

Electronic Batch Records for Photopolymer Production: Data Capture, Recipe Enforcement, Exceptions and Auditability

Designing electronic production evidence that reconstructs what actually happened, not what should have happened

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Abstract

An electronic batch record should capture the executed material, equipment, recipe version, operator actions, timestamps and measured results. A system may record that an operator entered a value without preventing an invalid value. Skipped steps, manual overrides, equipment alarms, repeated measurements and rework should not disappear into free-text comments. For regulated electronic records, the ability to reconstruct who changed what and when is fundamental. Balances, spectrometers, printers and cure chambers may each generate primary data. Qualification therefore depends on preserving the measured state, configuration and exception history needed to distinguish these mechanisms in production rather than relying on nominal recipe identity alone.

Keywords: electronic batch record; photopolymer production; recipe enforcement; audit trail; exceptions; traceability; manufacturing data

1. Significance and scope

An electronic batch record should capture the executed material, equipment, recipe version, operator actions, timestamps and measured results. The engineering question is whether an electronic batch record can enforce approved recipes, capture the executed state, preserve exceptions and audit trails, and still support reliable reconstruction of each production event. The review focuses on evidence that supports repeatable manufacturing decisions and excludes proprietary recipes, supplier-specific settings and undocumented operator heuristics.

1.1 Corpus boundary

ER-349 owns electronic batch-record architecture for photopolymer production and post-processing. It does not own enterprise cybersecurity, general document management or product-specific regulatory submission content. ER-348 owns cleanliness zoning, material segregation and contamination-control evidence; ER-350 owns cybersecurity and ER-347 owns post-processing automation. ER-349 remains limited to execution records, recipe enforcement, exceptions and auditability.

2. The record must represent execution

An electronic batch record should capture the executed material, equipment, recipe version, operator actions, timestamps and measured results. Copying a master recipe into a PDF after production creates documentation but not an execution record. ISA-88 explicitly separates recipe models and batch production records, which is useful for photopolymer manufacturing [1,2].

3. Recipe enforcement and recording are different functions

A system may record that an operator entered a value without preventing an invalid value. Where the risk justifies it, ranges, sequence dependencies, equipment identity and material status should be enforced at execution time. The record should then preserve both the requested action and the system response [1-3].

4. Exceptions are first-class data

Skipped steps, manual overrides, equipment alarms, repeated measurements and rework should not disappear into free-text comments. Structured exception types improve trending and make it possible to distinguish normal manufacturing variability from recurring control weaknesses [1-3].

5. Audit trails protect chronology and attribution

For regulated electronic records, the ability to reconstruct who changed what and when is fundamental. Part 11 guidance is one regulatory reference point, but even outside that scope, secure audit trails are valuable because they prevent later edits from erasing the original manufacturing history [2,4].

6. Integration should preserve source authority

Balances, spectrometers, printers and cure chambers may each generate primary data. The batch record should link or ingest those data without destroying source context, units, calibration status or timestamps. Manual transcription should be treated as a controlled fallback, not the default integration method [3,5].

7. Qualification architecture

A qualified system defines user roles, recipe approval, data sources, time synchronisation, exception handling, audit-trail review, backup and record retention. Software upgrades should be regression tested against representative batch flows before production use [1-5].

8. Evidence hierarchy and transfer

A visually complete record is not necessarily trustworthy. Strong evidence shows that critical fields are system-generated or independently verified, audit trails are reviewable, exceptions cannot be silently overwritten and record retrieval reproduces the executed batch history [1-5].

Table 1. Qualification matrix for electronic batch records for photopolymer production.

Record element	Preferred source	Control
Material identity	Barcode/master data	Status and lot check
Equipment identity	Connected asset ID	Qualified equipment list
Recipe/version	Approved master recipe	Version lock
Process values	Instrument/system capture	Units and calibration context
Exception	Structured event	Disposition and audit trail

9. Interpretation matrix

For electronic batch records, an anomalous result may reflect an execution deviation, an obsolete recipe, a manual exception or a failure of identity, timestamp or audit-trail capture. The decisive test is whether the event can be reconstructed from immutable recipe, user, equipment and exception records.

Table 2. Diagnostic interpretation matrix for electronic batch records.

Failure mode	Evidence risk	Safeguard
Manual transcription	Typographical error	Interface or second check
Editable final PDF only	Loss of chronology	Immutable audit trail
Generic override	Untrendable exceptions	Reason-coded event
Unsynchronised clocks	Ambiguous sequence	Time-source control

10. Limitations and evidence gaps

Electronic batch-record requirements vary with the manufacturing context, regulatory framework and degree of equipment integration. Public standards define useful principles for records, audit trails and recipe execution but do not specify one data model for photopolymer production. The architecture must therefore be validated against the actual source systems, exception workflows and retention requirements of the intended use.

11. Conclusions

An electronic batch record should reconstruct what was actually executed, including recipe version, source data, operator actions and exceptions. Recording and enforcement are distinct functions, and both need auditable provenance. The system is effective when an independent reviewer can recover the manufacturing history without relying on undocumented operator knowledge.

References

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Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. No comparative product recommendation is made.

Data availability

No new experimental dataset was generated for this review.