

Foundations of a Sustainable, High-Performing QA Program

Christy Abbas, PhD
Sr Product Marketing Manager

Why QA programs need to be sustainable

Reliable data depends on more than one good analytical run.

- QA helps laboratories produce reliable data and identify issues early
- Sustainability comes from routine monitoring, not one-time setup
- CRMs provide independent evidence for method, analyst, instrument, and corrective action decisions

Waters™ | ERA



A strong QA program turns quality checks into an early-warning system.

Today's roadmap

Four connected functions, one quality system.

PLAN

01

Method development

Define performance expectations and prove the method can meet them.

DO

02

Staff training

Build analyst capability and document consistent execution.

CHECK

03

Ongoing performance

Monitor drift across analysts, instruments, and environment.

ACT

04

Corrective action

Find root cause, fix it, and prove the fix worked.

First, align on the reference material language

CRMs give QA decisions a known, independently supported value.



RM Reference material

Homogeneous and stable for specified properties and fit for its intended use in a measurement process.

CRM Certified reference material

Characterized by a metrologically valid procedure and accompanied by a certificate with value, uncertainty, and traceability.

In plain language: a CRM is a standard with known value, known uncertainty, demonstrated homogeneity, traceability, and a certificate of analysis.

The QA system: four functions that reinforce each other Waters™ | ERA

Each function creates evidence the next function can use.



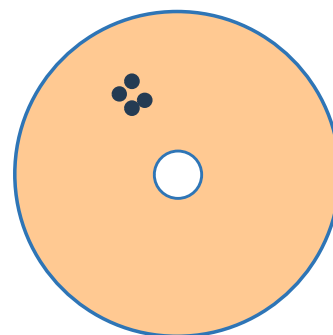
A sustainable program is designed to evolve as methods, analysts, instruments, and requirements change.

PLAN

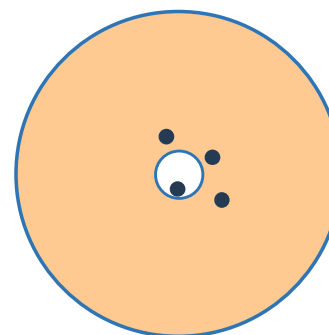
1. Method development: define what “good” means Waters™ | ERA

Start with sample needs, then prove the method meets criteria.

- Expected sample types and concentrations
- Precision: repeatability and reproducibility
- Accuracy: closeness to the true or expected value
- Analytical range and ruggedness



Precise, not accurate

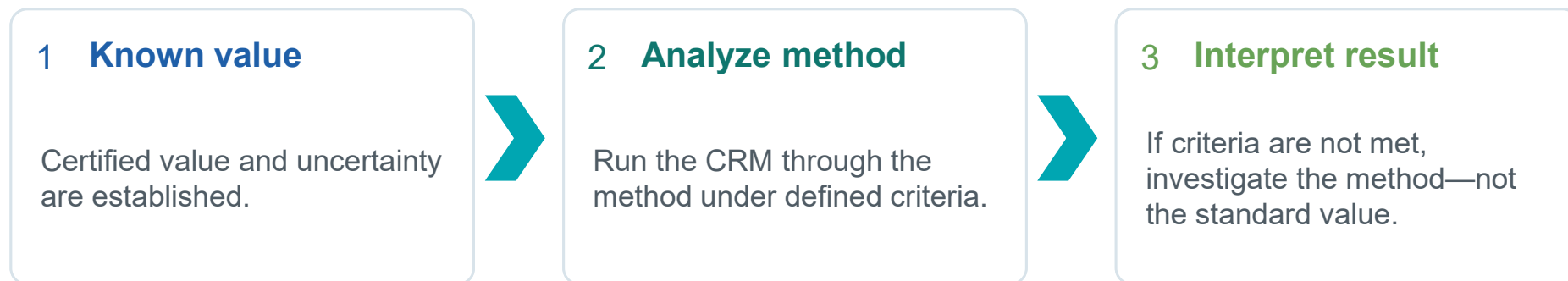


Accurate, not precise

Both matter. A method needs repeatable results and results close to the expected value.

Where CRMs strengthen method development

They help separate method issues from standard-preparation issues.



Practical benefit: fewer variables during development, clearer evidence when criteria are missed.

DO

2. Staff training: capability has to be demonstrated Waters™ | ERA

Training is effective when analysts can execute the method consistently.

1 Train

Hands-on instruction by experienced personnel; clear procedures, safety, and ethics.

2 Observe

Confirm analysts understand and follow the procedure in practice.

3 Document

Use CRM results to document competency.

A CRM turns training from “they were shown the method” into evidence that the analyst can produce acceptable results.

CHECK

3. Ongoing performance: monitor what changes over time

Even established methods can drift as conditions change.

Waters™ | ERA



Analysts

Technique can vary across people.

Instruments

Performance can change over time.

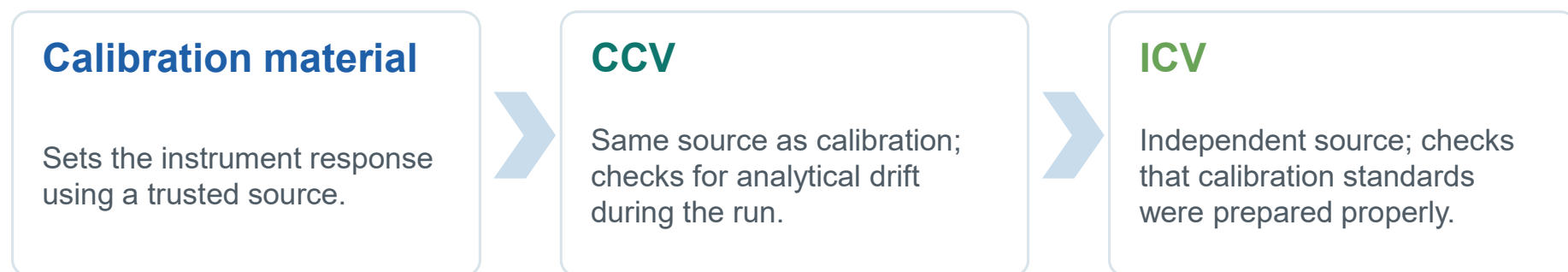
Environment

Temperature and humidity can affect equipment, reagent stability, sample integrity.

Routine CRM analysis gives the program a consistent check on the entire measurement process.

Calibration checks: know what each check is telling you Waters™ | ERA

Calibration, CCV, and ICV answer different questions.



The right check helps you avoid guessing whether the issue is drift, preparation, or the method itself.

Control charting: build an early-warning system

Percent recovery over time helps spot trends before failure.



- Plot CRM recovery routinely
- Warning limits suggest preventative action
- Outside control limits means stop and correct

What to do when the chart starts talking

Use the data to decide whether to prevent, correct, or document.

Within warning limits

Continue routine monitoring

Between warning and control limits

Apply preventative action while analysis continues

Outside control limits

Stop analysis, perform corrective action, document success

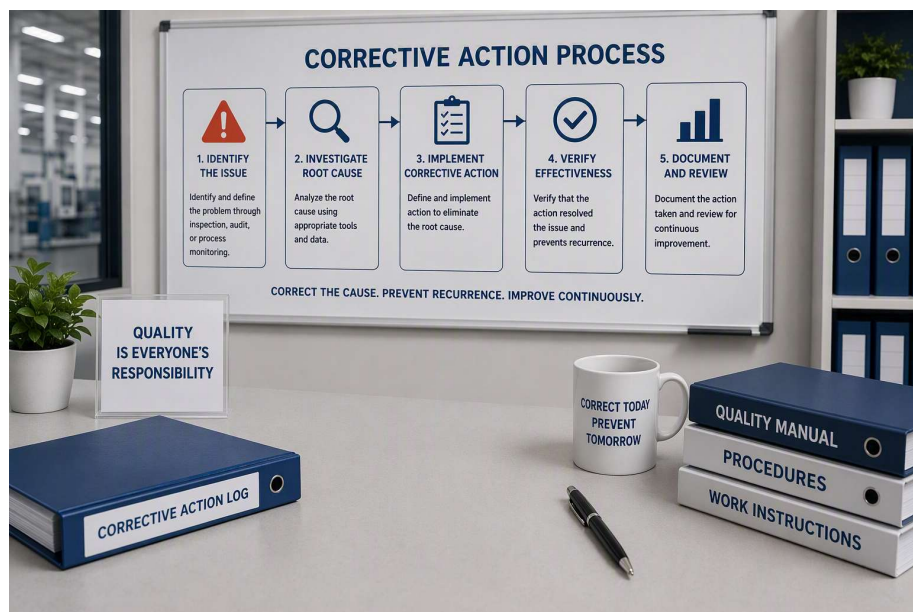
Preventative action is the value of trend awareness. Corrective action is the value of discipline.

ACT

4. Corrective action: find the real cause

A disciplined root cause analysis keeps the fix from becoming guesswork.

Waters™ | ERA



Analyst

Changes in analyst
or need for retraining

Machine

Instrument condition
or drift

Material

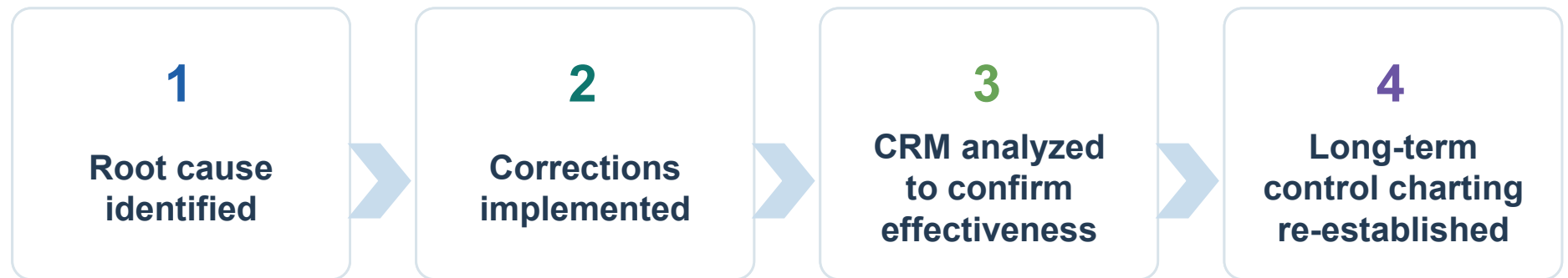
Standards, stock
solutions, dilutions

Method

Criteria or method
changes

Prove the fix worked—and sustain control

Corrective action is complete only after effectiveness is confirmed.



The goal is not just to recover from a failure – it is to make the program stronger after the failure.

Where CRMs add value across the full QA program

One tool, multiple evidence points.



Method development

Verify accuracy and reduce standard-preparation variability.

Analyst capability

Document initial and ongoing progress.

Control charting

Trend recoveries to catch drift early.

Corrective action

Confirm the fix is appropriate and effective.

Routine QC

Monitor the entire process with each batch or day of use.

Calibration support

Support calibration, CCV, and independent verification.



Three takeaways for a high-performing QA program

A strong QA program is designed, practiced, monitored, and improved.

Waters™ | 

1. Design for evidence

Define performance expectations and use independent materials to verify the method.

2. Monitor for movement

Use routine CRM analysis and control charting to spot drift before it creates bigger problems.

3. Close the loop

When something goes wrong, identify root cause, implement the fix, and prove it worked.

Practical strategies for building, strengthening, and sustaining reliable laboratory data.