what "roadblocks" exist in the participant's organization.
- 3. To develop immediate strategies to address the existing "roadblocks" within the participant's organization.

Chi Solutions, Inc.

2

©2011 Chi Solutions, Inc.. Proprietary and Confidenti

Time to play...

Laboratory Cl Roadblock Feud!



02011 Chi Solutions, Inc. Proprietary and Confidenti

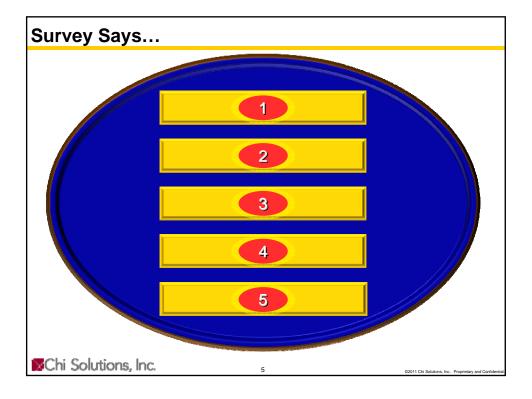
Laboratory Quality Professionals Surveyed:

What are the five top roadblocks that prevent continual improvement in laboratories?

- 1.
- 2.
- 3.
- 4.
- 5.

Chi Solutions, Inc.

©2011 Chi Solutions. Inc.. Proprietary and Confidentia



Roadblock #5: Lack of Proactive Approach to CI

What does it look like?

- Counter-productive approaches to CI:
 - Fire fighting.
 - It ain't broke, don't fix it.
 - Just solve it—not digging deep enough to discover root cause.
- Data rich, information poor.
- The end result of Roadblocks #4, 3, 2, and 1.

Chi Solutions, Inc.

.

©2011 Chi Solutions, Inc.. Proprietary and Confidential

Roadblock #5: Lack of Proactive Approach to CI

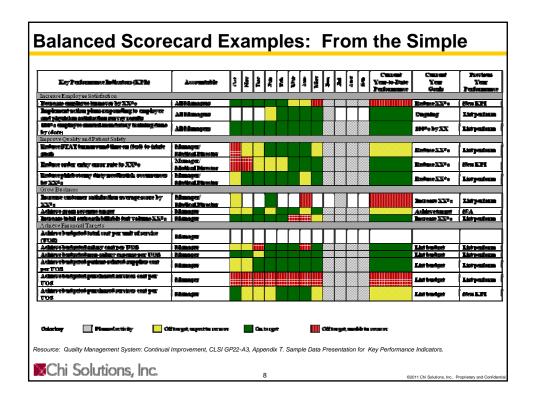
Killing trees, but are we saving lives?

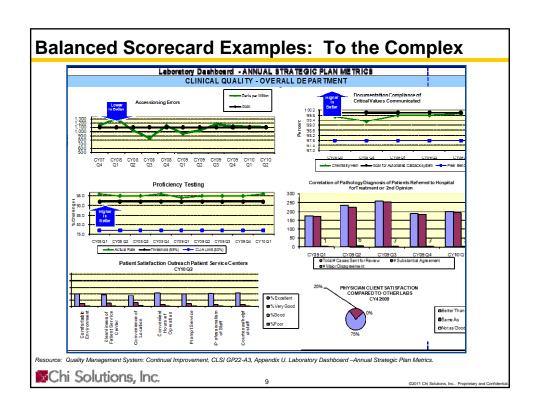
At a midsize community laboratory with the majority of its volume coming from local physician practices, the quality supervisor gathered all the quality data on a monthly basis and constructed a report that consisted of more than 30 pages of graphs, charts, and special reports. This information was presented to the medical staff and department managers at the monthly QA meeting; minutes were documented. Everyone felt they had an excellent QA program...

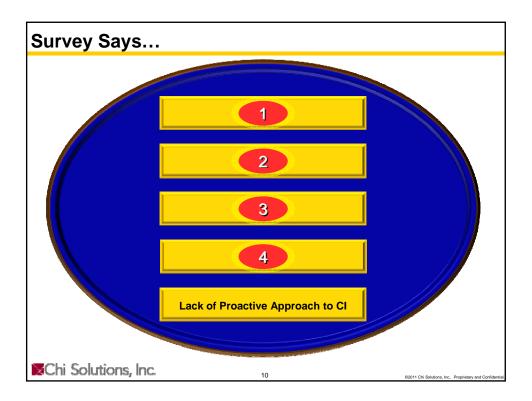
...Until the accreditation inspector arrived!

Chi Solutions, Inc.

©2011 Chi Solutions, Inc.. Proprietary and Confidentia







Roadblock #4: Lack of Resources—Especially IT

What does it look like?

- "We don't have time for quality!"
- Lack of personal accountability for quality; delegated to a select few.
- Inability to automate manual processes.
- Lack of IT, purchasing, facilities, finance, and HR participation in CI project teams.
- •Resources limited: too many projects at one time; need to set timeline and then follow through.
- Not everyone is meant to lead CI efforts.

Roadblock #4: Lack of Resources

Not my job!

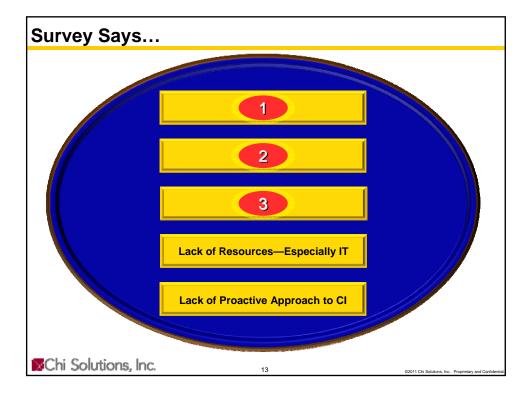
The quality coordinator at a large academic medical center with a rapidly growing outreach business was promoted to manager of one of the health system's community hospital laboratories.

The quality coordinator had developed a strong quality program with extensive performance metrics and quarterly reports along with monthly management quality review. When the coordinator left, the majority of all activities stopped.

Chi Solutions, Inc.

12

©2011 Chi Solutions, Inc.. Proprietary and Confidential.



Roadblock #3: Lack of CI Skills and Tools

What does it look like?

- Lack of systems thinking and approach.
- No understanding that ALL work is a process.
- •Limited training/skills on basic CI methods and tools:
 - "Where do we begin?" or "How do we know we are doing it right?"
 - "It's too complicated; we need to keep it simple."
- No understanding or focus on customer/output receiver.
- Lack of control process to assure improvements are maintained.

Chi Solutions, Inc.

1

©2011 Chi Solutions, Inc.. Proprietary and Confidential.

Roadblock #3: Lack of CI Skills and Tools

The Pile Up

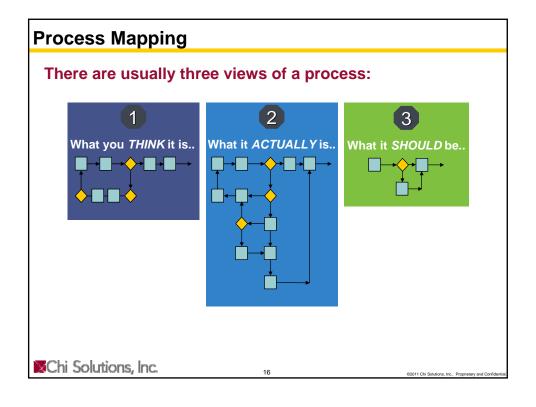
Volume was rapidly increasing in the specialty plasma testing laboratory over a six-month period due to a successful sales campaign. Staffing was analyzed and increased in response to the workload.

Within six months, TAT went from 20+ to 30+ days, a new frozen plasma storage warehouse was contracted with to handle the increasing inventory, and there was a growing concern of a reduced plasma supply for pharmaceutical production.

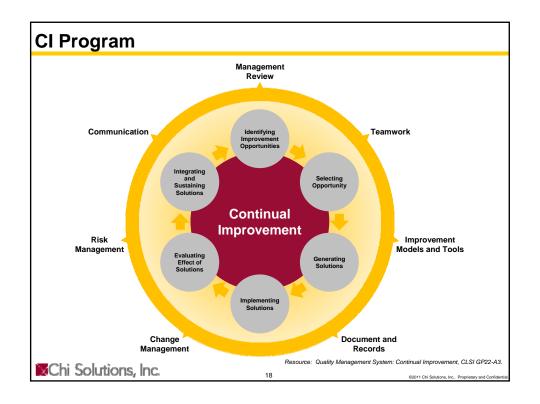
Chi Solutions, Inc.

15

©2011 Chi Solutions, Inc.. Proprietary and Confiden



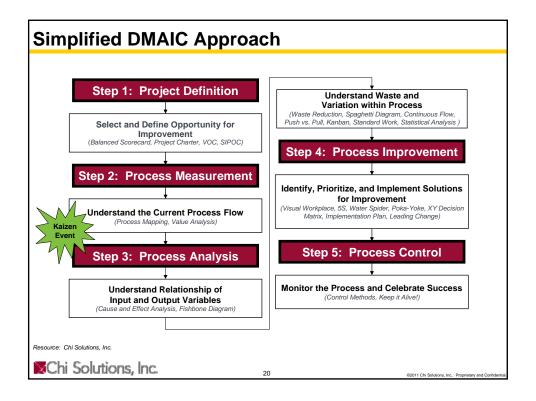




Improvement Models

- Plan-Do-Check-Act (PDCA)
- Six Sigma
- Lean
- Lean Six Sigma (combining Lean and Six Sigma)
- Root Cause Analysis (RCA)

Resource: Quality Management System: Continual Improvement, CLSI GP22-A3.



Improvement Tools

- Brainstorming/brainwriting/ affinity diagram
- Cause-and-effect (C-E) diagram*
- Checksheet*
- Decision matrix/prioritization matrix
- Failure modes and effects (and criticality) analysis
- 5S/workplace organization
- Five whys
- Flow chart/process map/value stream map

- Gap analysis
- Histogram*
- Pareto chart*
- Risk severity matrix
- Scatter plot/XY graph*
- Statistical process control (SPC)/control chart*
- Stratification*
- Survey
- Waste walk

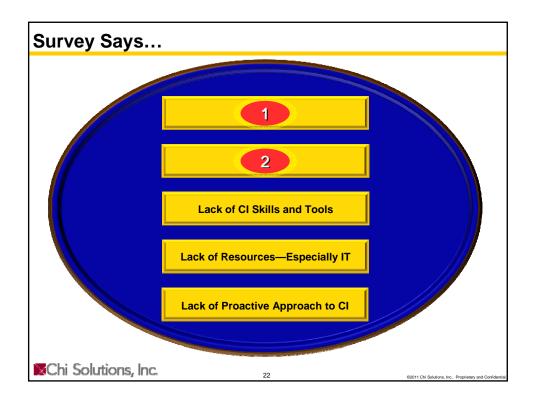
*Seven Essential Quality Tools

Resource: Quality Progress, ASQ, January 2009.

Resource: Quality Management System: Continual Improvement, CLSI GP22-A3.

Chi Solutions, Inc.

©2011 Chi Solutions, Inc.. Proprietary and Confidential



Roadblock #2: Lack of Management Support

What does it look like?

- 1.Leadership not fulfilling their roles and responsibilities in continual improvement:
 - Creating a culture of CI; setting expectation that CI is the way we work.
 - Providing the time and resources to accomplish Cl objectives.
- 2.Lack of support for the quality program, even if a quality specialist is hired.
- 3.Lack of decision making or makers: who's accountable?

Roadblock #2: Lack of Management Support

Lights are on, but nobody's home!

Hospital laboratory had a labeling problem with specimens coming from the GI lab. The lab staff measured, tracked, and trended until they figured out where the majority of problems were coming from.

They contacted the manager of the department, shared their results and suggestions, and put together a short presentation explaining the problem and how to fix it. Then, they arranged to meet with the nurses at the beginning of their shift. When the pathology manager and quality coordinator showed up, not only was the GI manager not there, she had never even told the staff they were coming.

Chi Solutions, Inc.

24

©2011 Chi Solutions Inc. Proprietary and Confidential

Management Review

- Reviewing performance-related information from a variety of sources to determine the effectiveness of the QMS.
- Identifying or verifying OFIs.
- Prioritizing, when indicated, and selecting OFI for referral to the CI process.
- Allocating necessary resources for follow-up action, including CI.
- Reviewing status and outcomes of CI initiatives.

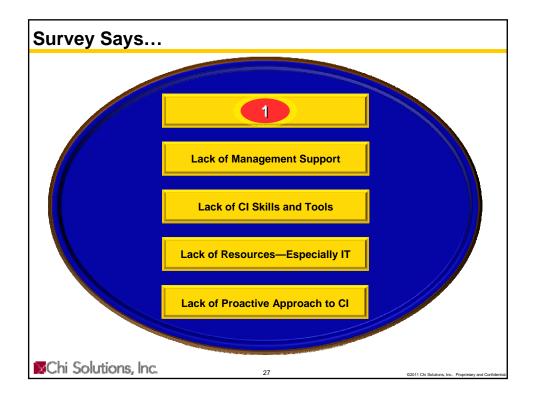
Resource: Quality Management System: Continual Improvement, CLSI GP22-A3.

Chi Solutions, Inc.

25

©2011 Chi Solutions, Inc.. Proprietary and Confiden

To Discuss Current Meting	Agenda Item					Α	Presenter(s)							
	1	Attendance	J	ľ	M	Α	M	J,	J A	S	0	N	D	
	···	Review Action Items from Previous Meetings		+	+	Н		+	+	1	Н	\dashv	+	
istomers and	_	<u> </u>		_	_	ш					ш	_		
iotomoro une	_	Customer Feedback, Awards, Survey Results, etc. (7.2. 8.2.1)	3;	T	Τ	П		T	Τ	Τ	П		Τ	
	4.	Quality Objectives and Results (5.4.1)		T		П	\top	1				\dashv	\top	
ality Manage	mer	nt System		_						1		_		
	5.	Corrective and Preventive Action Status (8.5.2; 8.5.3)		Τ	Т			Т				П	Т	
	6.	Audit Results (8.2.2)**		T								ヿ		
	7.	Quality Policy (5.3)*		T								T		
	8.	Process Performance/Product Conformance (8.2.3; 8.2.	4)*											
ocess Contro	ols													
	9.	Key Supplier Performance (7.4.1)*												
	10	. Equipment/Facility Needs and Maintenance (6.3)*												
	11	. Work Environment Controls and Maintenance (6.4)*												
provement														
	12	. Resources (6.1)*												
	13	. Training (6.2.2)*												
	14	. Changes Affecting QMS (5.4.2)*												
	15	. Improvement Recommendations (8.5.1)												
osing														
	16	. Overall Effectiveness (4.1)												
	17	. Review New Action Items		Т								T		



Roadblock #1: Lack of Quality Culture

What does it look like?

- •Focused on QC or QA or even CI—not even aware of QMS (quality management system).
- Not open for change (lack of effective suggestion process).
- Denial of mistakes or "we are right, others must adjust."
- •Quick to blame people vs. process/environment.
- Think quality is in addition to job, not the way to DO the job.
- Think quality is someone else's job.
- Silo mentality: lack of systems thinking.

Chi Solutions, Inc.

28

©2011 Chi Solutions Inc. Proprietary and Confidential

Roadblock #1: Lack of Quality Culture

Stripes but no stars!

A prestigious university-based laboratory had a formidable specialty molecular laboratory with over 60 percent of its volume coming from outreach clients within the region and some nationally. The quality specialist approached the medical director and laboratory management multiple times with concerns of unacceptable method validations practices by the department manager. No actions were taken.

Knock, knock... guess who?

CMS!

Chi Solutions, Inc.

20

©2011 Chi Solutions, Inc.. Proprietary and Confiden

CI Program Success Factors

- Leadership committed to CI as a way of "doing business" rather than as an add-on activity.
- An organizational culture that recognizes and expects everyone's involvement in Cl.
- Established and integrated processes and procedures that describe how CI should happen, which include instructions for how to do it at the task level.
- Knowledge and skillful application of CI concepts, models, and tools by laboratory management and staff.

Resource: Quality Management System: Continual Improvement, CLSI GP22-A3.

Chi Solutions, Inc.

30

©2011 Chi Solutions Inc. Proprietary and Confidential

Open Discussion/Q&A



D2011 Chi Solutions, Inc. Proprietary and Confidenti

Which of the Roadblocks Do You Need to Bust?

- 1. Lack of Quality Culture
- 2. Lack of Management Support
- 3. Lack of CI Skills and Tools
- 4. Lack of Resources—Especially IT
- 5. Lack of Proactive Approach to CI

Chi Solutions, Inc.

32

©2011 Chi Solutions, Inc.. Proprietary and Confidential

I commit to do the following:



Archway Entrance into the Greek Olympic Stadium

Chi Solutions, Inc.

33

©2011 Chi Solutions, Inc.. Proprietary and Confidential

For a complete set of presentation PowerPoint slides visit: www.labqualityconfab.com

Presenter Contact Information:

Anne T. Daley Senior Consultant Chi Solutions, Inc. (800) 860-5454 x414 adaley@chisolutionsinc.com www.chisolutionsinc.com



©2011 Chi Solutions, Inc. Proprietary and Confidential