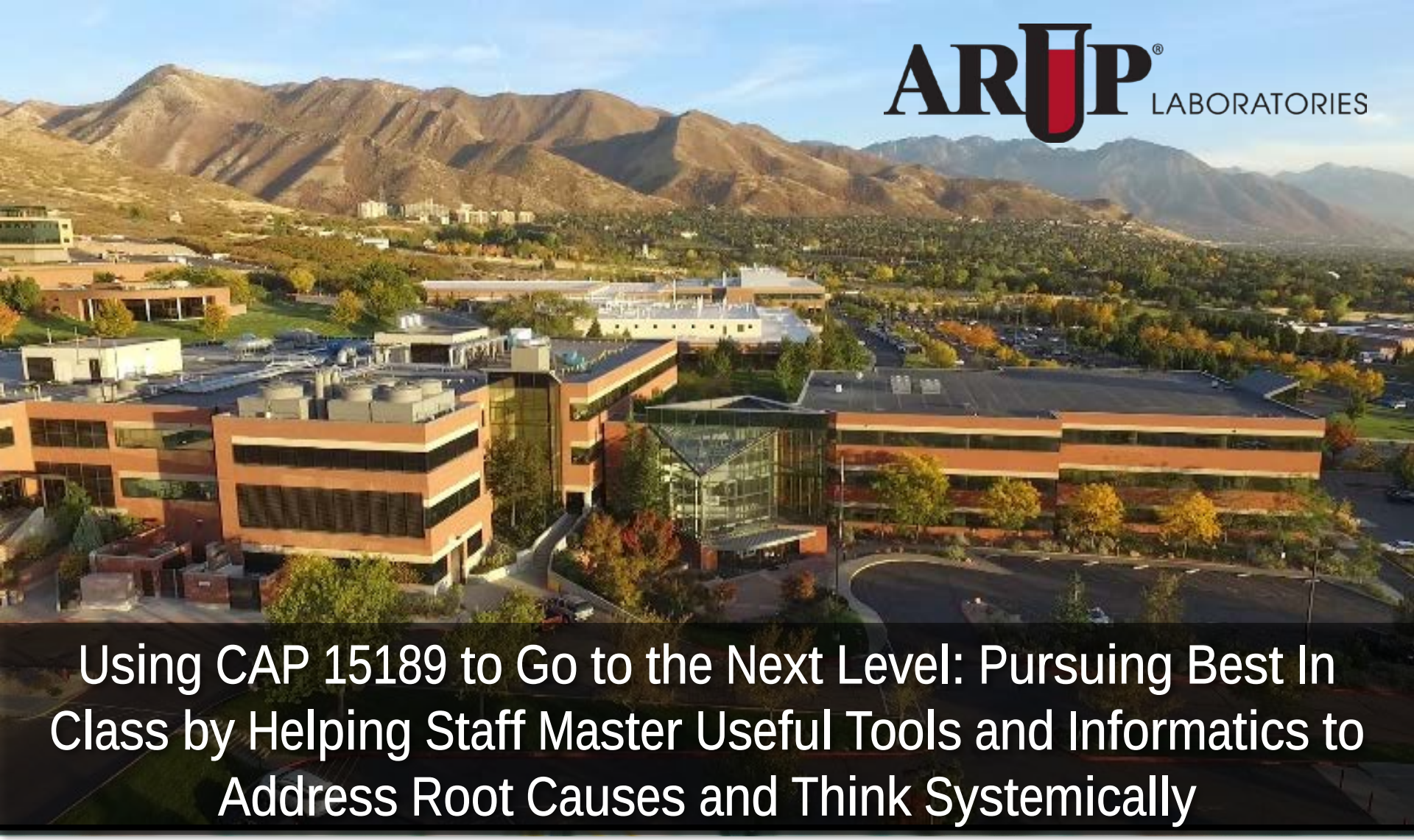

Using CAP 15189 to Go to the Next Level: Pursuing Best In Class by Helping Staff Master Useful Tools and Informatics to Address Root Causes and Think Systemically

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Outline

Background

Motives

Implementation

Outcomes

Lessons Learned

ARUP Laboratories: Background

Nonprofit, academic affiliate

HEALTH
UNIVERSITY OF UTAH

3,500+ employees

including 90+ medical directors

Provides testing for:

- genetics
- immunology
- oncology
- pediatrics
- pain management

One of the broadest test menus

3,000+ tests and test combinations

Clients include:

- university teaching hospitals
- children's hospitals
- multihospital groups
- commercial laboratories
- group purchasing organizations

>10 million specimens/year

>6.5 million patients affected/year

ARUP LABORATORIES

Motives

- Why ISO 15189?

Motives

- Quality Patient Care

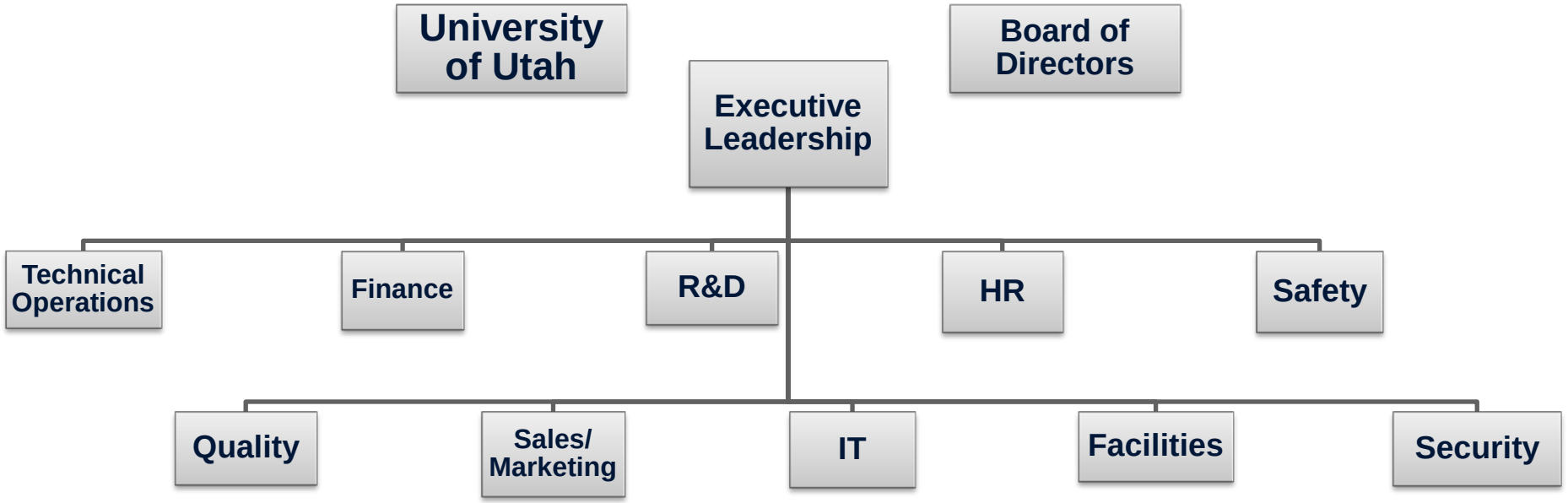
ARUP's Mission

Through excellence in laboratory testing, service, education, and research, ARUP's mission is to continually improve patient care and support the mission of the University of Utah.

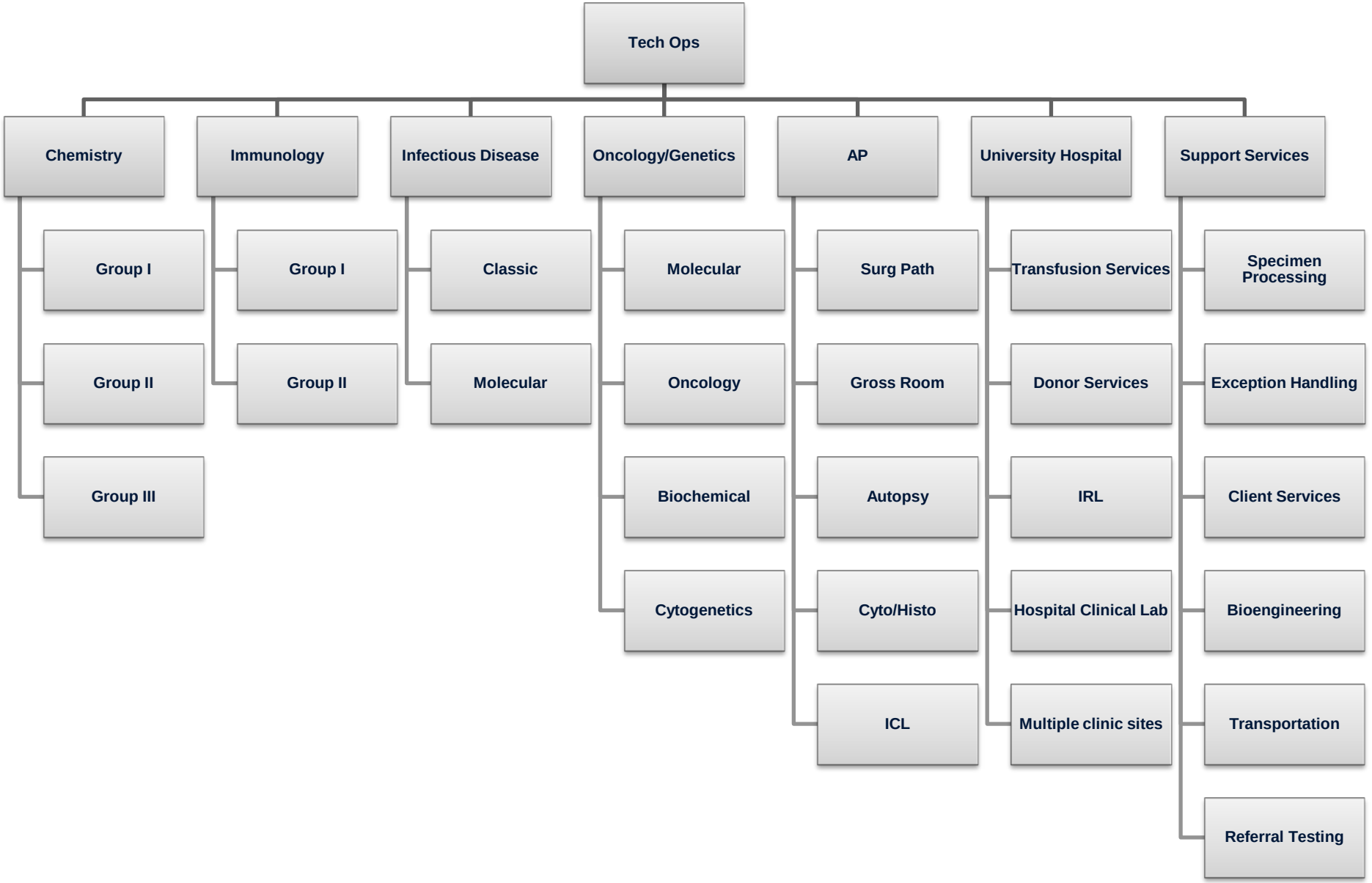
Motives

- Quality Patient Care
- Standardization

Complex Organization: General structure



Complex Organization: Technical Divisions



Motives

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It’s Complicated

ISO 15189 standardizes

- Standardization => sustainable quality culture
  - Document control
  - Quality data
  - Nonconforming event handling
  - Training & competency

  - All employees speaking the same language of quality
    - Higher levels of engagement
    - Empowered staff that can use quality tools

Motives

- Quality Patient Care
- Standardization
- Structured program

Example: CAP LAP

GEN.20208 QM Patient Care Services Phase II

The QM program includes a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services.

NOTE: There must be an organized process for recording of problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must record investigation and resolution of these problems. Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including "near misses" and sentinel events). Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.

Example: ISO 15189

4.10 Corrective action

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered. The laboratory shall have a documented procedure for:

a) reviewing nonconformities;

b) determining the root causes of nonconformities;

c) evaluating the need for corrective action to ensure that nonconformities do not recur;

d) determining and implementing corrective action needed;

e) recording the results of corrective action taken (see 4.13);

f) reviewing the effectiveness of the corrective action taken (see 4.14.5).

NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered “immediate” action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered “corrective” action.

ISO 15189: Quality Culture Framework

Motives

- Quality Patient Care
- Standardization
- Structured program
- Market

Implementation

Gap Assessment
August 2014

Accreditation Assessment
August 2016

Accreditation
December 2016

Surveillance Assessment 1
August 2017

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Quality Reporting Structure

QMS Updates

- Document Management
- Occurrence Management:
  Nonconformance/CAPA
- Internal Audits
- Quality Indicators
- Management Review
- Quality Steering Committee
- Team Huddles

Document Management System

- Document Control is foundational to quality
- Use of customized COTS EDMS
- Clarify definitions of controlled documents
- Shore up processes for doc control specialists
- Provide process for all staff to submit doc control requests
- Education
- Audits
- More education
- More audits

Occurrence Management System

- Nonconformance system
  - Occurrence management built into Salesforce
  - Every employee can submit occurrences
  - Rated as major, minor, document only, or not a quality issue
  - Trends monitored, reported, and escalated
  - Standard list of process categories, subcategories, outcomes, and root causes
  - Custom department lists of process categories

Occurrence Management System

- Corrective and preventive action system
  - CAPA solution built in MS SharePoint
  - CAPA is used to track commitments
  - Not every occurrence warrants a CAPA
  - Effectiveness checks are documented
  - Provides data to see common actions across departments

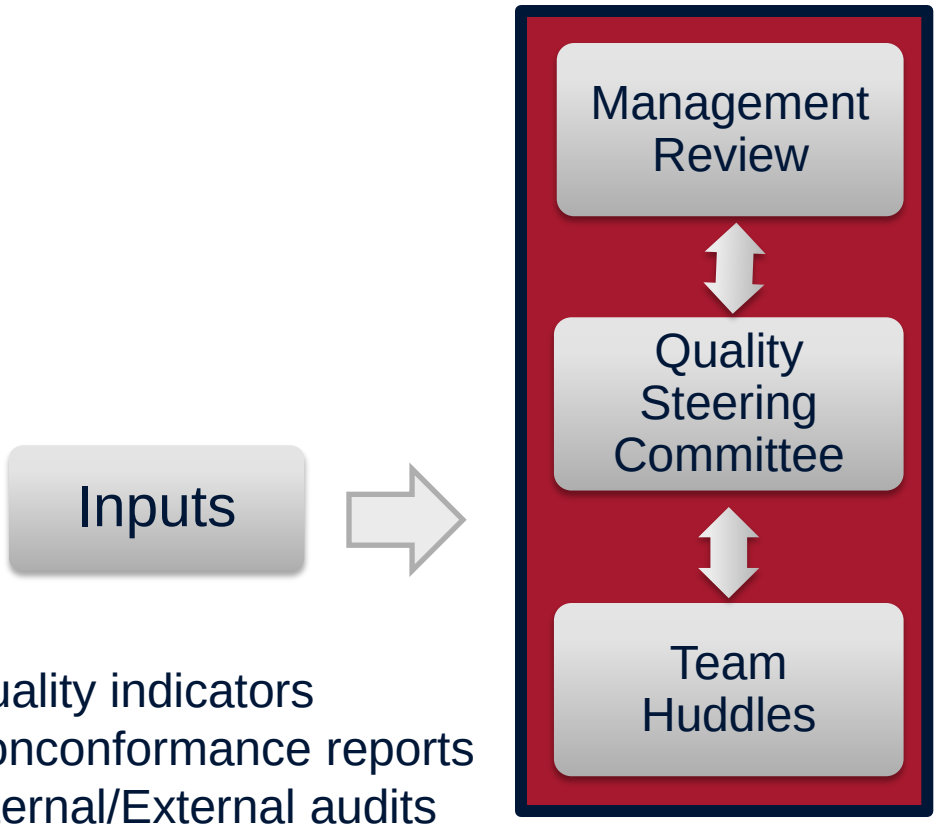
Internal Audit Program

- Audits are scheduled throughout the year—roughly monthly
- Auditors are trained from quality staff and volunteers from lab sections
- Audit coordinator summarizes and presents findings
- Global improvement opportunities are prioritized

Quality Indicators

- Normalized metrics to monitor quality in each lab and across the entire company
- Thresholds are set
- When thresholds are exceeded, corrective actions are taken and documented
- Effectiveness of actions taken is evaluated
- Corporate indicator performance is reviewed
- Global corrective actions are implemented if needed
- Each section monitors department-specific indicators

Systemic Flow of Quality Information



- Quality indicators
- Nonconformance reports
- Internal/External audits
- PT data
- Continual improvement data

Implementation

Team Huddles

- Communication from the front lines on quality, safety, and operational topics
- Flexibility in huddle formats to match needs of individual teams
- Provides a routine platform for staff to voice their opinions, thoughts, and concerns
- Leads to engaged staff with an understanding of quality issues
- Corporate quality issues can be filtered back down to all team members by management

Quality Steering Committee

- Combination of technical and quality staff
- All technical divisions represented
- Regular review of data and findings from quality systems
- Discussions on prioritization of improvement initiatives
- Ensures alignment between quality and technical operations

Management Review

- Reviews corporate quality performance metrics and trends
- Prioritizes improvement initiatives
- Filters and escalates issues for executive action

Systemic Flow of Quality Information

- Quality indicators
- Nonconformance reports
- Internal/External audits
- PT data
- Continual improvement data

- Tasks and initiatives prioritized
- Resources allocated
- QA plan/objectives adjusted
- Proposals approved/rejected

Quality is ARUP's Way of Life

Implementation

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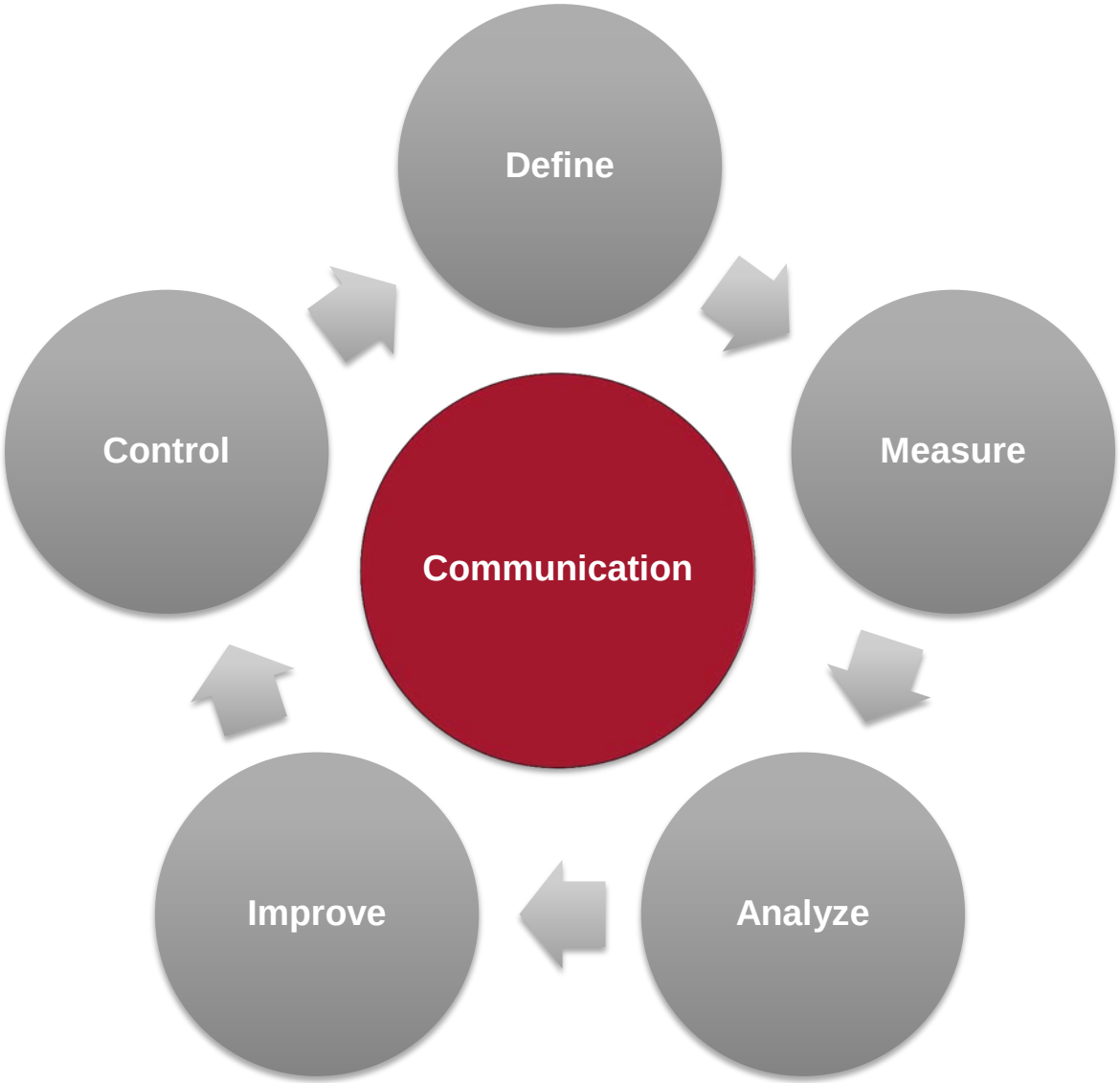
Summary



Implementation

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Outcomes

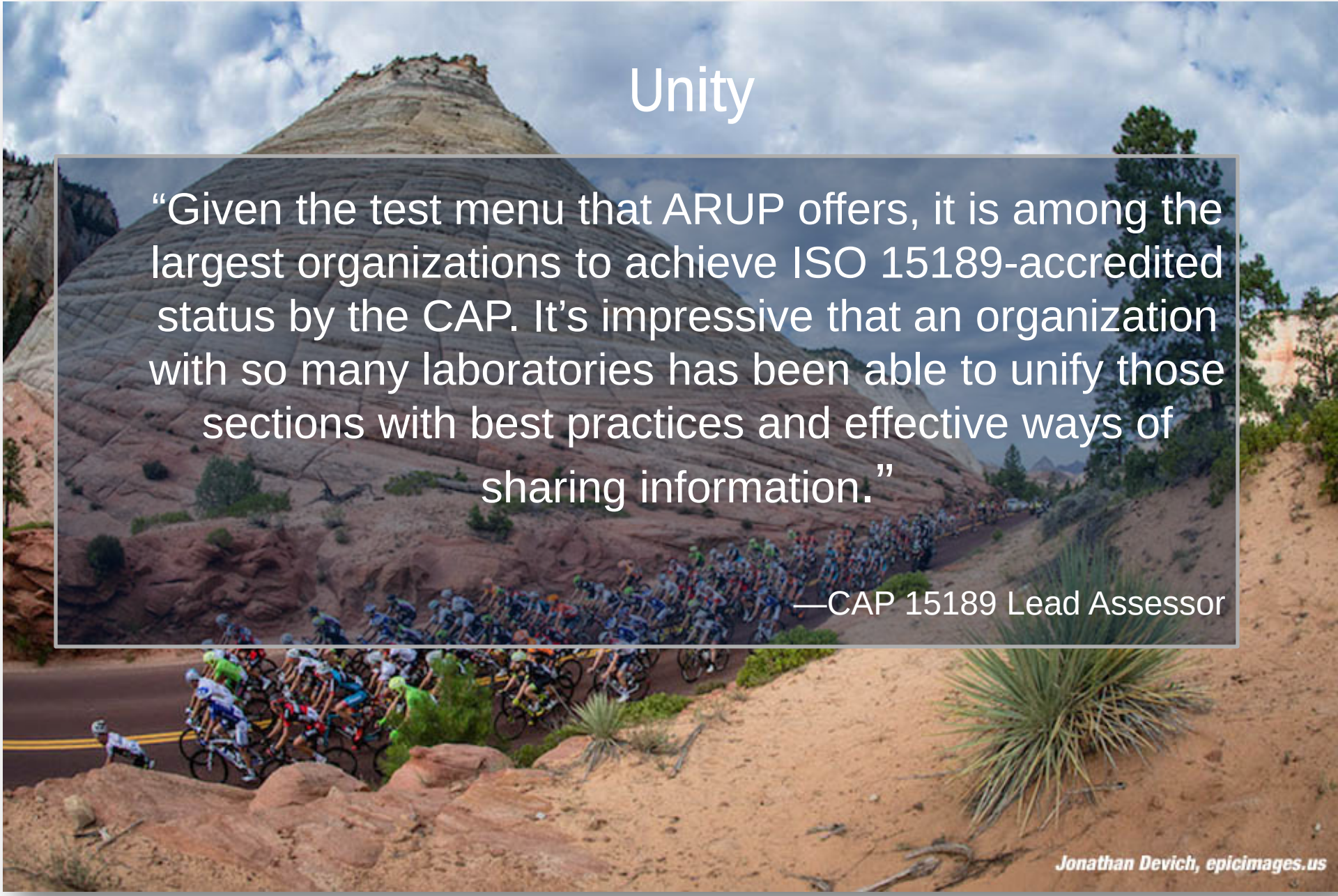
Culture, Culture, Culture

- ISO provides the scaffolding to build on
- “Best in Class”
  - Empowers staff to recommend and implement improvements
- Every employee has a role in quality
  - Standardization of processes
  - Quality metrics are communicated to all staff
  - Improved communication within department, between shifts, other departments, and corporate-wide
  - Culture shift from blame to empowerment
  - It’s the process not the person

Unity

"Given the test menu that ARUP offers, it is among the largest organizations to achieve ISO 15189-accredited status by the CAP. It's impressive that an organization with so many laboratories has been able to unify those sections with best practices and effective ways of sharing information."

—CAP 15189 Lead Assessor



Lessons Learned

What we did well…	What we could have done better…
Communicated “why” and “what” to the entire organization	Started sooner, and at the supervisor and bench level in small groups
Set a timeline and never gave up, although adjusted as needed	Thoroughly understood the time and resources required to make the necessary changes

Lessons Learned

What we did well…	What we could have done better…
Self-assessments and audits	Had a clearer understanding of how widespread the gaps might be
Celebrated the success	Continually communicated the small successes and progress during the process, in a way that showed the value to the individual employee

Was it worth it?


Questions?