Oops! What Now?

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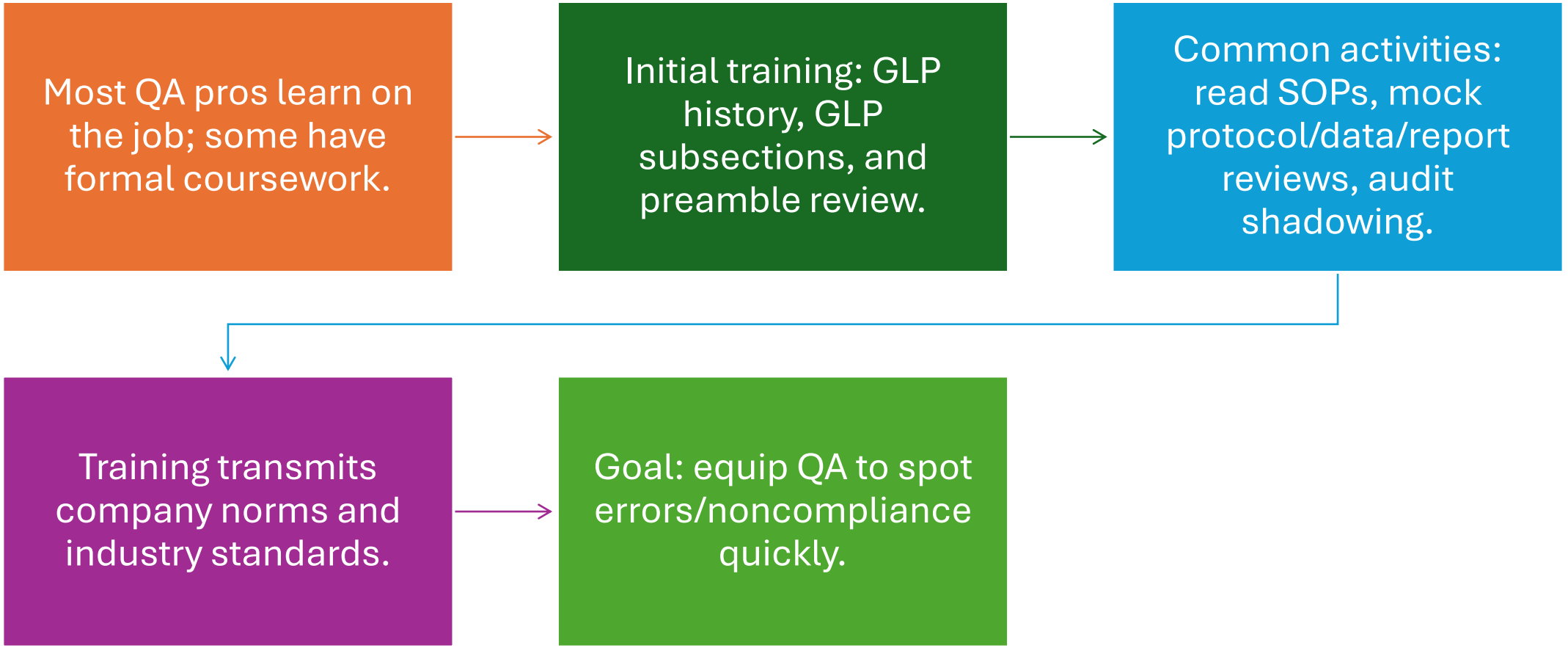
Intro

As QA, we analyze data and documents against protocols, GLPs, and SOPs to identify errors and provide recommendations. Despite our efforts to help prevent “Oops” moments, they inevitably occur, requiring thorough investigation and resolution based on varying approaches influenced by training, available resources, and personal skills.

Training


Most QA pros learn on the job; some have formal coursework.
Initial training: GLP history, GLP subsections, and preamble review.
Common activities: read SOPs, mock protocol/data/report reviews, audit shadowing.
Training transmits company norms and industry standards.
Goal: equip QA to spot errors/noncompliance quickly.

Resources

Primary regulatory sources: EPA GLPs and OECD GLP (plus member-country regulations).

Internal documents: SOPs, protocols, study records.

Advisory/guidance documents: EPA advisories, OECD consensus documents and guidelines (e.g., 860.1500 on crop field trials).

Professional learning: conferences and webinars (NAICC, SQA, etc.).

Peer consultation: QA from CROs, consultants, sponsor QA, and EPA compliance officers — valuable for troubleshooting.

Practical tools: phase-specific checklists to guide investigations.

Security note: never share sensitive or proprietary information when consulting outside your organization.

Personal Skills

QA needs natural skills in addition to formal training and checklists.

Training & resources are helpful, but innate judgment and observation are foundational.

QA is detective work: pattern recognition, uncovering hidden issues, and asking the right questions.

Core personal skills: attention to detail, clear communication, impartiality, patience, technical knowledge, critical/analytical thinking, and a strong desire for quality.

These skills enable effective detection of errors and practical resolution.

Examples

SOP, Protocol, and GLP “Oops!” examples from across the industry and the “What Now?” resolution.

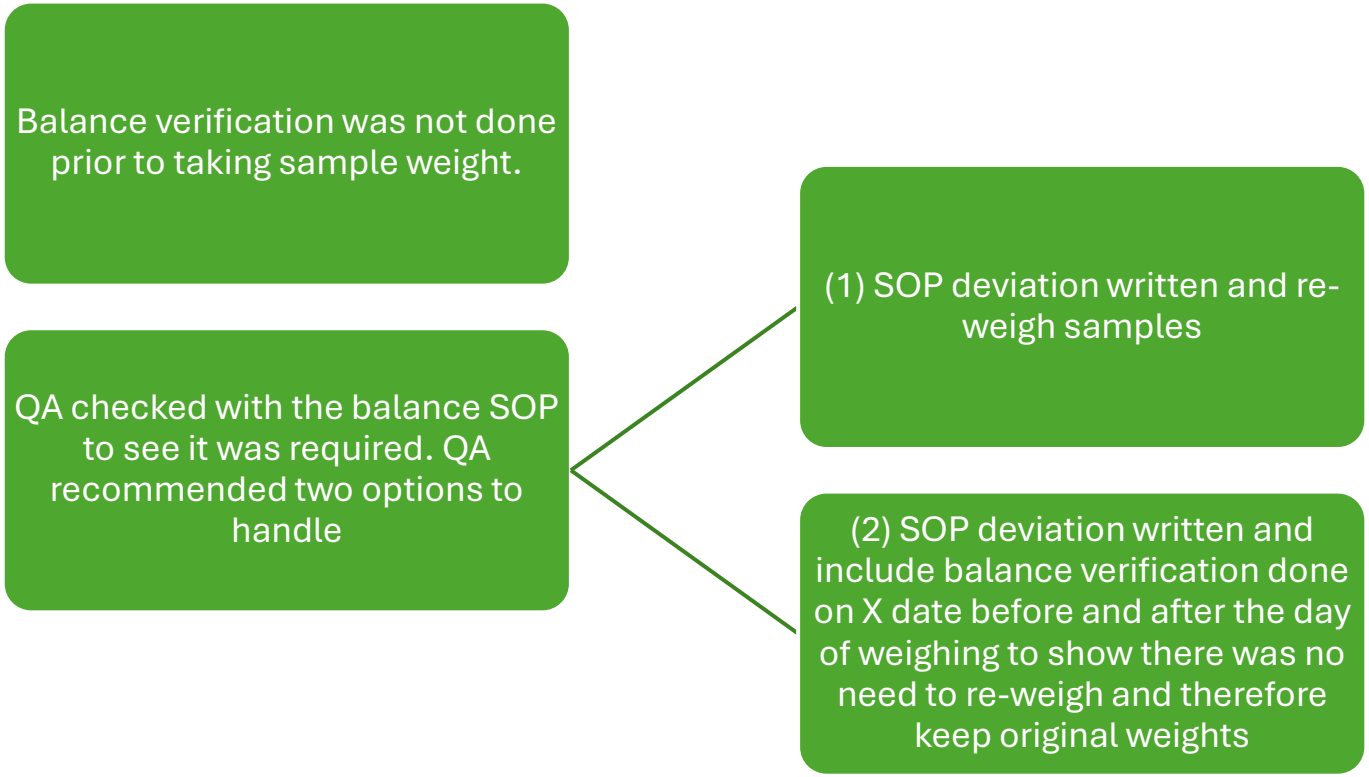
In some cases, mistakes may have various resolutions.

Example 1

A weight used to verify a scale was outside of tolerance according to SOP. The SOP allowed a 1% variance from the calibration weight when verifying a balance. The weight was verified at a 15% variance.

QA noted this after the fact during the data audit and recommended a SOP deviation.

Example 2


Balance verification was not done prior to taking sample weight.
QA checked with the balance SOP to see it was required. QA recommended two options to handle
(1) SOP deviation written and re-weigh samples
(2) SOP deviation written and include balance verification done on X date before and after the day of weighing to show there was no need to re-weigh and therefore keep original weights

Example 3

The SOP states, for GLP studies that records must be archived prior to or on the date of final report signature. The signed analytical sub-report was not archived within the required timeframe because the API overlooked the required archival timing requirement for the study records.

Although the signed analytical sub-report was not archived in a timely manner, it was in the care of the API. In addition, the sub-report was electronically signed so the Study Director received a copy of the electronically signed sub-report.

The API documented a SOP deviation. QA also recommended that the API re-complete SOP training (read and document reading) to understand the required archival timeframe for GLP study records.

Example 4

When the study began at CRO, a person who was serving as TFM assigned a PAI, was signing QA audits as TFM and doing other roles and responsibilities as TFM. About half-way through the study, the TFM transitioned into a QA role and their name appeared on QA audits as the auditor. They did not feel this was a compliance issue and argued that during their role as TFM they did only TFM things and as QA they did only QA things and did not cross responsibilities.

Their QA, new TFM, and a person with 30 years experience in GLP all agreed with this stance. The external Study Director and Study Director QA did not agree.

After working with Sponsor QA, Study Director and Study Director QA, wording was produced in a GLP exception that went on compliance pages for Sponsor, Study Director and CRO. It was written on the page what occurred and that while serving in both roles the person did not cross functions, and acknowledged that it was not compliant.

In the overall final report, the exception was noted the same but added that the Study Director could not assure that it did not impact the study since they could not positively verify that the person did not cross roles during the conduct of the study.

Example 5

Study Director reached out to QA about doing a termination amendment for a study. No actual work was done and turned out the study was never officially started because the protocol was never signed.

QA recommended to document a note to file explaining the situation to include with any facility documentation and have archive cancel the study number.

Example 6

Backpack sprayer tank blew dry mid-application. Prior to incident, the calibration, application calculations, and timed trial were good, however, it was mentioned that the overage was not likely to be enough at 5% and ran the risk of blowing dry. PI decided to proceed with application as is. When tank blew dry, QA advised to mark spot with flags and contact SD immediately.

It was decided to make more application based on new measurements and restart from the flagged spot. A protocol deviation was also documented. Afterward, it was decided to use 10% as the minimum overage. In later review of the incident, it was determined that several things compounded together caused the incident. There was not enough overage calculated into the application initially, boom charge was too long, and actual walking speed in progress was too slow.

At the time of sampling, the Study Director had that section of plot excluded since it couldn't be completely assured that the stop & restart points weren't over sprayed.

Example 7

QA noted there were some clear write-overs and illegibility in the raw data.

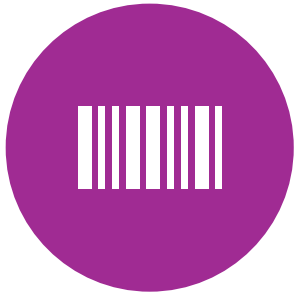
The resolution was to make correction with error code and clarification along with documenting an exception to GLP 160.130 (e) on the compliance statement.

Example 8

Original signature pages lost in transit; copies were available.

Note To File written to indicate original signature pages lost by shipping company and noting exact copies were available.

Exception added to compliance statement about missing original signature pages.



Important to ensure there is a policy in place requiring verified scan/copy of original documents when being shipped.

Example 9

- An Air blast application within a designated orchard plot was about to occur. The test substance was mixed and ready for first application when it was learned the orchard owner conducted an air blast maintenance spray all over the orchard the day prior, but didn't directly spray the test plots.
- QA discovered the maintenance substance included use of the same chemistry as the study. The protocol had same chemistry restrictions along with time and distance restrictions.
- QA advised application to be paused and contact the SD to determine next steps. While waiting for the SD, QA suggested to look up and document the wind conditions for the SD from the previous day, which turned out to be windy. There was discussion of taking pre-application samples from control and treated plots to use for checking contamination and documenting necessary protocol deviations.
- The sponsor and Study Director determined with the windy conditions, the risk for contamination to control and over exposure to treated plots was too great so the study was cancelled for restart the following year.

Example 10

Technicians used personal smartphones and an unauthorized app to capture study images; images lacked reliable metadata, audit trail, and secure transfer.

During a routine in-phase inspection of a study, QA noted that images filed in the study notebook:

- were inconsistent in file format and naming,
- had missing or altered metadata (no ID or timestamp),
- did not match the log timestamps and sample IDs,
- and some images were edited (brightness/crop) without documentation.

QA interviews with technicians revealed use of personal phones and a third-party image app that automatically compressed/stripped metadata and uploaded to a cloud album for convenience.

Example 10 Continued

Resolution:

- Stop-use order for personal devices in areas where study data are generated, post signage.
- Secure preservation of all images associated with the study
- Issued a GLP exception on the compliance statement and opened CAPA record.

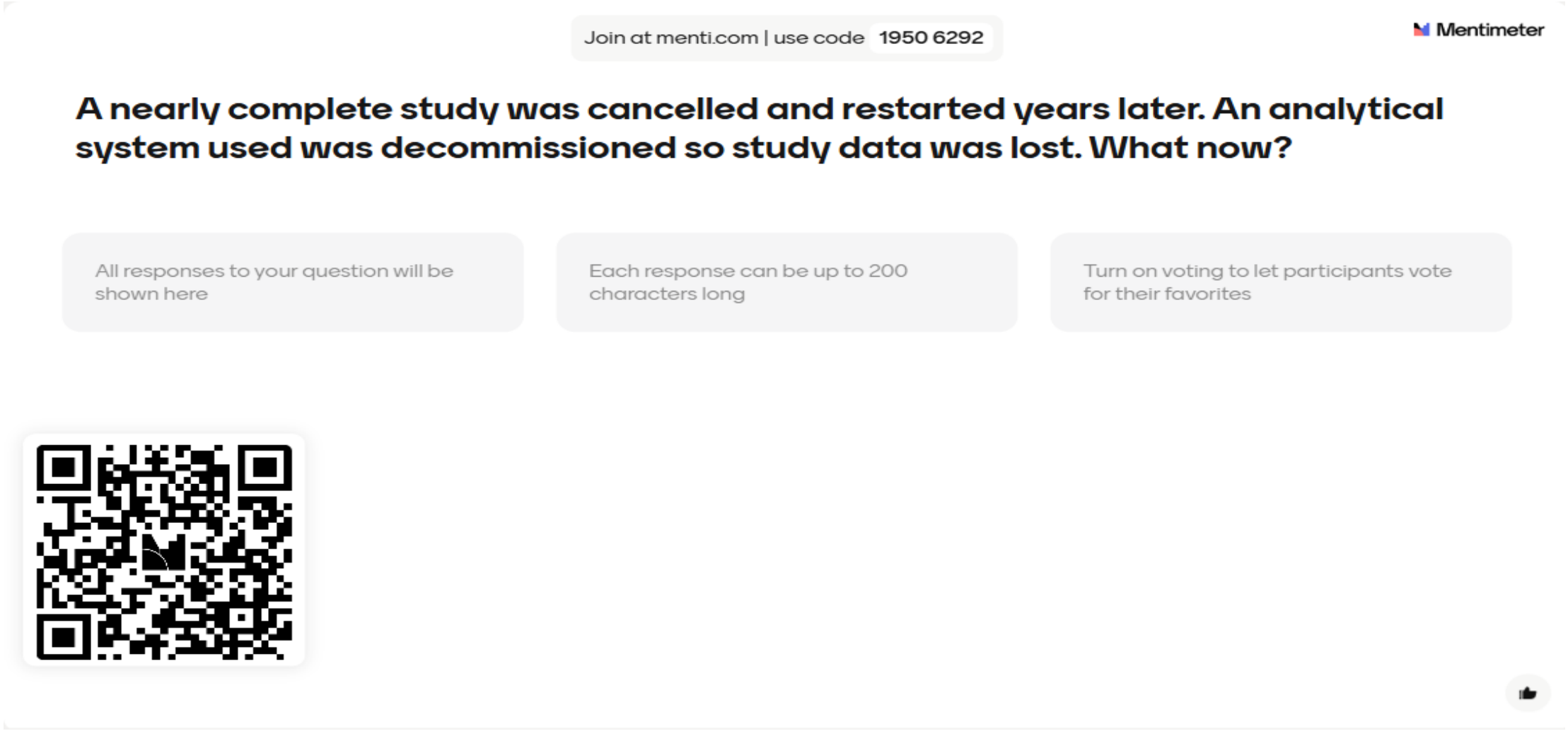
Root Cause Analysis:

- Convenience and speed drove staff to use personal smartphones and a consumer cloud app.
- No SOP or protocol template language existed for digital image capture management.
- Training gap: staff unaware that image metadata are GLP data.
- No validated mechanism to input images into the study record (LIMS/ELN) showing if they have been modified

A “What Now?” Moment for You

A study with multiple trials was field complete. The protocol required 1 UTC and duplicate TRT 1 & 2 samples collected from 2 different matrices. Sample analysis was started, however, a business decision was made to cancel the study. Ten years later, it was decided to finish the study and submit to EPA. One system that stored data had been used during analytical phase was decommissioned unannounced during those 10 years. After reopening the study, it was found that analytical data from UTC and TRT 1 & 2 samples for 1 of the matrices was missing in one trial due to the decommission. An analytical summary report was checked for the missing information, but it hadn’t been reported yet as the samples for the missing trial were received 4 months after the initial summary report was printed. This particular trial was added (by amendment) later than the other trials. It was determined an updated summary report was not printed after the samples were received and processed. There were also no retain samples available.

What Would You Recommend?



Closure

QA professionals play a critical role in identifying, investigating, and resolving the inevitable “oops” that occur

QA is equipped to systematically evaluate errors and guide effective resolution.

QA can turn mistakes into learning opportunities that strengthen compliance, improve processes, and ultimately support the integrity and quality of the work performed.