

Incorporating ISO 15189 Medical Laboratory Accreditation

ADVANCE PATIENT CARE, SUSTAIN LAB STAFF QUALITY CULTURE,
AND BE CLIA INSPECTION-READY

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Key Agenda Topics

- Overview of Wisconsin Diagnostic Laboratories
- Journey Toward ISO 15189
- ISO 15189 Inspection
- Evaluating and Measuring Our Success

Overview of Wisconsin Diagnostic Laboratories

- ✓ Affiliates and Partners
- ✓ Team Members, Services, Customers
- ✓ Operations

Wisconsin Diagnostic Laboratories (WDL)

Owned Subsidiary - Froedtert Health Network



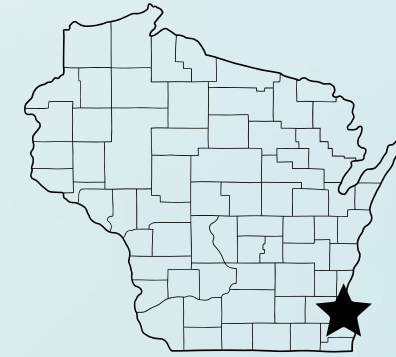
Medical College of Wisconsin
& MCW Pathology



2,300
Physicians

Main Campus (FMLH)

- Milwaukee, WI
- 735 beds
- Level 1 Adult Trauma Center

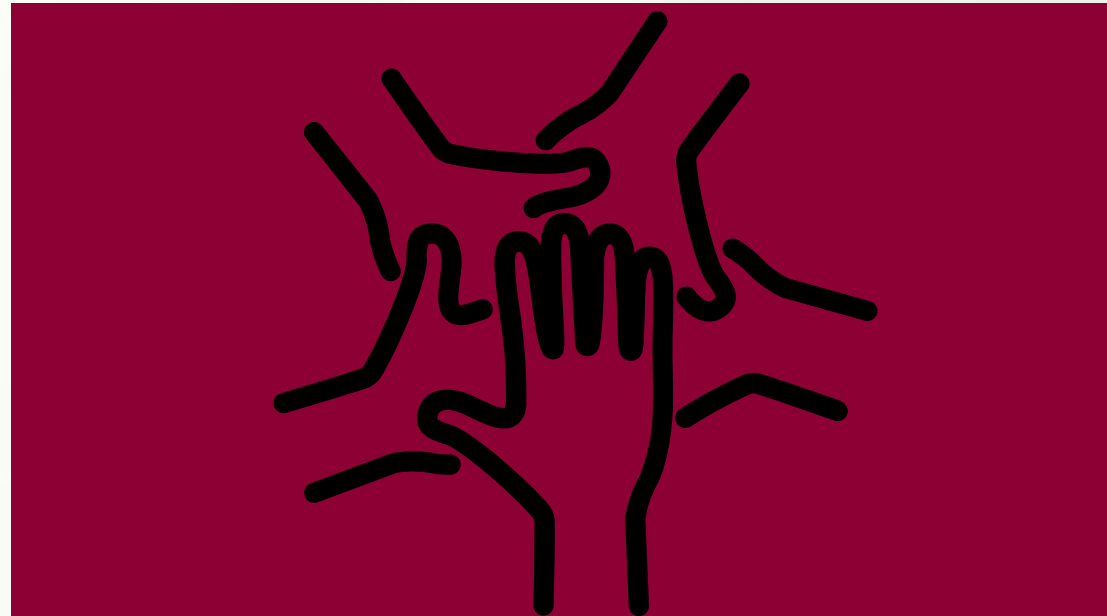


10 Hospitals



45 Health Centers/Clinics

Our Team



- 447 Employees (385 FTEs)
- 47 MCW Clinical Faculty
 - 15 Medical Directors
 - 16 Path Residents
 - 5 Fellows

Our Services



- 34 Service Lines
- 21 Specialties & Subspecialties

Our Customers



- 40 Hospitals
- 900 LTC Facilities
- 200 Physician Groups
- 85,000+ Annual Incoming Customer Calls

WDL Operations

ISO 15189 Accreditation
Tech Knowledge & Experience
Engaged Leadership
Medical Director Support
Reliable & Accurate Testing
Patient Focused Mindset
Testing TAT

Strengths

Adaptability to Ops Changes
Local & National Competition
Support Services
Retention of Qualified Staff
IT Support
Lack of Capital & Space

Threats

SWOT

Analysis

Weaknesses

Opportunities

Limitations

- IT Support (Interfacing)
- Space
- Capital to Stay Current

Manual Supply Management Processes
Accounts Payable Support – Credit Holds

Additional Lab Space
Atalan - National Lab Network
Precision Medicine Laboratory
The d care Lab Partnership
Acquiring Necessary Capital
Electronic Supply Inventory System

Journey Toward ISO 15189

- ✓ Beginning Our Journey
- ✓ Resources to Implement
- ✓ Budget Considerations
- ✓ CAP Accreditation Process
- ✓ QMS Development

Beginning Our Journey

- ✓ Organized a high functioning leadership team
- ✓ Established a focus on meeting the 12 Quality System Essentials (QSEs)
- ✓ QSEs – noting opportunities for improvement
- ✓ “Reactive fire fighter” - not making for a good environment
- ✓ GMP background – recognized prospect to realize higher quality standards
- ✓ Create a proactive & quality focused culture

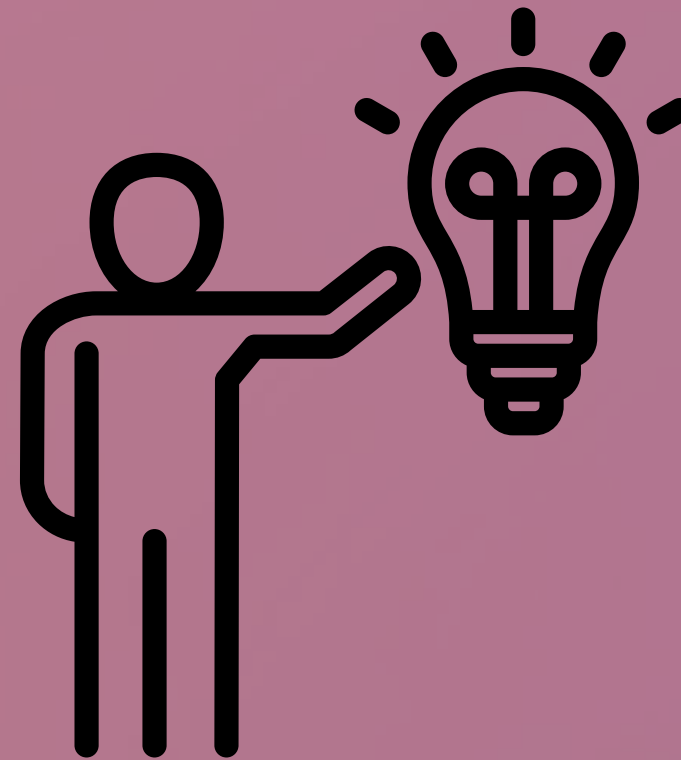
Gained a Controlled Environment

Reactive



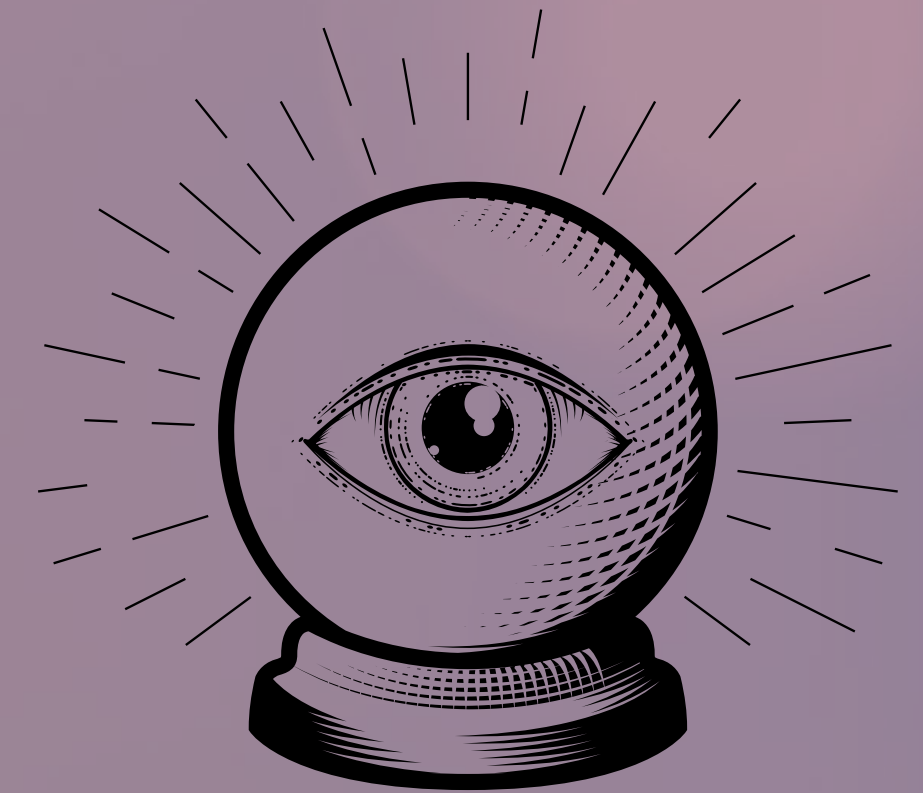
REACT TO ISSUES
AS THEY COME

Proactive



EMPLAC E AC TIONS
WITH HOPE OF
AVERTING ISSUES

Predictive



IMPLEMENT
PRO C ESSES SO ISSUE
NEVER C O MES UP

Prepared a Development Plan

KEY FOCAL POINTS ARISING FROM THE GAP ANALYSIS

Developmental Opportunities to meet 12 QSEs

Coordinate External Resource Assessment

Plan to Contact Accreditation Body

Determine Available Resources

Realistic Timeline Established

Primary Areas Targeted for Improvement

SUPPLY MANAGEMENT:

Change from Manual to Electronic

EQUIPMENT TRACKING:
MAINTENANCE & SERVICE
RECORDS

EVENT REPORTING:
EMPLAC E EFFEC TIVE AC TIONS
AND EFFEC TIVENESS C HEC KS

CHANGE MANAGEMENT:
PLANNING SHARED OR LIMITED RESO URCE S



DOCUMENT CONTROL:
TIMELINESS & ALL
INC LUSIVE/ ATTAC HMENTS

CUSTO MER RELATIO NS
MANAG EMENT (C RM)
PRO C ESS

TRAINING PRAC TIC ES &
TRAINER SUPPO RT

SYSTEMS AUDITS:
LEADING TO PRO C ESS IMPRO VEMENTS

Found a Consulting Lab

- Criteria : Previously ISO 15189 Accredited



Virtual Desk Audit

- Pandemic Impacted onsite audit
- WDL QSE Leaders Provided Documents



External Resource Audit



Follow-up Actions

- Create an action plan for each QSE

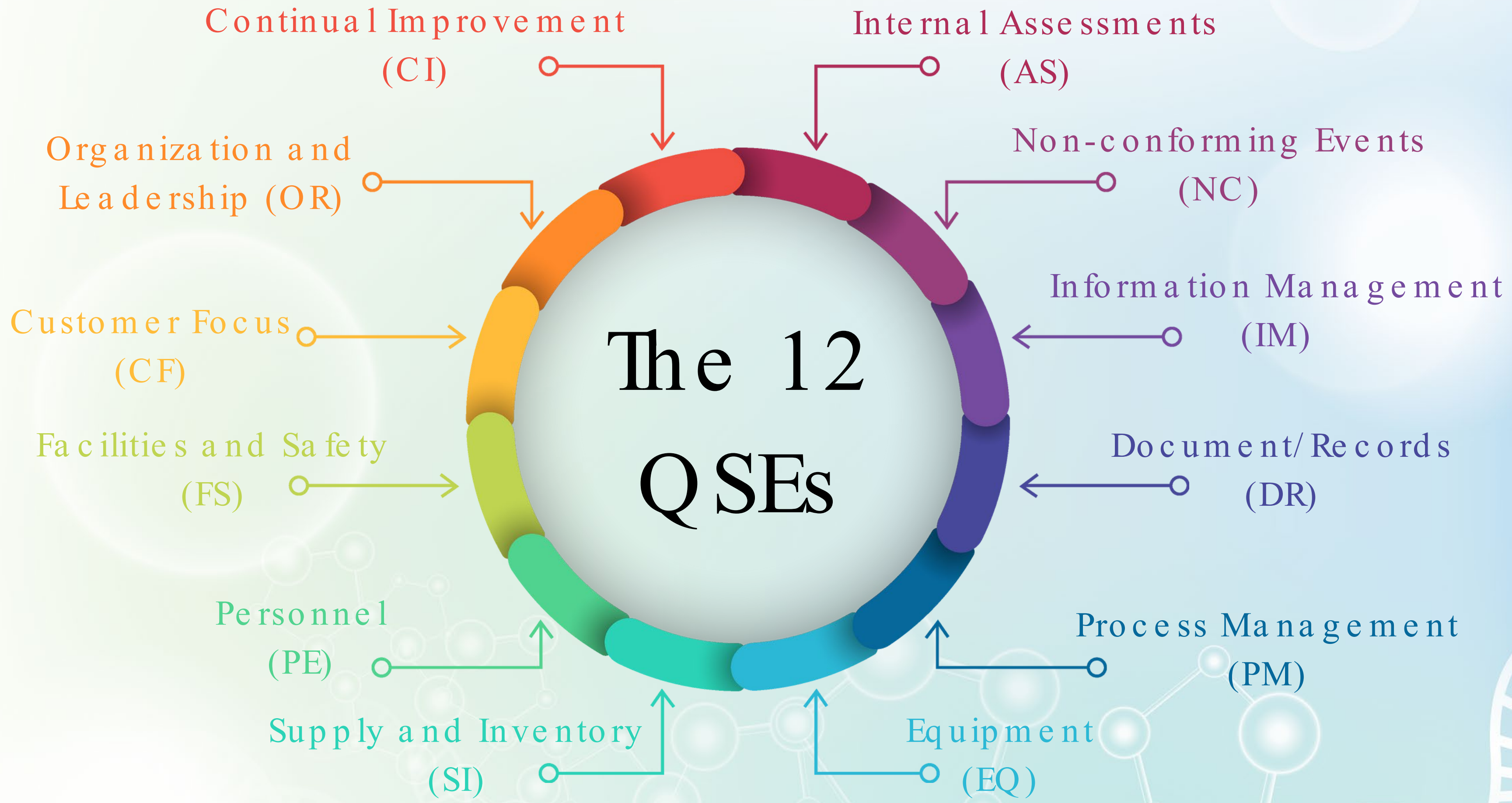
Auditor Evaluations

- Reported % Compliance
- Identified
 - QSE Shortfalls
 - Strengths
- Provided Recommendations



Evaluate Feedback

- Organize feedback
- Make available to
 - QSE Leaders
 - Subject Matter Experts
 - Support Staff



Assessment by QSE

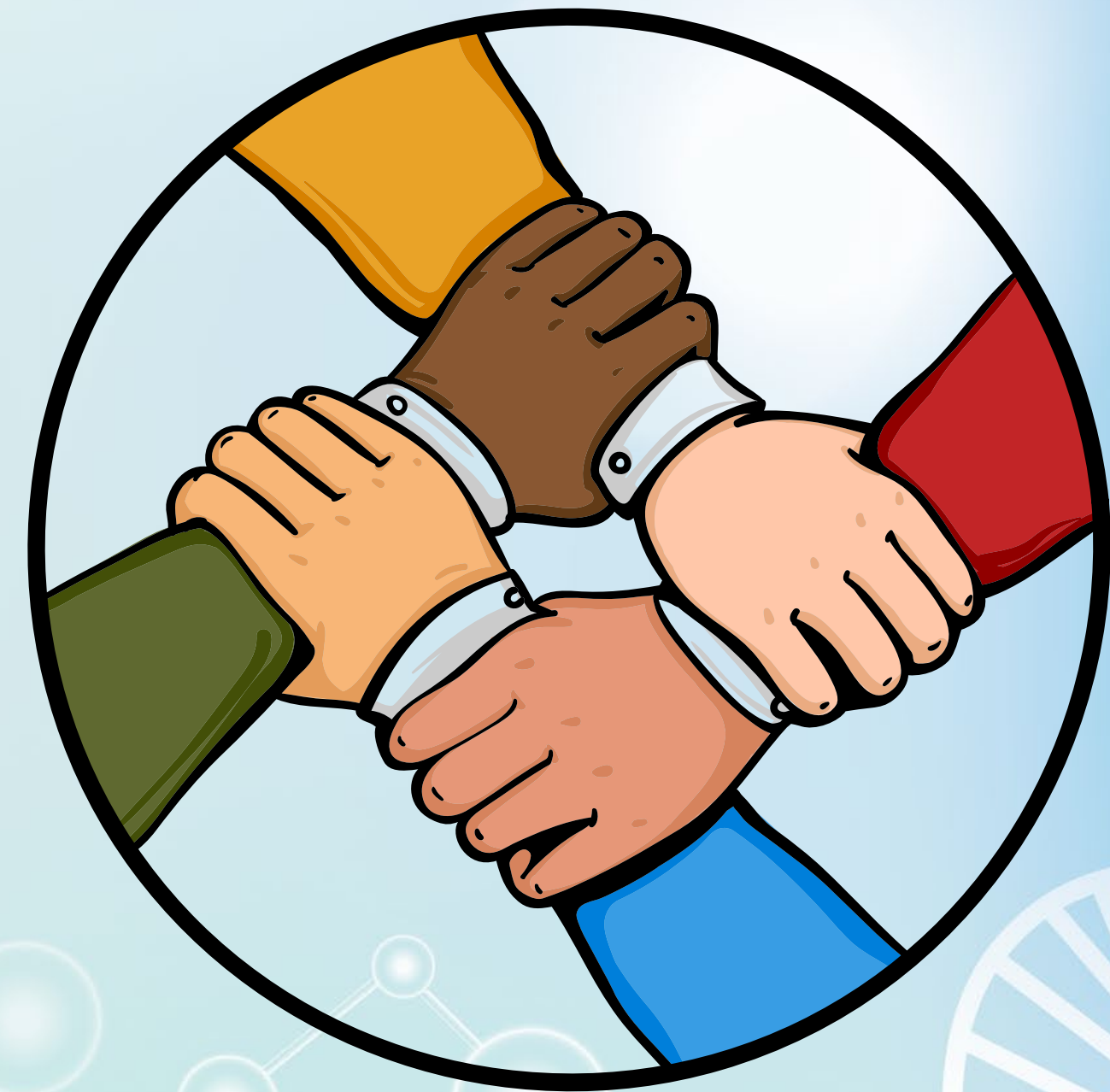
Score	Status of Gap Analysis
N/A	Not Applicable
0%	Nothing Defined, Documented, or Implemented For the Assessment Element
20%	Minimally Started
40%	Good Progress Made
60%	More Than Halfway Complete
80%	Nearing Completion
100%	Fully Defined, Documented, and Implemented Assessment Element

Overall
Readiness
= 64%



Resources to Implement

- ✓ CAP ISO 15189 Auditors - Reference Resource
- ✓ External Consultant - Audit WDLQMS
- ✓ My Role - Champion Leader of the Project
- ✓ Project Leader - Hire in a New Quality Manager
- ✓ Department Managers - QSE Leaders
- ✓ Technical Supervisors/ Specialists - Partner with QSE Leaders
- ✓ WDL Team Members - All Hands On Deck



General Risk Assessment

- ✓ Safety - None expected initially
- ✓ Reputation
- ✓ Financial
 - Initial Costs
 - Unknown Costs
- ✓ Regulatory
 - Higher Regulatory Standards than CAP LAP
 - 3 year Accreditation Cycle
- ✓ Operations/ Employees
 - Disruption of Operational Areas
 - Employee Burnout & Turnover
 - Possible Union Concerns
- ✓ External Factors
 - COVID-19
 - Shortages
 - Workforce
 - Supply Shortages
 - Unknowns
- ✓ Preparedness
 - Systems & Processes in Place to Remedy Issues
 - Lab Quality Culture Survey - Overall Positive Results

Gain Support

Identify

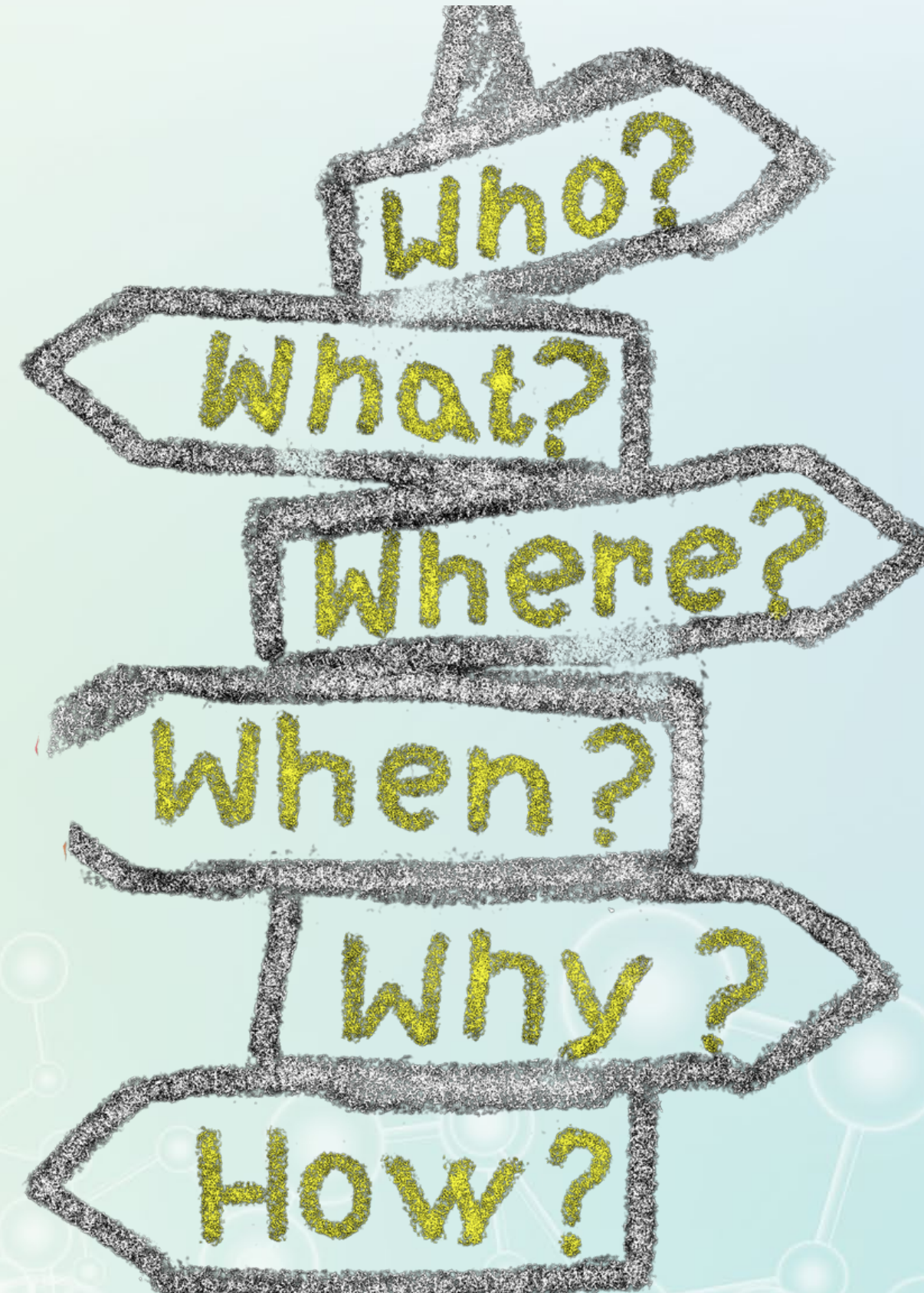
- Impacts
- “What’s In It For Me?”

Slow to Start

- OK, Good, Better, & Best
- Set Dates to Meet Goals

Communicate

- What is ISO 15189?
- Wall Display
 - Key Events & Timeline
 - Changes coming



Leaders and Team Members

On-site Assessment &
Inspection at WDL Campus

Shift to a Quality Mindset

- Identify Issues
- Reporting
- Evaluate Risks

Address Staffing Challenges

- ✓ Developed Certification Training and Education Programs
 - Hired Non-certified Technical Staff (NCT)
 - Added Lab Trainer Role
 - Coordinated CLS Apprenticeship Program with State
 - In progress - Expand to include Medical Lab Assistant (MLA)
- ✓ Increased Career Awareness
 - Participate in Events - ASCLS, HOSA, WSCA, WCLN, WSLH
 - Present at Career Day Events for Local Schools
 - Host Job Fairs
- ✓ Work Life Balance Awareness & Education
 - Incorporated Alternative Schedules (i.e., 4-10hr shifts)
- ✓ Established a National Education Collaborative



Key Leadership Responsibilities

✓ Commitment

- Additional Meetings
- Ensure Compliance of Quality Policies
- Allocate Funds - Direct & Indirect Costs
- Timely Completion of Training & QSE Assignments

✓ Champions of Implementation

- Understand ISO Standards & QMS
- Provide Resources to Create & Maintain QMS
- Support Quality in Day-to-Day Work



Development of the WDL Quality Team

- ✓ My Role at Beginning
 - Interim Quality Manager
- ✓ Manager of Regulatory Accreditation & Safety
- ✓ Project Handoff
 - Hire d Quality Manager
 - Added 3 Quality Specialists



Quality Manager:
Overall Scope

QSE Teams:
Evaluated QSE
Wins & Shortfalls

Establish
a Realistic
Timeline

GANTT Charts
Developed for
QSE Actions

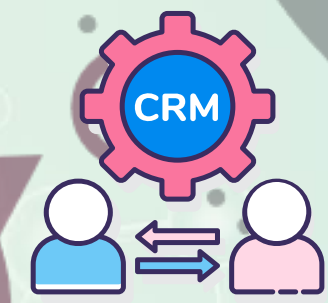
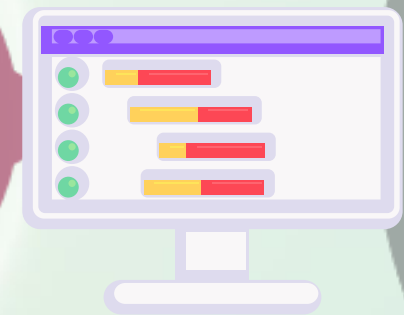
Identified
Competing
Resources

Hurdles/ Showstoppers

- Functional CRM Tool
- NCE Management

Established Targets

- Application
- Audits



Budget Considerations

Software & Supplies

- CAPA
- CRM Tool
- NCE Report System

Facilities & Equipment

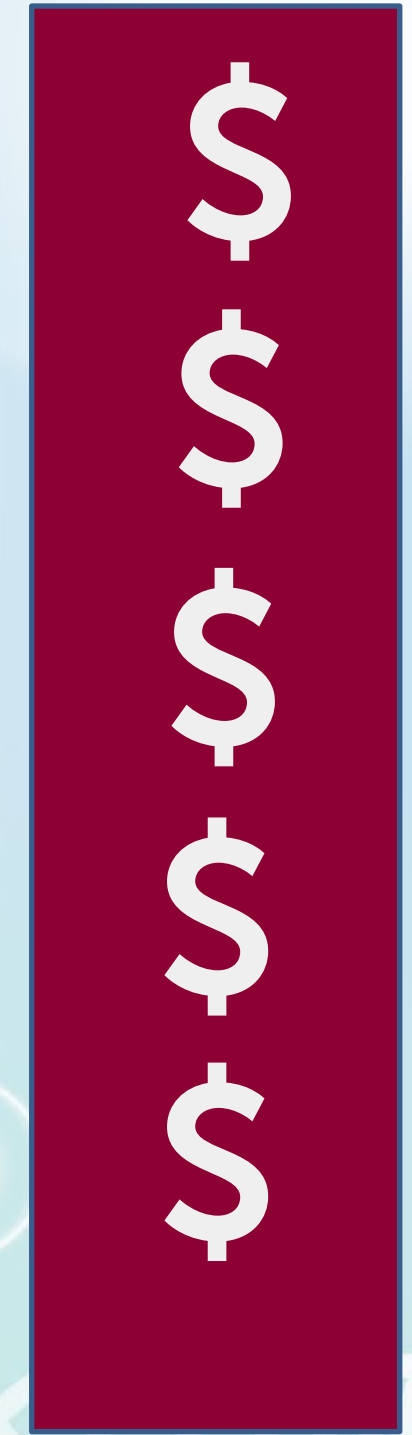
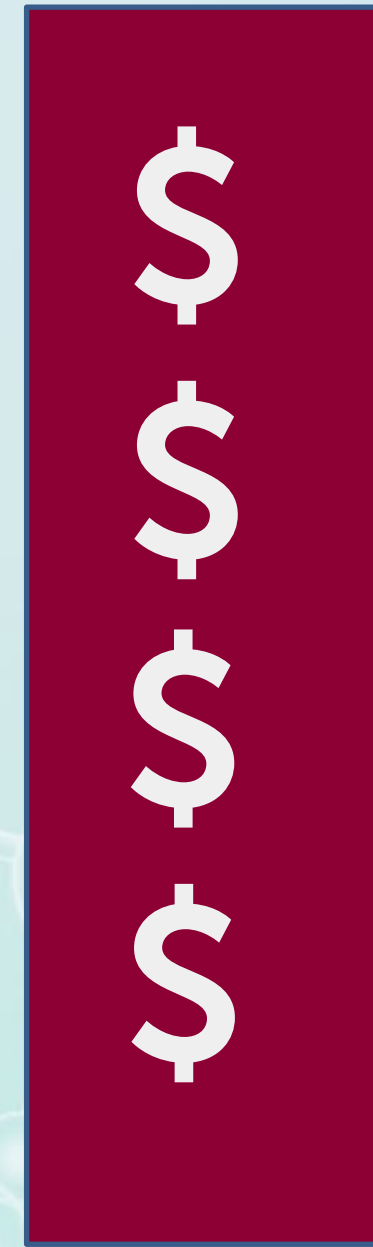
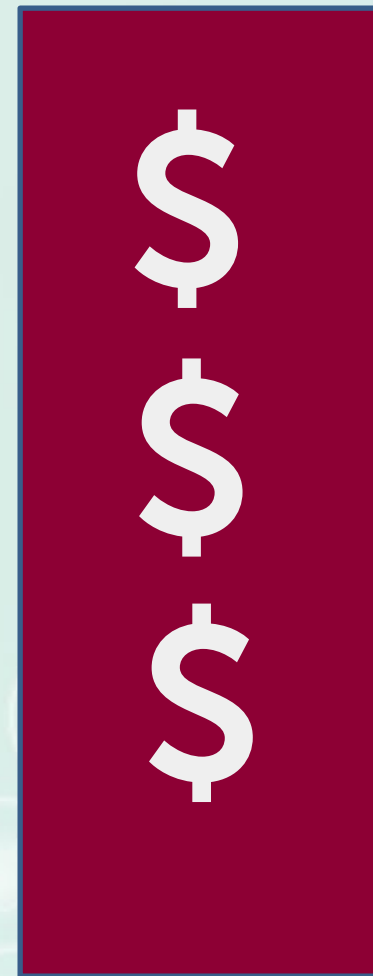
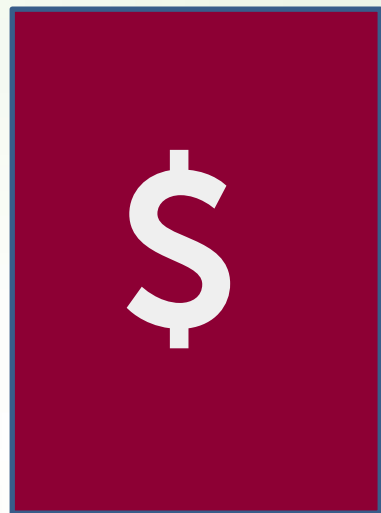
Labor

- Team Needs
- Training
- + FTE for Quality

CAP Accreditation Fees

Incentive

- Recognition/Reward
- Celebrate Key Milestones



CAP Accreditation Process

Establish leadership commitment: the principle element for a successful quality management system

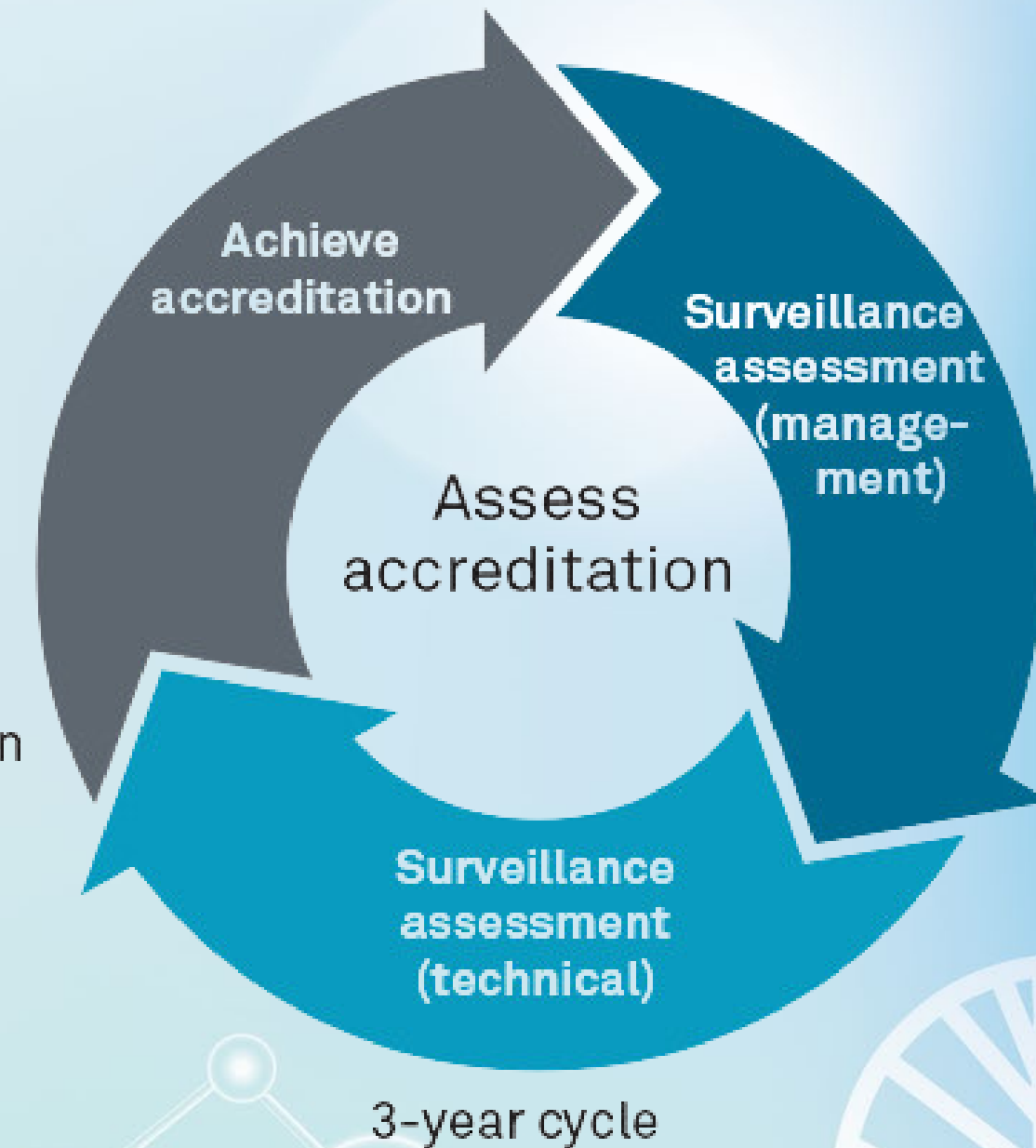
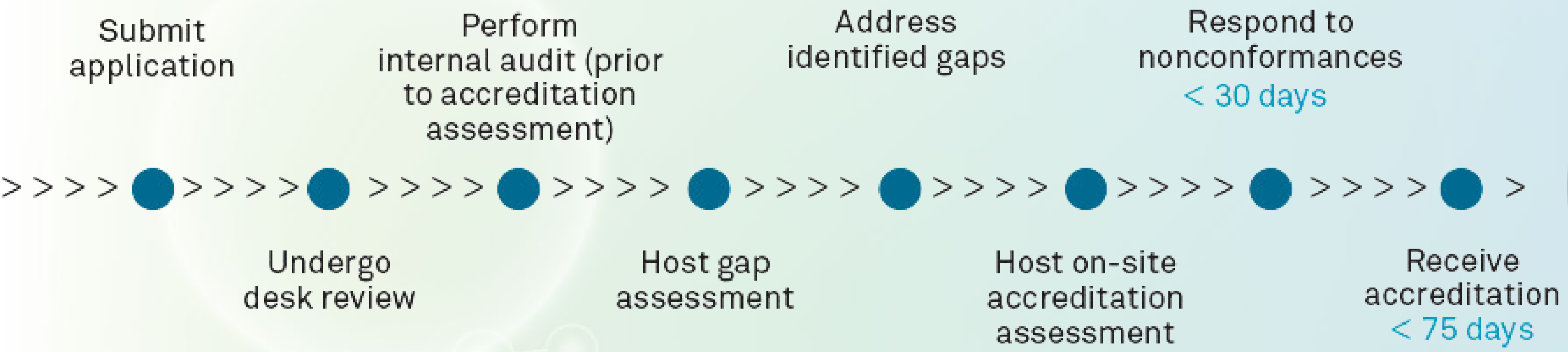
Identify champions to show the way, encourage and foster the “spirit” of quality in the lab

Quality team develops an implementation plan to illustrate the way forward

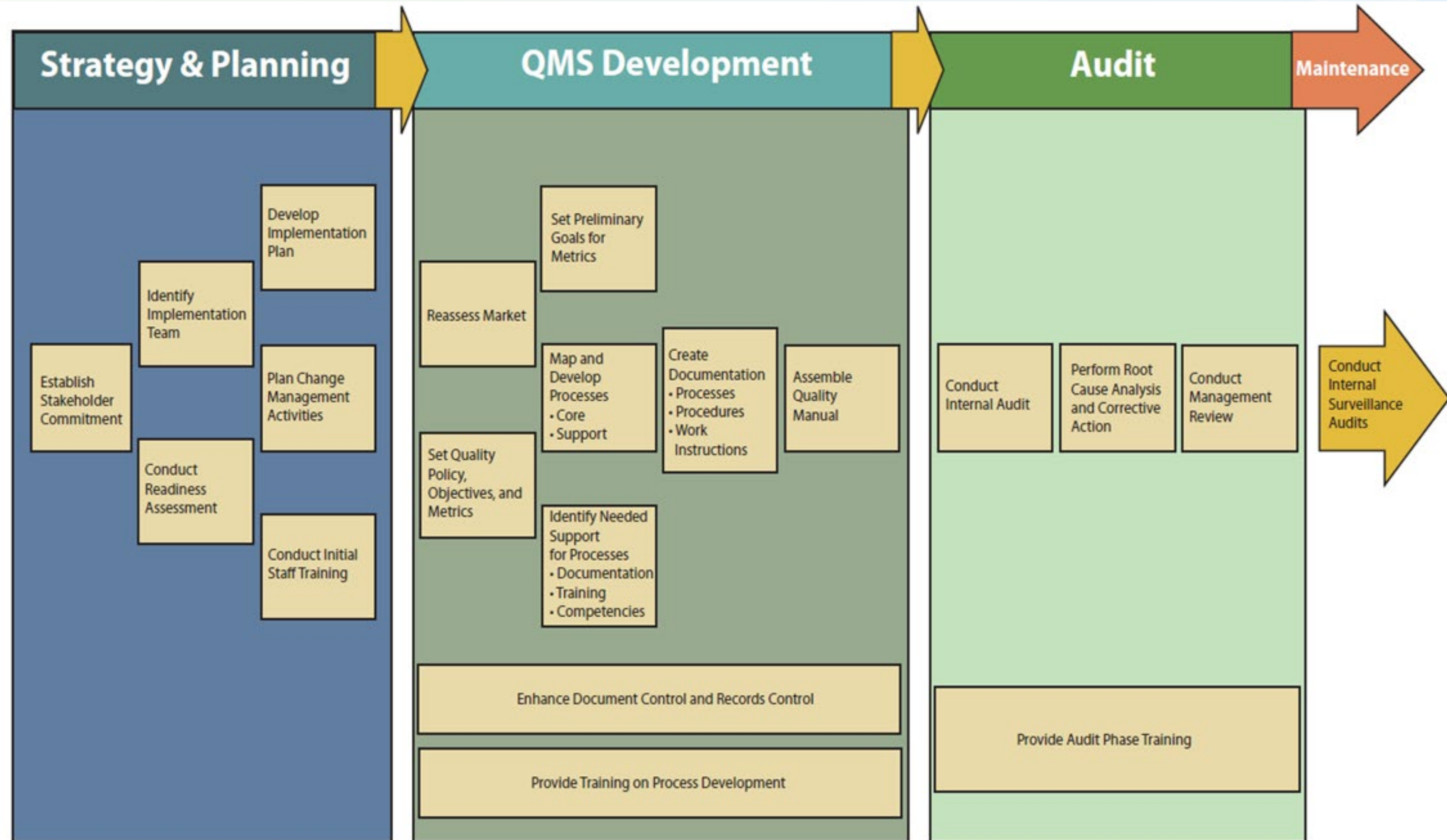
ISO 15189 – CAP Accreditation Process

Initial Accreditation Cycle

The timing for the initial accreditation varies depending on the laboratory's readiness, resources, and level of commitment.



Implementation Roadmap



Build a Quality Culture

August 2021 to January 2022

Quality Recognized Culture Goals

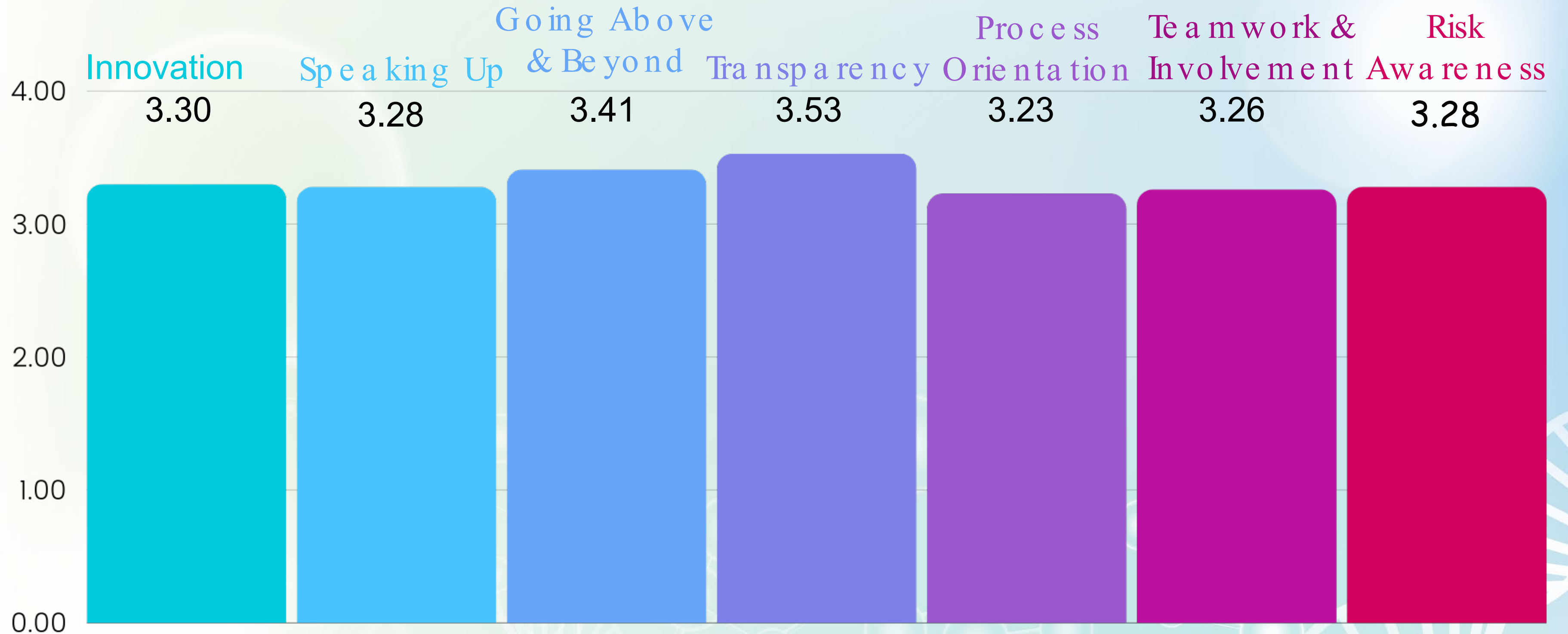
- Innovation
- Speaking UP
- Going Above & Beyond
- Transparency
- Process Oriented
- Teamwork & Involvement
- Risk Awareness
- Totally Responsible Person -
Be above the Line

Actions Taken

- ✓ Conducted a readiness assessment to measure different “attitudes” or mindsets on quality in the laboratory
- ✓ Developed a quality policy with objectives and metrics
- ✓ Enhanced document and records control
- ✓ Conducted leadership training

WDL Quality Culture Survey Results

November 2021



QMS Development

- ✓ Study diagram and understand processes
- ✓ Assemble documentation for quality manual
- ✓ Identify risk and needed controls to manage processes
- ✓ Identify improvements - positive outcomes that minimize error
- ✓ Maximize efficiency and effectiveness of internal processes

Core Processes



Test Ordering
Specimen Collection
Specimen Transport
Specimen Receipt

Testing
Results Review
Interpretation
Equipment Validation
Quality Control
Performance Testing

Results Reporting
Archiving Specimen
Management

Support Processes

Training
Document Control
Records Management
Complaint Handling
Internal Audit

Management Review
Corrective Action
Contract Review
Advisory Services
Purchasing



QMS Development

July 2022 to December 2022

Document Control Goals

- Create an Effective System
- Everyone sees the Same Document
- Current Version is Accurate
- Consistency of Critical Tasks
- Document Review is Timely
- Attachments Controlled
- Postings/Job Aids Controlled

Actions Taken

- ✓ Create New Documentation
- ✓ Make System Improvements
- ✓ Manage Changes
- ✓ Train Leaders to Perform Internal Assessments

QMS Development - Assessment Phase

September 2022 to January 2023

1. Perform internal audits of the quality system
2. CAP reviews documentation
3. Host on-site gap analysis - CAP Auditors
4. Root cause analysis to address gaps
5. Management review of quality system
6. Make changes - continual improvement

Root Cause Analysis

Tools for Root Cause Analysis

1

DEFINE THE PROBLEM

- Assemble the team
- Interview individuals who have insight into the problem
- Review the data
- Develop problem definition



2

MAP CURRENT PROCESS

- Interview individuals doing the work
- Review lab documents
- Create and/or expand flow charts



DEVELOP SOLUTION

- Consider solution types:
- **Stronger**—Make physical changes to environment or redesign process
 - **Intermediate**—Provide information at point of need
 - **Weaker**—Provide training, warnings, and additional checks
- Interview key players and stakeholders about feasibility of various options

4

IMPLEMENT SOLUTION

- Identify possible sources of resistance
- Develop a "change management" approach
- Develop a plan and schedule for implementation
- Implement



3

FIND ROOT CAUSE

- Choose the most appropriate tool, such as:
- **Flowcharting**—Treat each step as a possible cause, and break into smaller steps
 - **Five Whys / Fault Tree**—Identify possible causes at each level of the system
 - **Cause-and-Effect Diagram / Fishbone Diagram**—Brainstorm a list of possible causes
- Select the most likely cause(s) based on the possibilities and the evidence



6

ASSESS EFFECTIVENESS

- Choose an assessment approach such as:
- Monitor an established metric
 - Perform a focused internal audit
 - Set up a simulation/experiment
- Example: Announce a condition, and see if people do the right thing—(aka, "Fire Drill" method).
Make necessary changes



TOOL	DESCRIPTION
<p>Brainstorming</p>	Brainstorming is a joint undertaking by a group to generate a number of creative and practical ideas from different perspectives.
<p>Fishbone Diagram / Cause-and-Effect Diagram</p>	A fishbone diagram is a tool to show different possible causes that may be contributing to an outcome or event. It prompts the users to think of many areas of possible causes, beyond the obvious.
<p>Five Whys / Fault Tree</p>	Five Whys/Fault Tree is a set of tools that share a common characteristic: They each take an event or problem, and continually look for more basic reasons or causes by asking why.
<p>Interviewing</p>	An interview is a way of eliciting specific information surrounding an event or a process from frontline staff.
<p>Process Mapping</p>	Process mapping is an exercise to identify all the steps and decisions in a process in the form of a diagram.
<p>Six Thinking Hats</p>	<p>Six Thinking Hats is a tool created by Edward de Bono to encourage creative and unconventional thinking about a topic. It encourages teams to look at a problem from different perspectives. It also pushes individuals out of their typical mode of thinking. The six hats correspond to the following different thinking modes:</p> <ul style="list-style-type: none"> • White—Factual, as in "black and white" information • Red—Emotional, gut feelings • Black—Negative, pessimistic • Yellow—Sunny, optimistic • Green—Creative, fertile • Blue—Big picture, higher perspective (view from the sky, from above)

Interested in learning more about root cause analysis? The CAP's QMED™ online course on root cause analysis will introduce you to real-world methodology and tools you will need to complete a thorough root cause analysis leading to more efficient results. Earn six CE credits with the completion of this course.

For more information, visit cap.org and search QMED™.

ISO 15189 Accreditation

- ✓ On-site Inspection
- ✓ Accreditation
- ✓ Surveillance

ISO 15189 Inspection

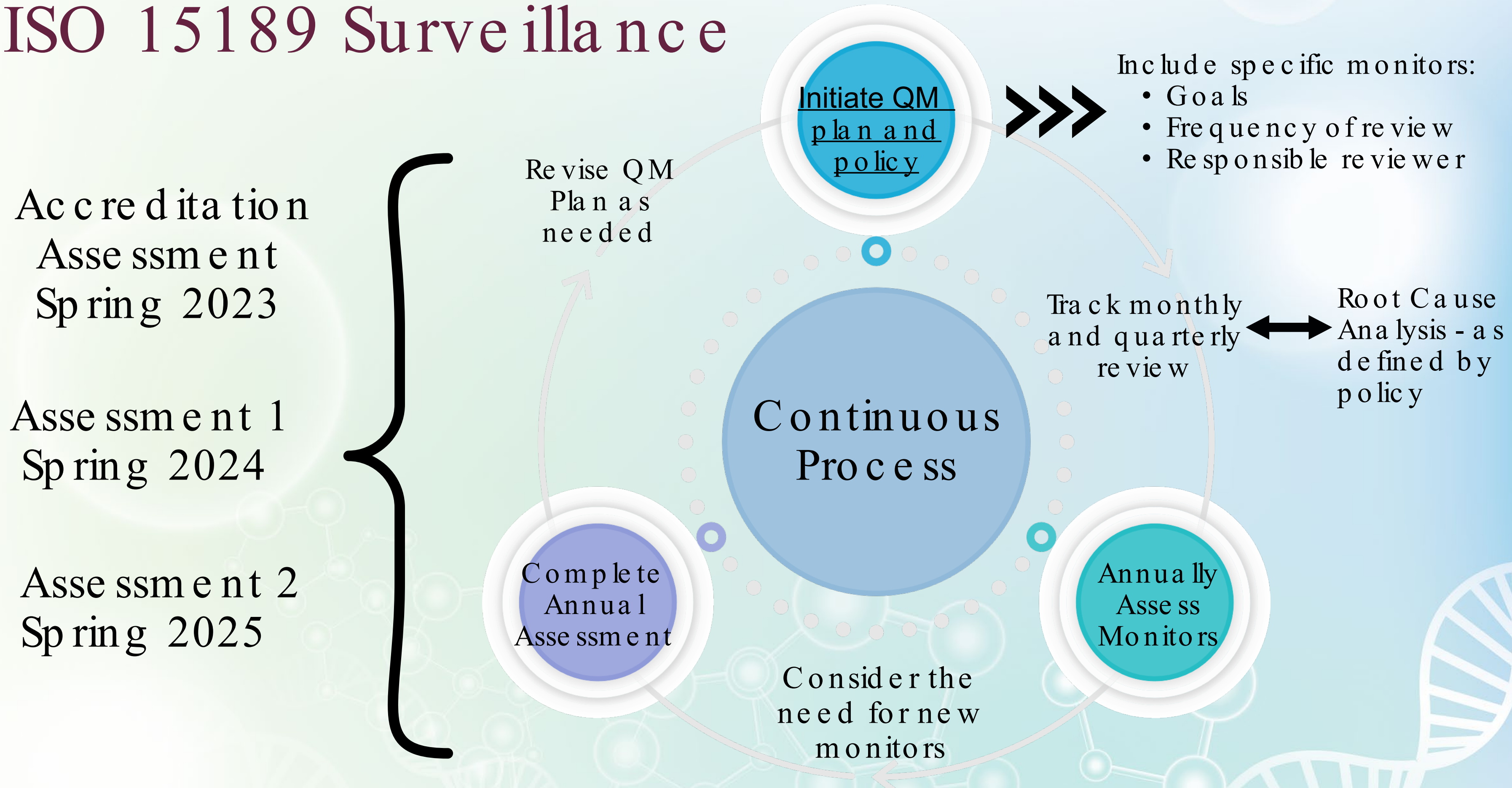
June 28-30, 2023

- ✓ Addressed Identified Gaps
 - January Gap Assessment
 - 2 ISO 15189 CAP Assessors
- ✓ Host Onsite Accreditation Assessment
 - Same ISO 15189 CAP Assessors from Gap Assessment
- ✓ 30 days Response Window to Address Nonconformities

ISO 15189 Accreditation

- ✓ Expect Notice of Accreditation within 75 Days
- ✓ Accreditation effective : last day of inspection - June 30, 2023
- ✓ Official Notice Received on October 5th, 2023
- ✓ Celebratory Dinner with entire WDL Team

ISO 15189 Surveillance



Evaluating and Measuring Our Success

✔ Noted Benefits

- What Improved or Increased
- What Became more Effective or Efficient
- What Was Reduced or Eliminated

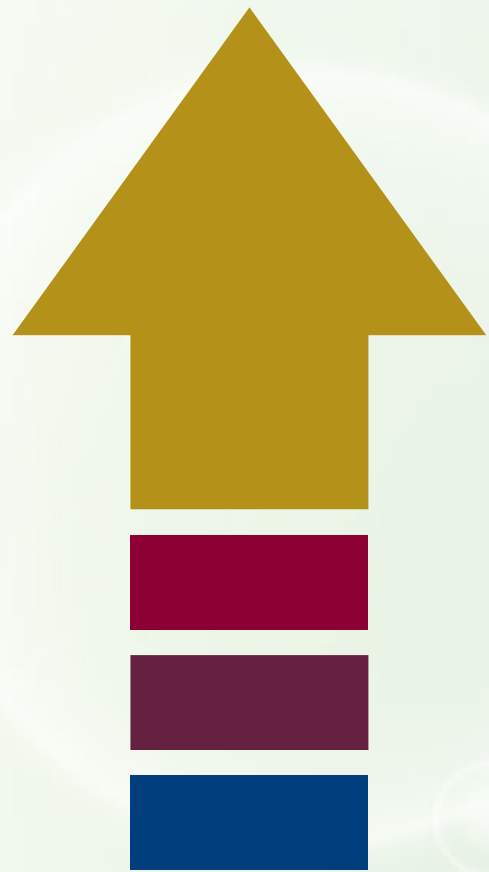
✔ Workload Capacity Measures

✔ Measures of Success

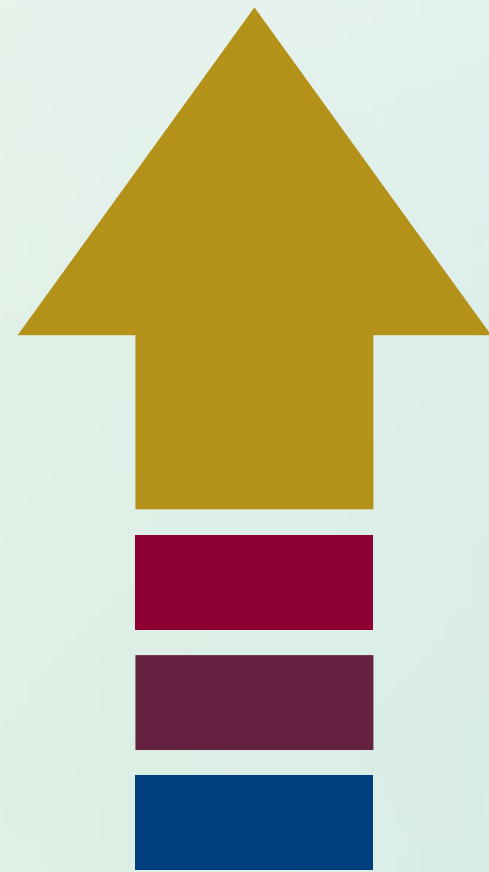
✔ Lessons Learned

- What Went Well
- What Could Have Been Better

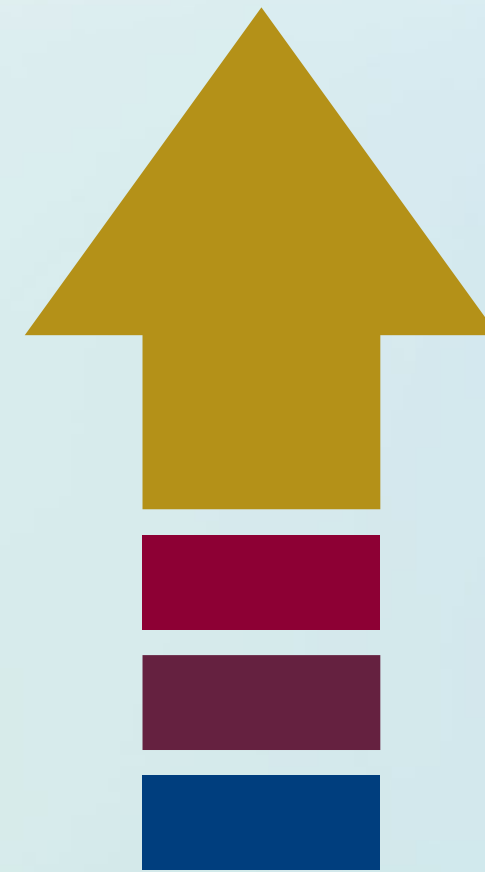
Noted Benefits: What Improved or Increased?



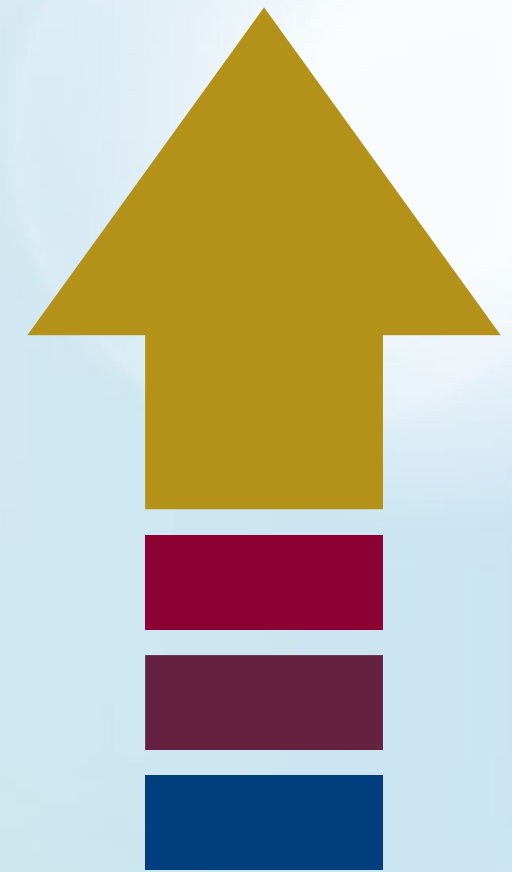
Level of patient
safety and care



Likelihood of
meeting customer
expectations



Job
Satisfaction



Job
performance

Noted Benefits:
What Became
More Effective
or Efficient?



Noted Benefits: What Was Reduced or Eliminated?



Call backs and result
modifications or
cancellations



Errors



CAP inspection
deficiencies

Workload Capacity Measures

- ✓ Maximize Department Efficiencies
- ✓ Establish Measures
 - Staff Member Productivity Metric
 - Instrument Capability
 - Unique Department Characteristics
- ✓ Overcome the Need for Perfect Math
- ✓ Standardize Across the Laboratory
- ✓ Color-coding to Quickly Identify Status



Workload Capacity Measures

Date Range	Monthly Sample Total	Normal Monthly Sample Total	Sample % to Normal	Monthly Staffing Hours Staff	Monthly Staffing Normal Hours	Staffing % to Normal	Staffing to Volume Ratio or Index	OT %	TAT Neoplastic Average (Days)	Percentage of Capacity	Overall Monthly Rating
1/1/23-1/28/23	327	336	97%	2070	2416	86%	1.14	1.95%	7.15	45%	Optimal State 41-60%
1/29/23-2/25/23	359	336	107%	2381.1	2416	99%	1.08	2.28%	9.15	56%	Optimal State 41-60%
2/26/23-3/25/23	297	336	88%	2283.4	2416	95%	0.94	2.30%	7.35	41%	Optimal State 41-60%
3/26/23-4/29/23	446	420	106%	2785.2	3020	92%	1.15	2.26%	9.34	56%	Optimal State 41-60%
4/30/23-5/27/23	333	336	99%	2324.3	2416	96%	1.03	1.83%	9.98	51%	Optimal State 41-60%
5/28/23-6/24/23	320	336	95%	2037.9	2416	84%	1.13	1.26%	10.14	50%	Optimal State 41-60%
6/25/23-7/29/23	422	420	100%	2550.3	3020	84%	1.19	3.12%	10.62	67%	Stretch capacity 61-80%
7/30/23-8/26/23	320	336	95%	1852.6	2416	77%	1.24	3.00%	9.04	59%	Optimal State 41-60%
8/27/23-9/30/23	453	420	108%	2795.3	3020	93%	1.17	2.26%	8.93	55%	Optimal State 41-60%
10/1/23-10/28/23	340	336	101%	2375.1	2416	98%	1.03	2.03%	8.1	46%	Optimal State 41-60%
10/29/23-11/25/23	326	336	97%	2173.6	2416	90%	1.08	1.23%	9.63	47%	Optimal State 41-60%
11/26/23-12/30/23		420	0%		3020	0%	#DIV/0!				

CAPACITY RANGE	RATIO/INDEX	OT %	TAT Neoplastic (Days)
Underutilization 0-20%	< .8	< .8%	< 6 days
Excess capacity 21-40%	.8-1.10	.8%-1.0%	6.0 days- 7.0 days
Optimal State 41-60%	1.11-1.25	1.1%-2.0%	7.1 days- 8.0 days
Stretch capacity 61-80%	1.26-1.40	2.1%-3.0%	8.1 days- 10 days
Overutilization 81-100%	>1.40	>3.0%	>10.0 days

Measures of Success

- ✓ 33 Corrective Actions Preventive Actions (CAPAs)
- ✓ 7 Root Cause Analysis (RCAs)
- ✓ 24 Internal audits
- ✓ Events Logged Identifying System Issues, Risk, OFI
 - Media Lab NCE - 100+ internal events
 - Outreach (PS) - 200+ events
 - Patient Safety (PSR)
 - 828 events rated <5
 - 22 events rated >5

Lessons Learned: What Went Well

- ✓ Leadership Team
 - Engaged to meet improvement needs
 - Organized to compliment each other
- ✓ NCE Recording and Tracking in Media Lab
- ✓ Share Point Resource Site for ISO 15189 Program
- ✓ Shared Efforts Across the Lab Team
- ✓ Time lines
 - Established realistic time lines
 - Leader buy-in and ownership
 - Kept on Track with Established Time lines
- ✓ Improved Document Control



Lessons Learned:

What Could WDL Have Done Better

- ✓ Celebrate After Key Milestones
- ✓ Broaden Communications to Catch Everyone
- ✓ Address the Complex Froot Health System Relationship
- ✓ Non-laboratory Departments have Different Standards.
- ✓ Discourage Perfectionism
- ✓ Senior Executive Messaging to Show Visual and Active Support
- ✓ Management of Competing Priorities
- ✓ Divided Leadership Can Produce an Unequal Focus

Presentation Summary

- Overview of Wisconsin Diagnostic Laboratories
- Journey Toward ISO 15189
- ISO 15189 Inspection
- Evaluating and Measuring Our Success

Questions?

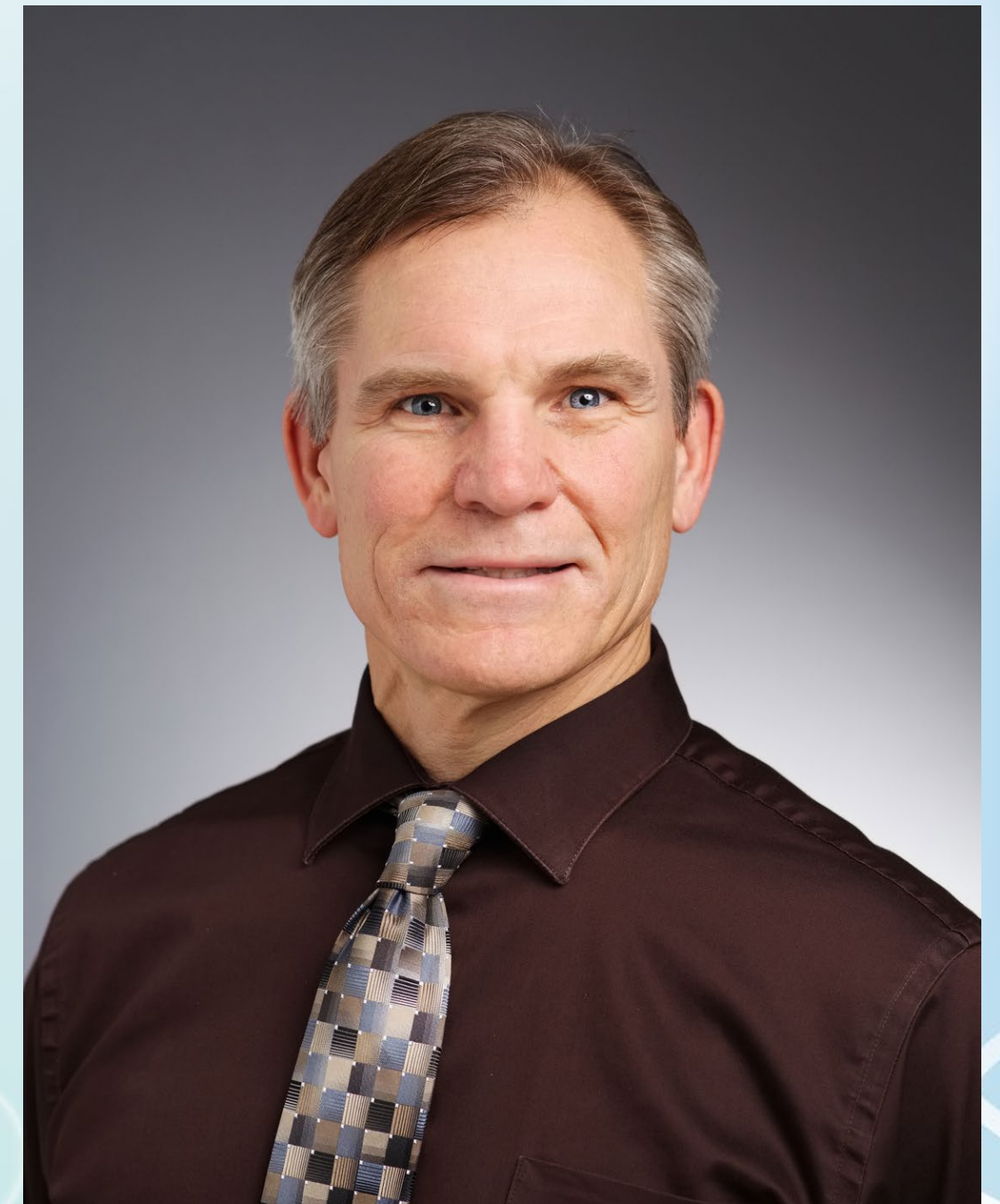


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Check out the WDL Education Collaborative

A National Lab Network to share alternative staffing and education solutions to meet the growing challenges with addressing staffing shortages in the clinical laboratory.

If you are interested in participating, please email
WDLEducationCollaborative@wisconsin-diagnostic.com




WISCONSIN
DIAGNOSTIC
LABORATORIES

Thank you