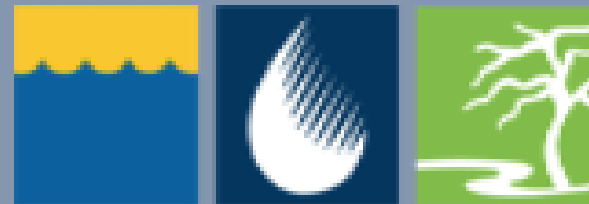


# Quality Assurance and Compliance

## Best Practices and Trends

Michael J. Perry, QA Officer  
Las Vegas Valley Water District  
August 2023 NEMC



Las Vegas Valley Water District  
Southern Nevada Water Authority  
Springs Preserve™

# AGENDA

- I. QUALITY**
- II. FOUNDATIONAL PILLARS**
  - I. GOOD DOCUMENTATION PRACTICES**
  - II. DISCREPANCY (CAPA) SYSTEM**
  - III. DATA INTEGRITY (ETHICS, MDLs, MANUAL INTEGRATION, ETC.)**
- III. STANDARD OPERATING PROCEDURES (SOPs)**
- IV. POLICIES**
- V. QUALITY DRIVEN BEST PRACTICES**
- VI. TRENDS IN THE LABORATORY INDUSTRY**
- VII. CHANGE**
- VIII. SUMMARY**



quality  
regulations

control

program

goals  
training  
admincode  
logbooks  
capa  
ethics  
competencies  
budget  
cfr  
proficiency  
documentation  
standards  
values  
leadership  
sops  
lims  
instrumentation  
vision  
traceability  
audits  
mission  
processes  
data  
accreditation  
safety  
instrumentation

# QUALITY PROGRAM AREAS

**Training**

**Ethics**

**LIMS**

**Quality Control**

**Peer Review**

**Data**

**Competencies**

**Accreditation**

**Logbook Program**

**Safety**

**Compliance**

**Discrepancy (CAPA)**

**Budget**

**Reference Manuals**

**CFR**

**Administrative Code**

**Instrumentation**

**Audit Program**

**SOPs**

**Document Control**

**Traceability**

**Proficiency**

**Strategic Plan**

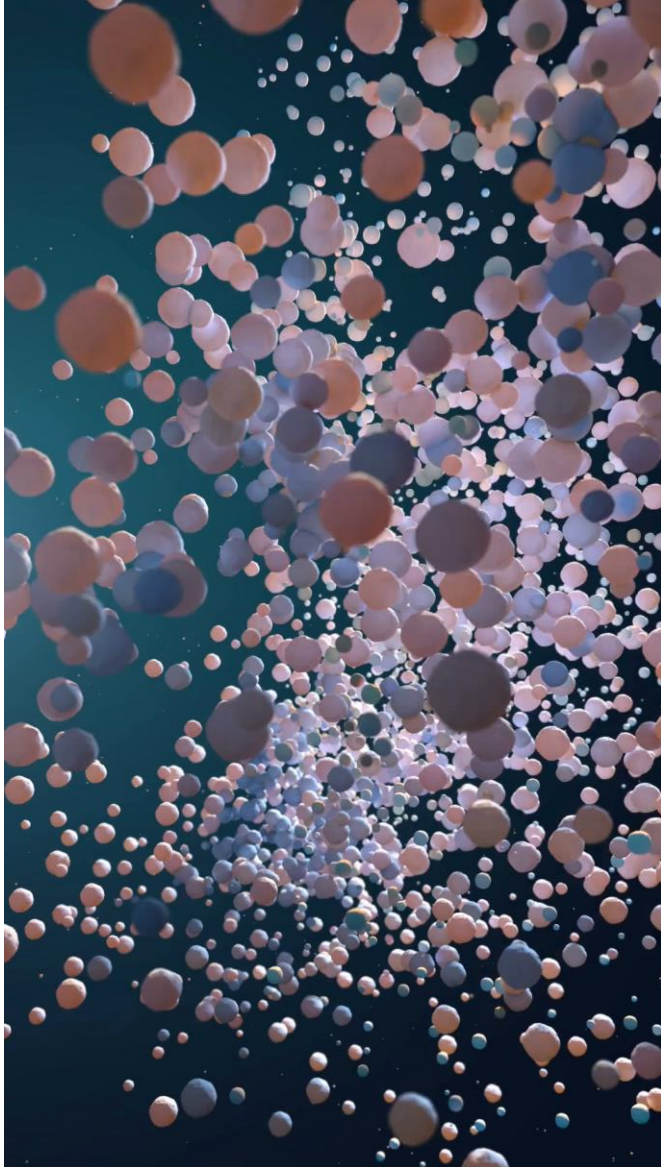
**Leadership**

**Regulations**

**Standards**

**Processes**





# FOUNDATIONAL PILLARS

## ➤ DATA INTEGRITY

- Ethics
- Method Detection Limits & Reporting Limits
- Proper Practices (Accountability)

## ➤ GOOD DOCUMENTATION PRACTICES

- DOCUMENT, DOCUMENT, DOCUMENT!!!
- It never happened if it is not documented.

## ➤ DISCREPANCY (CAPA) SYSTEM

- Root Cause
- Corrective Actions



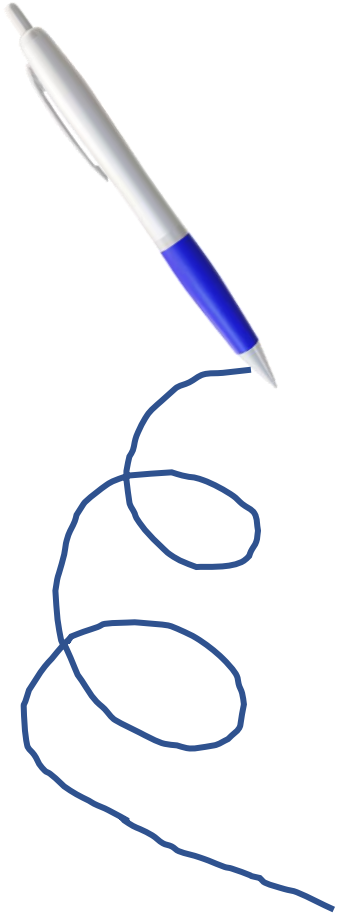
# DATA INTEGRITY

- **DATA OF KNOWN AND DOCUMENTED QUALITY FOR ITS INTENDED PURPOSE**
  - **Ethics: Right vs. Wrong, Professional Decisions**
  - **Quality Control: Traceability to Certified Reference Material**
  - **Instrumentation: Proper maintenance, calibration, and appropriate operating parameters**
  - **Training: Reading and Understanding proper work practices**
  - **Peer Review: Method Acceptance Criteria**



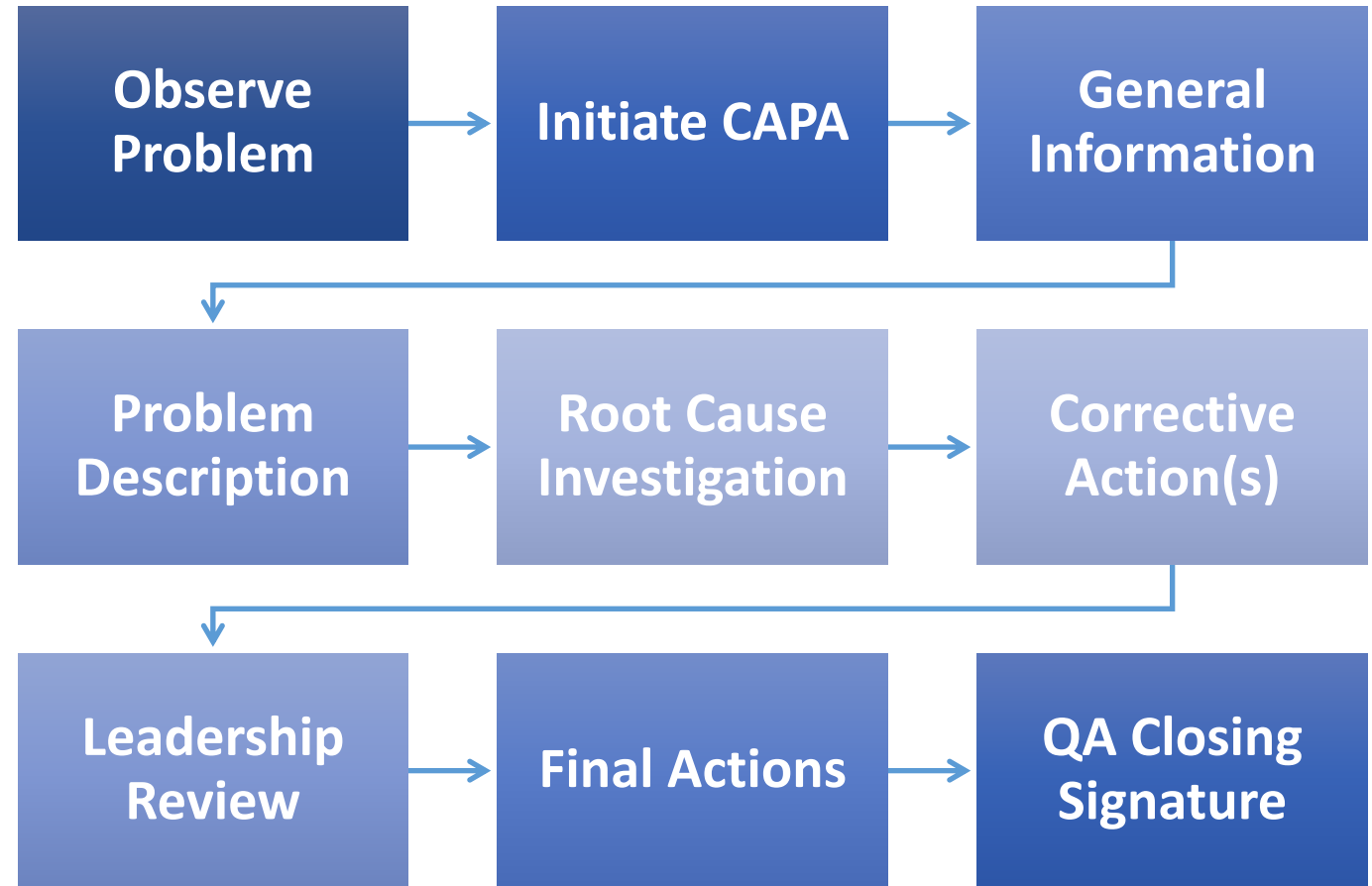
# **GOOD DOCUMENTATION PRACTICES**

- **If its not written down, it never happened!!!**
  - **SOPs & Manuals: Black and White documented procedures and policies**
  - **Logbooks: Document observations as they happen**
  - **Pens: Proper documentation writing tools**
  - **Traceability: Descriptive information that tells a story**
  - **Discrepancy: Transparency that paints a picture**

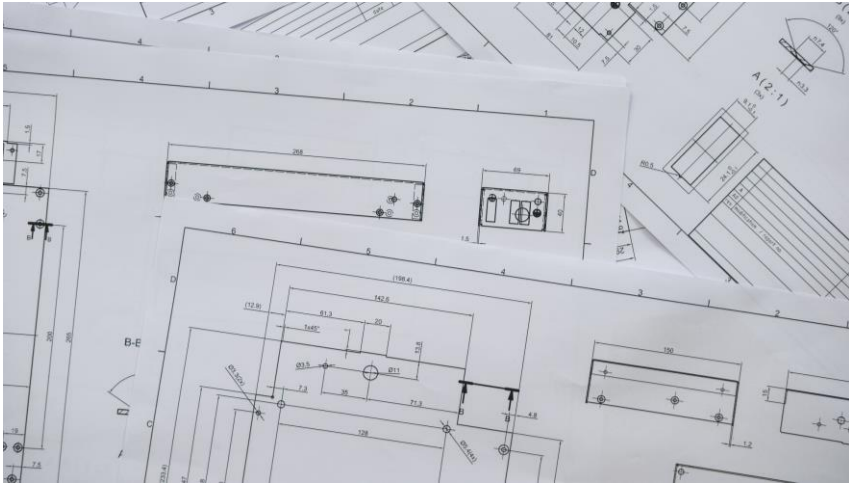




# DISCREPANCY (CAPA) SYSTEM







# STANDARD OPERATING PROCEDURES (SOPs)

- **Black and White instructions (a recipe) for performing processes**
- **Provides acceptance criteria for data of known and documented quality**
- **Document all steps within a series of processes that will provide information needed to validate the data**
- **Conduct annual reviews of SOPs using document control procedures where updates are identified with new revision #'s**





# POLICIES

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- **Quality Assurance Manual: Specific policies that provide decision making guidance**
- **Chemical Hygiene Plan: Occupational Health and Safety Policies**
- **Organizational Policies: Conflict of Interest, Dress Codes,**
- **Human Resources Trainings: Bullying/Violence, Flexible & Remote Working, Performance Management**
- **Federal Employment Laws: Occupational Safety & Health Act, Title VII Discrimination, Americans with Disabilities Act**



# **QUALITY DRIVEN BEST PRACTICES**

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**Clearly defined policy statement**

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**Continuous quality improvement throughout the lifecycle**

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**Quality measures and metrics**

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**Proactive instead of reactive: checks and balances**

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**Periodic review of quality standards and metrics**

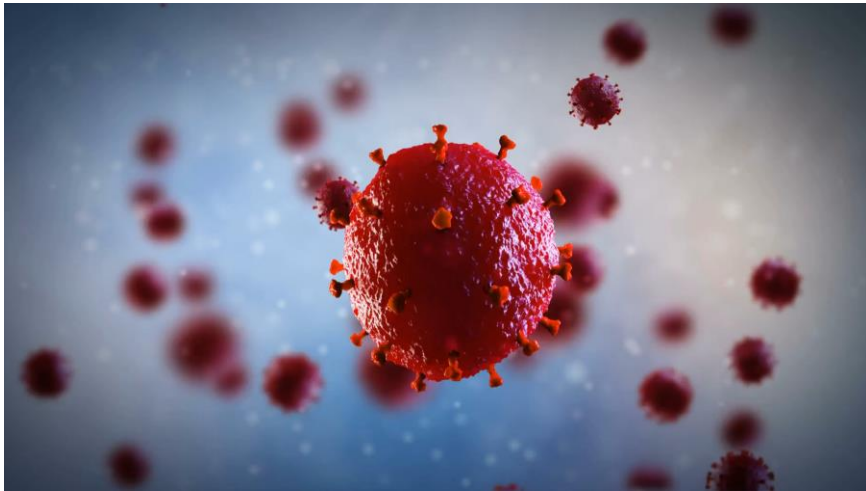
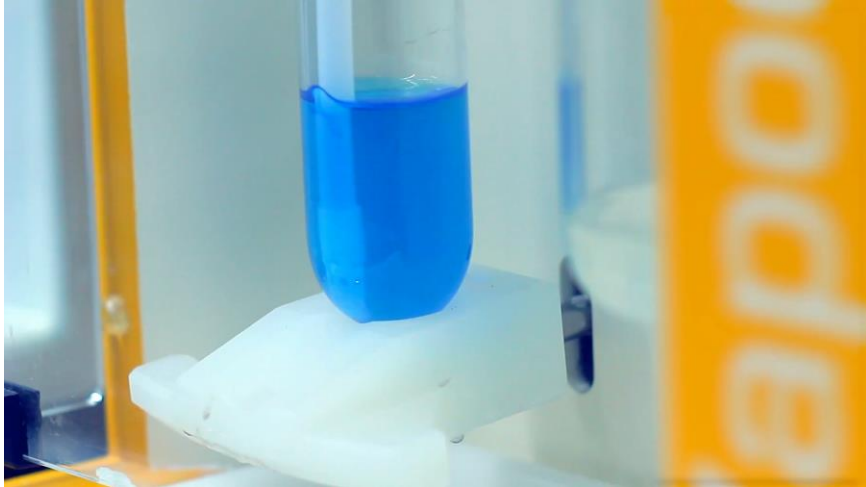
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**Adoption of industry related best practices**

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**Establish limits requiring corrective action**





# CHEMISTRY VS MICROBIOLOGY

- **Holding Times:** Chemistry samples have variable hold times whereas microbiology samples are used up within a short hold time
- **Quality Control:** Differences in terminology that are similar in nature
- **Reagent Prep:** Accuracy is required, sterility is also required for all microbiological analyses
- **Standards (Qualitative vs Quantitative):** Many chemistry parameters are measured quantitatively where microbiology parameters are qualitative and quantitative
- **Instrumentation:** Automated sample analysis available for chemistry analyses
- **Manual processes:** Most microbiology methods are processed manually





# LABORATORY INDUSTRY TRENDS



**Office of Inspector  
General Oversight**



**Constantly evolving  
regulatory guidelines**



**All industries moving  
towards an ISO focused  
quality system**



**Generational adaptation  
required to attract new  
talent**



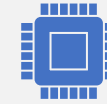
**Lean practices being  
adopted to drive  
efficiency and  
profitability**



# LABORATORY INDUSTRY TRENDS (CONT)



**Digital (paperless) documentation requirements: Adopting technology required for paperless operations**



**Data processing capabilities: Implementation and use of properly sized systems to support business operations**



**Data storage: Investing in technology to support transition to digital environment**



**Record retention policies: Unequivocal traceability for all operations and activities within an organization**



**Technological improvements: Adjusting to technological changes that drive continuous quality improvement.**





# CHANGE

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- **Acquisitions: Small companies purchases and mergers**
- **Restructuring: Operational or economical adjustments**
- **Physical location moves: Adjusting to new (smaller or larger) spaces**
- **Growth versus downsizing: Managing growth and downsizing decisions**
- **Ability to adapt within any given industry: Organizational flexibility to transition processes needed to meet current industry practices**





# Wrap-up

- Quality, The Big Picture
- Foundational Pillars
  - Data Integrity
  - Documentation
  - CAPA
- SOPs & Policies
- Quality Best Practices:  
Chemistry vs Microbiology
- Laboratory Industry Trends
- Change



# QUESTIONS

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