CLIA, CAP, Lean/6 Sigma and ISO

How Avera McKennan Blends All Of Them
For The Benefit Of Our Patients

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Why All The Emphasis on QMS?

- We have had CLIA regulations since 1967.
  - These are regulations – we MUST meet them.
- CAP Lab Accreditation Program has been around for over 40+ years.
  - This program combines CLIA regulations with good laboratory practice to enhance performance.
- LEAN and other Process Improvement Systems are now the rage
  - They all combine to provide a basis for a complete QMS.

Why CLIA?

- Pre-1967, laboratories were largely un-regulated. Accreditation was not a requirement and there was no standard to which they would be held. Quality was limited to QC (if at all).
- The purpose of CLIA was to set minimum standards for all laboratories to follow and to determine if laboratories are achieving those standards.

- CLIA began in the late 1960's when problems arose in the cytology laboratories that read PAP smears. The personnel in these laboratories were overworked and had a very high error rate.
- In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA), which set standards to improve the quality of clinical laboratory testing in all laboratories in the nation that conduct testing on human specimens for health assessment or for the diagnosis, prevention, or treatment of disease.

- The regulations establish three categories of testing on the basis of the complexity of the testing methodology: a) waived tests, b) tests of moderate complexity, and c) tests of high complexity. Laboratories performing moderate- or high-complexity testing or both must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category.

College Of American Pathologists Laboratory Accreditation Program

- Francis C. Coleman, MD, FCAP, CAP President 1960-1961, leads the Ad Hoc Committee on Accreditation to develop the plan for the launch of the Inspection and Accreditation Program (now the Laboratory Accreditation Program).
- In October, the CAP heralds the Laboratory Accreditation Program in the Pathology Daily News at its annual meeting in Seattle. In November, the CAP Bulletin publishes an advertisement about the program.

- 1962

  The CAP Board of Governors approves the Ad Hoc Committee of Laboratory Accreditation report to establish the Inspection and Accreditation Program and appoints Hollis N. Allen, MD, FCAP, as the Commission on Laboratory Inspection and Accreditation Program's first chair.
- 1964

  CAP Inspection and Accreditation Program accredits first laboratories, the first being Medical Laboratory Associates, Birmingham, Alabama.

- 1965

  Dennis B. Dorsey, MD, FCAP, CAP President 1975-77, designs first laboratory accreditation checklist.

- 1967

  U.S. government enacts Medicare.

  CAP Surveys participation becomes a requirement for CAP accreditation program.

  Clinical Laboratories Improvement Act of 1967 (CLIA '67) passes.

  The Joint Commission on Accreditation of Hospitals (JCAH) adopts CAP laboratory accreditation standards.

- 1969

  The Communicable Diseases Center (CDC) declares CAP Inspection and Accreditation Program "equivalent to or more stringent than" CLIA '67 standards

  CAP offers first regional laboratory inspection workshops and publishes first Inspector's Manual.

  International interest in the CAP's accreditation program comes from as far away as India.

  The CAP Board of Governors names Maj. Gen. Joseph M. Blumberg, MC, USA Ret., FCAP, as commission chair.

- 1973

  The CAP shortens the laboratory accreditation cycle from 3 to 2 years.

- 1979

  General Blumberg retires as commission chair. CAP Board of Governors appoints John K. Duckworth, MD, FCAP, as chair.

  CAP renames Laboratory Inspection and Accreditation Program, calling it Laboratory Accreditation Program (LAP).

  Continuing medical education (CME) credit approved for laboratory inspectors.

- 1988

  U.S. government enacts Clinical Laboratories Improvement Amendments of 1988 (CLIA '88).

  Commission names its vice chair, Robert R. Rickert, MD, FCAP, as the CAP's first Overseas Commissioner.

- 2011

  The CAP launches the Accreditation Program for Biorepositories.

  The CAP enhances all accreditation program checklists and releases them in July.

  At CAP '11 in September, the CAP kicks off the 50th anniversary celebration for the Laboratory Accreditation Program.

Why Process Improvement?

- We use Process Improvement methods to accomplish the following:
  - Compensate for staffing shortages
  - Reduce errors
  - Improve efficiency
  - Improve Turn Around Time

Lean/6 Sigma

- Lean vs. 6 Sigma
  - Lean and 6 Sigma are nothing more than process improvement tool boxes
  - Both share many of the same tools.
  - Often, the best approach is a combination of the two processes.
  - Remember- THERE IS NO RIGHT WAY! It is whatever works best for your lab.

- Lean, 6 Sigma and ISO are complimentary and not exclusionary. They are “Process Improvement” tools and programs.
- In our experience, this is a progression that helps you achieve ISO accreditation with less pain and in an organized fashion.
- We used Lean first, then 6 Sigma in order reduce variation and have a solid foundation for ISO.

Lean Introduction

- What is Lean?
  - Lean is another term for the Toyota Production System (TPS).
  - We follow the TPS principles in order to provide the highest quality, most efficient service to our clients, patients and customers.
  - The TPS uses processes which stress single piece flow, First In-First Out (FIFO), minimal work in progress, no excess inventory and no backlog of work; it focuses on processes rather than functions.
    - Everything works to a beat determined by the rate of customer demand (TAKT Time)

Lean as a Culture

- Lean becomes a way of life. It is about eliminating waste, adding value to what you do.
- Lean requires total commitment from ALL levels of the staff, starting with the very top management.
- It is a planned, disciplined approach to problem resolution and process improvement.

5 Steps to getting Leaner

- Agree on what the customer really wants
  - The voice of the customer (VOC)
- Understand your processes
  - Value Stream Mapping
- Smooth the flow
  - Single piece flow, FIFO – reduced batches
- Shift from a PUSH to a PULL philosophy
  - Customer Demand dictates your work processes
- Continue to attack WASTE
  - Waste is anything that does not add value to a product

Visualizing the Processes

- Value Stream Mapping
  - Allows for visualization of the processes in an orderly fashion
  - Allows for a timeline that shows time for each process or sub-process
  - Process Mapping just shows the processes in an orderly fashion-no timeline
- Spaghetti Diagrams
  - Useful for visualizing walk patterns pre and post lean design

The Concept of FLOW

- This is the central concept of Lean.
- Smoothing the flow means ensuring that every piece of work is continuously worked on – there is little or no waiting.
- The key to this is "Single Piece Flow"
  - A sub key is FIFO (First In-First Out)
  - This defines the order of work – eliminate waste of motion, walking, inventory
- Self managing employees- every employee has ownership = is responsible and authorized to ensure that quality is #1.

5 S (Clearing Clutter)

- A Huge Key to Lean- Clean, Neat, Orderly
  - Sort
    - Clear out un-needed items
  - Segregate
    - Configure the workcell-arrange in order of use
  - Scrub
    - Clean-eliminate dirt, rubbish, trash, scraps
  - Standardize
    - Everything has a place all the time- work the same
  - Sustain
    - Work to the standards-measure and post the data

Error Management

- Error proof
  - Mistake proof the workcell and processes.
  - Use shut out types and attention types
- Standard Work Document
  - Shows the work sequence, takt & cycle times
  - Defines standard Work In Progress
  - Clearly documented in an SOP
- Root Cause Analysis
  - Look for cause and effect – uses FMEA (failure mode and effects analysis)

Six Sigma

- Where Lean eliminates waste and organizes the workplace, the addition of 6 Sigma, allows for a reduction in variation.
- Together, they make the solid foundation upon which ISO-15189 compliance can be built.

What is 6 Sigma

- A statistically based process improvement system that focuses on reduction of variation in a process or processes.
- A business philosophy that focuses on continuous improvement by understanding customer needs, analyzing business processes and instituting proper measurement methods.

6 Sigma Tools

- DMAIC
  - Define, Measure, Analyze, Improve, Control
- CTQ Tree (Critical To Quality)
  - Identify measures from the customer perspective (gathering useful data).
- FMEA
  - Failure Mode Effects Analysis –anticipate/prevent failures.
- SIPOC (Supplier, Input, Process, Outcome, Customer)
  - Understanding the process at a high level

Why ISO - 15189

Because it ties all of the above into one neat package.

Quality Management AND Technical Competence

The CORE of ISO-15189

- Technical competence in the US Clinical laboratory environment is at a high level due to CLIA as well as organizations such as the CAP.
- Quality Management competence has not achieved the emphasis and thus is only now coming to its own with efforts by the AABB, CAP-ISO and Joint Commission.

12 QSE's

- **Q**uality **S**ystem **E**ssentials
  - Organization
  - Personnel
  - Equipment
  - Purchasing and Inventory
  - Process Control
  - Documents and Records
  - Information Management
  - Occurrence Management
  - Internal and External Assessment
  - Process Improvement
  - Service and Satisfaction
  - Facilities and Safety

Process Mapping, Process Improvement and Documentation

- There are a variety of sources for help with process mapping.
  - Lean, 6 Sigma and other such systems teach and make use of Process Mapping.

    Examples include:
    - Lean Tool Box – Quest Worldwide, Surrey, UK
    - Lean Hospitals – CRC Press, USA
    - Creating a Lean Culture – Productivity Press, USA

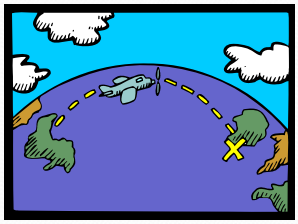
- Audits are a key area for QMS
  - training, review, root cause analysis are all critical components of a QMS program.
  - Suggested CLSI documents include:
    - EP 18-P3 Risk Management techniques to identify and control laboratory error sources
    - GP 32-A Management of non-conforming laboratory events
    - GP 17-A2 Clinical Laboratory Safety

  Use methods such as PDCA (Plan Do Check Act)
  Fish Bone Diagrams (Ishikawa Diagrams)
  FMEA (Failure Modes and Effects Analysis)

Summary

- As you can see, this is a journey that takes one through many areas.
- Lean, 6 Sigma and CLSI documents all play a part in achieving ISO-15189 Accreditation.
- Why re-invent the wheel when the guidance materials are there for you?
- Remember- It is all about improvement!

Lessons Learned



- ISO 15189 is a **journey not** a **destination**
- ISO 15189 is **not** about **perfection**
- ISO 15189 is all about

Continual Improvement

Questions??

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