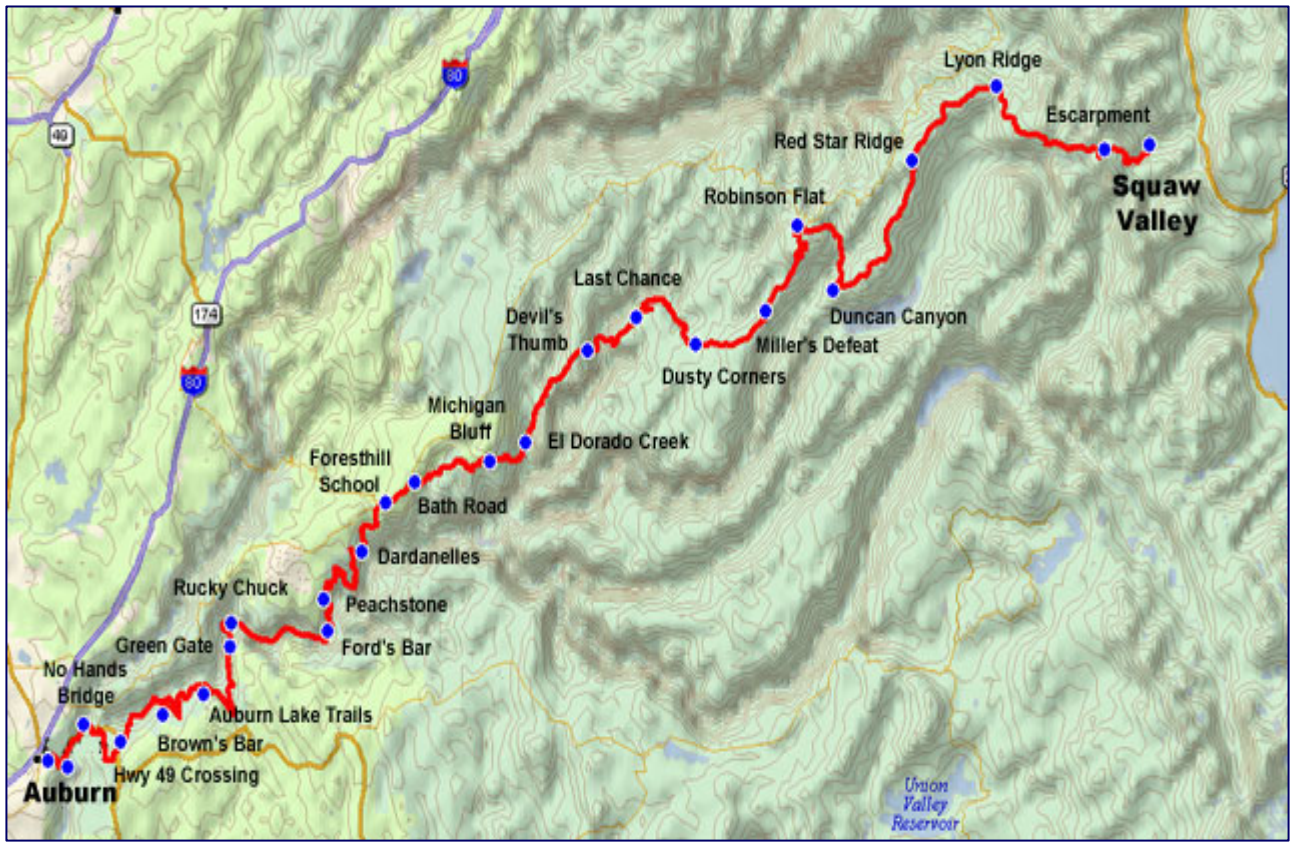
Describing the Incredible Journey in Less Than 30 Minutes

Implementing A Quality Management System For The Laboratory

Christine Flaherty, MHA, MT(ASCP), CPHQ

Implementing a Quality Management System

It takes longer than the usual initiative



Implementing a Quality Management System

It is not easy

Implementing a Quality Management System

The finish is worth the pain

Implementing a Quality Management System

Implementing a Quality System

- 5 hospital laboratories
- 1 medical foundation laboratory
- Ambulatory lab serves physicians
- 20 remote draw sites – 1000+ patients per day
- 3.8M billed tests per year
- $400M gross revenue
- 300 employees

Implementing a Quality Management System

The Start - 2000

- 5 hospital laboratories with 5 different approaches to managing quality (QC-focused)
- Medical Directors engaged with differing levels of enthusiasm
- Variation
  - Work processes and procedures
  - Document structure and version control
  - Position descriptions, training, assessing competency
  - Process control, internal assessment
  - Cost and quality indicators
- Cost was high, while quality and service were variable

Implementing a Quality Management System

The Finish - 2006

- 5 hospital laboratories and 1 medical foundation laboratory with a single, standardized approach to managing quality (quality system based)
- Medical Directors engaged at an optimal level
- No (or little) variation
  - Work processes and procedures
  - Document structure and version control
  - Position descriptions, training, assessing competency
  - Process control, internal assessment
- Cost, quality and service significantly improved

Implementing a Quality Management System

Every Incredible Journey Begins with the First Step

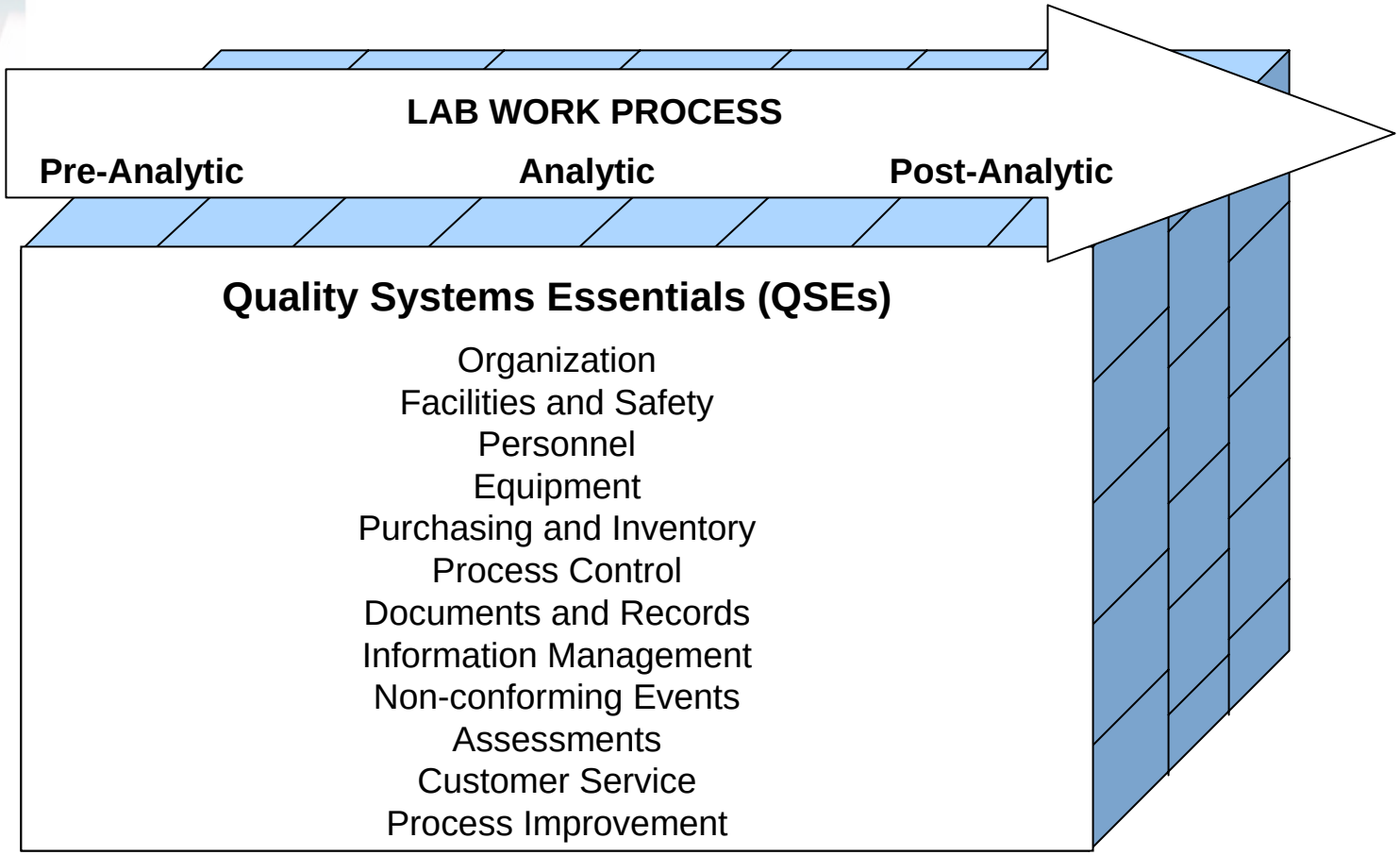
First step – redefined ***quality***

"The ability to consistently provide laboratory results efficiently and effectively."

Second step – adopted a quality management system model to guide our design and implementation

- Application of a Quality Management System Model for Laboratory Services (CLSI GP26A3)
- A Quality Management System Model for Healthcare (CLSI HS1-A2)

Implementing a Quality Management System



Implementing a Quality Management System

It takes longer than the usual initiative

- Began in 2000
- 95% implemented in 2006
- Estimated hours - development
  - My own = 1,500 hours in 7 years
    - 0.1 FTE total
  - Laboratory Management Team (5) = 600 each in 7 years
    - 0.2 FTE total
- Estimated hours – at implementation
  - 8 hours/employee

Implementing a Quality Management System

It is not easy

- Began by mapping the laboratory's work process
  - Pre-.post-and analytic phases
  - Developed documents of work process
- Wrote new technical procedures
  - Developed document numbering system
  - Developed standard document templates
- Developed standardized position descriptions
  - Based on work process activities and tasks
  - Included quality process activities and tasks

Implementing a Quality Management System

It is not easy

- Developed standardized orientation process
- Developed training and competency assessment process
  - Pre-.post-and analytic phases
  - Developed documents of work process
- Developed "Change Management Tool"
  - Used to plan quality into every change
  - Comprehensive project checklist based on the QSE's

Implementing a Quality System

It is not easy

- Developed the integrated and standardized Quality Management Program (QMP) and the Quality Manual
  - Developed policy documents for 12 QSE's first
- Created the Medical and Operations Management Team – oversight of the QMP
  - Decision making body for standardization to "best practice"
  - Conduct monthly quality review
  - Assess the effectiveness of the QMP at meeting the quality goals
- March 2007 – SMF Lab CAP accredited
- November 2008 – CAP System accreditation

Implementing a Quality System

The Finish is Worth the Pain

- Improvement snapshot
  - Reduced number of position descriptions, procedures, etc
  - Reduced time to train new employees
  - Ability to assess competency (pre-, post- and analytic)
  - Cost reduced from $15/uos to $7.20/uos
  - Proficiency testing success rates (5/6 exceed SH avg)
  - Employee satisfaction scores increased by >10%
  - Testing timeliness
  - Patient and physician satisfaction at 2 of hospital labs

Implementing a Quality System

Things Learned Along The Way

- The quality system model is descriptive, not prescriptive
  - Requires each laboratory to create its own, making design decisions along the way
- An integrated model
  - Like a puzzle - more than 1 potential starting place
  - Work is not wasted during implementation
- Will endure and can be easily updated and refined
- Enables standardization to "best practice"
- Changes the operational context for quality
  - Goes beyond QC and QA

Implementing a Quality System

Thank you!

Questions?

flaherc@sutterhealth.org

(916) 551-9511