TECHNICAL Q&A

Watson™ LIMS Decommissioning

Direct answers to the questions QA Directors and Bioanalytical Lab Directors raise before committing to a decommissioning project.

Introduction

The StudyPlus Archive module exports completed Watson™ studies to a vendor-independent, cryptographically integrity-checked archive of PDF/A documents, CSV, and XML data. Once archiving is complete, Watson™, its Oracle Enterprise Edition™ database, and its Windows server tier can be decommissioned. The archive satisfies regulatory retention requirements without keeping any part of the Watson™ stack alive.

This document addresses the questions that QA Directors and Bioanalytical Lab Directors typically raise before committing to a decommissioning project. The answers are direct: where the module covers something fully, that is stated; where it does not, that is stated equally clearly.

Regulatory Compliance and Data Integrity

For QA Directors and Compliance leaders.

Q Does the archive satisfy 21 CFR Part 11 §§11.10(b) and (e), and EU GMP Annex 11 §7?

§§11.10(b) requires accurate and complete copies of records in both human-readable and electronic form. The archive exports each study as PDF/A documents (human-readable; ISO 19005 long-term preservation standard) and as CSV and XML (machine-readable structured data). The audit trail is exported as HTML/XML. Per-file cryptographic hashes, combined with a manifest and a hash-of-hashes, allow integrity to be demonstrated at any point after archiving. No Watson™ installation, database, or operating system is required to read or verify the archive.

§§11.10(e) requires that audit trails be computer-generated and include the date and time of operator entries and actions that create, modify, or delete electronic records. The Watson™ audit trail — study-level and system-level — is exported in full, preserving user identity, timestamp, and action for every event Watson™ recorded against the study.

EU GMP Annex 11 §7 requires that data remain accessible, readable, and accurate throughout the retention period. The archive is readable on any computer that can open a PDF, a spreadsheet, or an XML file. The hash manifest allows verification of accuracy and completeness at any time.

Q Is the Watson™ audit trail fully captured — including system-level audit events?

Yes. Both the study-level audit trail and the system audit trail are exported. Watson™ records every user action against a study — result acceptance and rejection, run approval, study reopen events, approval withdrawals — together with user identity and timestamp. System audit events are captured alongside the study audit trail in the same export. The export preserves the complete chronological record as HTML/XML; no entry is summarized, aggregated, or filtered. What Watson™ holds at the time of the archive run is what the archive contains, including entries from reassays, reopens, and re-approvals.

Q If a regulatory authority raises a query against an archived study, what can we reconstruct?

The archive contains the complete study record as it stood at final Watson™ status: all analytical results, regression and calibration data, sample handling records, method parameters, QC data, and the full audit trail with user attribution and timestamps. The archive records provide a complete account of what data was available, how it was processed, and what decisions were made, by whom, and when.

> **Important:** The archive contains what Watson™ held as part of the study record. System-level data maintained outside the study — for example, lot qualification records for reference standards held at the Watson™ system level rather than within an individual study — is not in scope for the archive. If such data is relevant to a potential regulatory query, its separate retention must be addressed before decommissioning.

Q Are method parameters and analytical settings captured, or only the study results?

Everything documented in Watson™ at the study level is exported. This includes the regression method and weighting factor, calibration range, acceptance criteria, analytical parameters, and QC settings. These are part of the Watson™ study record and are present in the archive.

Q Watson™ holds many qualifications for reference standards and calibrators at the system level, beyond individual studies. Is that data in the archive?

No. The Archiving Module covers study records, sample handling, and audit trails. Data maintained at the Watson™ system level — including lot qualifications for reference standards held outside an individual study — is not in scope.

> **Action required:** If system-level data of this kind carries independent regulatory retention obligations for your organization, its long-term retention must be addressed separately, outside the Watson™ archiving process. Identifying this data is a standard item in the pre-decommissioning study inventory.

Q Watson™ does not link a bioanalytical study to its supporting method validation study. Does the archive change that?

No. Watson™ does not maintain cross-study references, and the archive faithfully represents that reality. Locating the method validation study that underpins a given bioanalytical run requires knowing the study identifier — the same situation as in Watson™ today. The archive does not reduce navigability relative to the current system; it replicates it.

Establishing and recording cross-study identifiers before decommissioning is the practical answer. This is a standard item in a decommissioning project plan and does not require any additional capability from the Archiving Module.

Q What is our internal validation obligation for the Archiving Module?

up to data is vendor-qualified under GAMP 5 and ISO 9001:2015 certified. The module has been tested and validated with Watson™ 7.3, 7.4, and 7.6. Under GAMP 5 vendor qualification, the customer's validation obligation reduces to a business-cycle test: confirming that a representative set of known studies can be located in the archive and that their contents are complete, readable, and hash-verified. This is substantially less than a full IQ/OQ/PQ cycle.

Q A static archive is not a running system. Does it require periodic revalidation?

No. A hash-verified static archive has no configuration, no update cycles, and no processes that could alter its content between reads. Unlike a validated running system, there is nothing to revalidate. The hash manifest verifies integrity at the point of creation; that verification can be re-run against the stored files at any time.

If the archive is migrated to a new storage infrastructure, the hash manifest should be re-verified against the original to confirm bit-for-bit integrity. That is a single verification operation, not a revalidation cycle.

Q What does a GxP-compliant Watson™ decommissioning documentation package look like?

Decommissioning a validated GxP system requires a Decommissioning Specification that defines the scope and acceptance criteria, Execution Records that document that the process was followed and that data integrity was maintained throughout, and a Decommissioning Report. The Archiving Module generates a processing protocol in StudyReporter for each archive run; this forms part of the execution record. up to data can provide a documentation template structured to meet these requirements as part of the engagement.

> **Reference:** Boehringer Ingelheim has completed a Watson™ decommissioning using the Archiving Module and is an active reference. Peer conversations can be arranged as part of the up to data reference program.

Laboratory Operations and Data Completeness

For Bioanalytical Lab Directors and Study Directors.

Q What exactly does the archive contain for each study?

For each study, the archive contains: PDF/A documents structured by run and by study, presenting all study data in human-readable form; CSV and XML exports of every analytical result, regression, calibration curve, QC dataset, and sample result table; sample handling records; and the study-level and system audit trail as HTML/XML. A per-file SHA hash and a manifest with a hash-of-hashes protect and document integrity. No Watson™ installation, iStudyReporter license, or proprietary viewer is required to read any part of the archive.

Q Are failed runs, rejected samples, reassays, and deactivation comments included?

Yes. The archive exports the study as Watson™ holds it at final status. Runs that were rejected, samples excluded from regression, reassay events, and deactivation comments are all part of the Watson™ study record and are included. Nothing is filtered or cleaned. The archive reflects the complete history of the study, including the audit trail entries associated with those events.

Q Does the archive include raw chromatography data from Empower, MassHunter, or Analyst?

No — and this distinction matters operationally. Watson™ stores integrated results from instrument data acquisition systems, including peak areas, retention times, and calculated concentrations. The underlying raw chromatography files reside in those systems, not in Watson™. The Archiving Module covers the Watson™ data layer.

> **Separate retention question:** Raw instrument data files typically carry independent regulatory retention obligations under 21 CFR 58.195 and FDA data integrity guidance. Their long-term retention must be addressed independently of Watson™ archiving. A Watson™ decommissioning project is also a natural point to review the retention status of instrument data.

Q Does the study need to be in a particular Watson™ status before it can be archived?

Yes. The Archiving Module exports a study in its final Watson™ status, including all audit trail entries up to that point. A study that is still active, or that has been reopened for reassay and not yet returned to final status, cannot be archived until the reassay is complete and the study is re-approved.

> **Operational prerequisite:** Before beginning an archiving engagement, a study inventory should identify all studies not yet in final status, any studies with open sponsor queries, and any pending reassays. This determines the realistic archiving timeline and should be the first step in the project plan.

Q How is the archive structured for someone who has never worked in Watson™?

The archive is a directory tree of flat files — PDF/A, CSV, and XML — organized by study and by run. The output is designed to be navigable without Watson™, StudyReporter, or any proprietary viewer. Any computer that can open a PDF, a spreadsheet application, or an XML file can read the archive.

The PDF/A documents present study data in a review-oriented layout: organized the way a scientist or inspector reads a study, not the way a database stores it. This is a deliberate design

choice — the archive is intended to be usable by someone who was not involved in the original study and has no Watson™ background.

Q How does a sponsor receive legacy study data after Watson™ has been decommissioned?

Delivery is a file transfer operation. The relevant study directory is copied from the archive and transferred to the sponsor by whatever secure file transfer method the CRO and sponsor use for data exchange. The sponsor requires no Watson™ installation, no StudyReporter license, and no proprietary viewer. They receive PDF/A documents and structured CSV/XML data files readable in any standard application.

Q Can the CSV data be imported into another system for re-analysis?

The CSV files contain structured data — concentrations, regression parameters, peak areas, sample results — in a format that can be opened in any spreadsheet application or imported into a data system. Whether a specific target system can ingest the format directly or requires a transformation step depends on that system's import specification. up to data can provide the CSV column specification and data dictionary on request.

Q Which Watson™ versions does the Archiving Module support?

The Archiving Module has been tested and is validated with Watson™ 7.3, 7.4, and 7.6.

Next Step: Decommissioning Assessment

The standard entry point is a Decommissioning Assessment: a structured conversation covering study inventory, Watson™ environment scope, estimated archiving timeline, and a preliminary ROI calculation specific to your site configuration. The output is a fixed-price Pilot Statement of Work.

To request an assessment, contact us at **info@uptodata.com** or visit our website **uptodata.com**.

About up to data

up to data has been supporting pharmaceutical and life sciences companies with automated laboratory processes for regulatory study data management for over 20 years. Our solutions eliminate data silos, implement secure automated data transfer processes, and reduce manual activities while ensuring full regulatory compliance.