



ISO 15189's Essential "Do's & Don'ts" Lessons from Early-Adopter Laboratories

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Objectives

- What has CAP Learned?
 - Market needs
 - Customer needs
- Embracing the Quality Strategy
 - Do's and Don'ts
- A Customer's Perspective – Genzyme Genetics

CAP promotes quality patient care by influencing standard setting and performance measurement

Mission Statement

The College of American Pathologists, the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine

An ISO program offers laboratories the ability to demonstrate their commitment to quality

- 2008 pilot and launch of the CAP 15189 Accreditation Program
- Today have 25+ organizations in program, with 50+ in pipeline
 - Reference laboratories (large general to highly specialized)
 - Clinical trial laboratories
 - Large IDN core facilities
 - National and global in reach

Laboratory market for accreditation at sunrise, desire for sustainable improvement on the rise

- Expansion of the CAP 15189 Program to include QMS education
 - Support the early adoptors
 - Provide tools from a menu divided by subject and customization depending on laboratories goals
 - Develop and launch in 2010 through 2011
 - *Seven online interactive subject matter educational tools*
 - *Onsite customizable laboratory assessments*

The Do's and Don't List From Early Adopter Laboratories

Do's and Don't Lessons

MANAGEMENT COMMITMENT

Quiz: On a scale 0 to 10, 0 = not at all, 10 = Very much so

1. Climate supports a quality culture
2. Sr. Mgmt provides strong support and empowerment to the team
3. Sr. Mgmt understands and is involved in the quality process
4. Quality goals equally understood by management down to the bench level

Bonus: Quality metrics are part of Sr. Mgmt's objectives

And your score.....



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Embracing the Quality Strategy

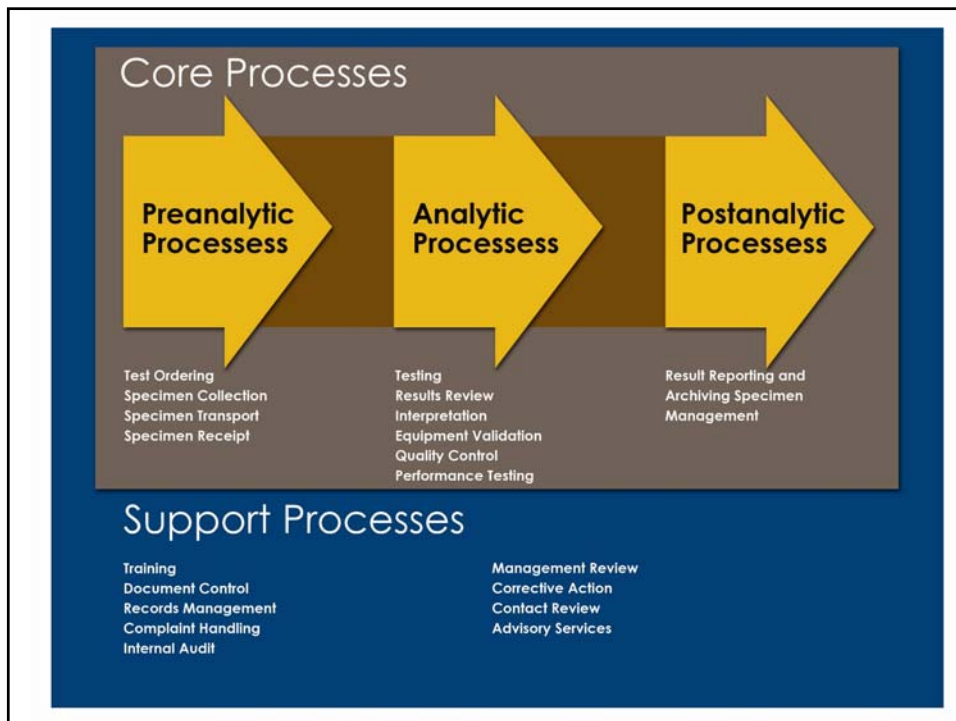
#2 Do and Don't

PUTTING THE PIECES TOGETHER

Procedure vs. Process

Quiz: On a scale 0 to 10, 0 = not at all, 10 = Very much so

1. Lab personnel have a good understanding of process vs. procedure
2. Lab personnel understand the interaction between processes (upstream/downstream)
3. There are mechanisms in place to report variations in process and are used

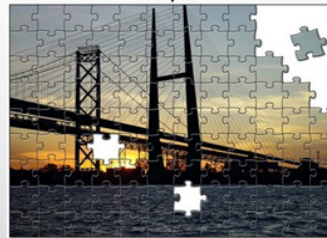


Do's and Don't Lessons

Processes Are Like Puzzles



We need to put them together into a logical interconnecting flow in order to see the big picture



Embracing the Quality Strategy

#3 Do and Don't

Root Cause Containment vs. Corrective Action

Quiz: On a scale 0 to 10, 0 = not at all, 10 = Very much so

1. Lab problems do not frequently reoccur as lab practices rigorous root cause
2. Lab does not focus on procedures or individuals as a way of preventing mistakes
3. Lab recognizes that most mistakes are not caused by people, but are frequently caused by process failures

Do's and Don't Lessons



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Do's and Don't Lessons

A way of looking at the management of quality to reduce errors.....

The goal is to create an entire system whereby it is EASY to do the right thing, and DIFFICULT to do the wrong thing

It is not the person who fails; it is the system that fails.

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So What Can You Do Today

- **LEARN** quality management principles for labs
- **ASSESS** your market and competitiveness
- **EVALUATE** your system resources
- **GAUGE** your readiness for quality improvement
- **CONSIDER** accreditation to ISO 15189

