

MULTI-VARIATE BATCH INTELLIGENCE — WHAT YOUR MES AND ERP
CANNOT TELL YOU

Save batches. Improve yield.

Every solid-dose and biosimilar manufacturer runs batches that drift days before their MES sees it, investigates the same root cause across campaigns and plants without connecting it, writes CAPAs for events that were preventable, and never quite reconciles the dollar impact of yield loss to a number a CFO can defend. **These look like four problems. They are four readings of one signal** — the trajectory of the batch itself, across every plant and every product.

01 Drift starts before your MES sees it

02 One root cause, hidden across plants and products

03 CAPAs written for what could have been prevented

04 Yield costs absorbed, uncounted

The data is already in your plants

You don't need new sensors, a new MES, or a re-platforming project. The signal that predicts each batch outcome exists days to weeks before the batch tells you — sitting in the systems you already run, across every plant.

SAP MES · EVERY CAMPAIGN

Genealogy captured

Materials, operators, equipment IDs, in-process results, deviation logs, exception handling — every batch's full genealogy already structured and permanent in SAP MES across your plant network.

INCOMING QC + INTERMEDIATE TESTING

API signatures logged

API CoAs, particle-size distributions, impurity profiles, moisture content, in-process assays. The upstream fingerprint of every campaign — logged before the batch even enters compression or fermentation.

LIMS · EVERY RELEASE

Outcomes measured

Dissolution profiles, assay results, content uniformity, stability data, biosimilar comparability panels. The dependent variable of every batch — waiting to be joined to what upstream drove it.

SENIOR OPERATORS · EVERY PLANT

Signal held in heads

Which API suppliers to distrust. Which compression tooling runs hot. Which humidity zones breed dissolution issues. The pattern lives in the memory of your most experienced operators — carried in conversation, not captured in any system, and lost every time one of them retires or transfers to another plant.

Read it against your own plants

If you run **SAP MES, incoming QC, and LIMS** — and you do — you already have three of the four inputs the platform reads. The fourth lives in the heads of your senior operators. What you don't have is a layer that reads them together, in real time, against the pattern of your own history, across your plant network. The signal is not missing. It is scattered — across three systems and the memory of the people who built your plants.

02 — THE COST IS REAL, AND MOSTLY INVISIBLE

One drift, four department problems

The loss is never labeled “loss.” It shows up as a routine investigation, a batch rework, a stability failure, a supplier drift discovered weeks after the CoA. Here is the same underlying batch drift, surfacing as four separate departments’ problems.

qc

The dissolution failure caught too late

A subtle API lot signature — particle-size shift, impurity variance, moisture drift — produces a dissolution failure at final assay. Batch investigated, reworked, or rejected. The signal that would have flagged it was in the incoming CoA weeks earlier.

Owned by: QC / QA

FORM.

The lot that fails uniformity

Compression parameters, granulation moisture, or blending time drift subtly across a campaign. Content uniformity fails at end-of-batch testing. Same investigation, same conclusion, same delayed action — repeated next campaign.

Owned by: formulation & process engineering

BIOSIM

The batch outside the envelope

A biosimilar batch drifts on potency, glycosylation profile, or aggregate content. Comparability panel flags it after release testing. Regulatory scrutiny follows. The upstream signals that would have kept it inside the envelope were readable in the bioreactor and downstream data.

Owned by: biosimilars manufacturing & regulatory

PROCURE

The supplier drift that reached your line

An API (or excipient, or coating) supplier's CoA passes incoming QC — technically within spec, but subtly drifting on particle-size distribution, impurity profile, or moisture content. The lot moves to production. Three campaigns and two plants later, the pattern connects — and by then, the batches are already committed. The signal was in the supplier's own release data and your incoming-QC history all along. Nobody read them together against your batch outcomes until the deviation surfaced.

Owned by: procurement & incoming QC

The batch is one process. You see many.

This is the core of it. A batch — whether a solid-dose commercial run or a biosimilar campaign — is a single, continuous multi-parameter process. Your organization is built to experience that process as a set of disconnected signals, each captured by a different system and routed to a different team.

HOW THE BATCH EXPERIENCES IT

One continuous multi-parameter trajectory.

Every parameter connected to every other. Every hour connected to the outcome three weeks later. To the batch it is one process, one story, drifting or holding across dozens of dimensions simultaneously — API lot, excipient variance, granulation, blending, compression, or (for biosimilars) cell-line, media lot, feed schedule, harvest, purification.

HOW YOUR SYSTEM EXPERIENCES IT

Four disconnected signals.

The same trajectory is split at the door and handed to teams who never compare notes:

SAP MES sees a batch record.

Historian sees a trend.

LIMS sees a QC result.

Manufacturing sciences sees a deviation.

Every batch has multiple stakeholders across many systems — and the industry has quietly accepted the yield drift that follows as the cost of doing business.

Large, sophisticated manufacturers paper over this with deep MES-Historian integration and senior data-science functions whose full-time job is to stitch the signals back together. That is a real solution. It is also one that depends on bench strength and multi-year investment most growth-stage manufacturers structurally do not have — which is precisely the divide the next section is about.

04 — THE FOUR SYMPTOMS

What the split costs you

Each disconnected signal becomes its own chronic symptom — and each maps to value that was recoverable, if anyone had read the trajectory in time.

01

Batches that fail at release

The batch drifted days before your MES flagged it — dissolution, assay, uniformity, comparability. The signal was in the trajectory. It was just unread until the release panel came back — and by then, the batch was already committed.

02

The same investigation, three campaigns in a row

The root cause is discovered at campaign one, forgotten by campaign two, rediscovered at campaign three. Each investigation costs weeks and hundreds of thousands of dollars. Each was preventable at the second occurrence.

03

CAPAs written for what could have been prevented

04

Yield variability absorbed as the cost of doing business

The CAPA is thorough. It documents what happened, why, and what will change. It arrives after the batch is lost. The best CAPA is the one you never had to write.

Campaign-to-campaign yield swings treated as inherent to the process. The pattern of what drives the high-yield campaigns is sitting in your own historical data — read once and never revisited.

05 — WHY THE CURRENT MODEL KEEPS LOSING GROUND

The gap widens on its own

None of this is a failure of effort. Quality and manufacturing teams work hard inside the tools they have. The model itself is what keeps losing ground — for four compounding reasons.

01 You find out too late

Conventional MES and LIMS reporting is a rear-view mirror. The dissolution result arrives after the batch is committed. The comparability panel is read after biosimilar release. By the time the number lands on a dashboard, the moment to act on it has usually passed.

02 You pay four times for one signal

Four teams, four tools, four budgets — each chasing a different reading of the same underlying batch trajectory, none of them aware of the others. Across every plant and every product. The spend is real and recurring; the coordination is not.

03 The build-it-yourself path is closed to most

The manufacturers that genuinely solve this in-house are the ones with the largest data-science benches and dedicated manufacturing-intelligence groups. For growth-stage generics and biosimilar manufacturers competing on cost and speed, “we’ll build it ourselves” is not a plan — it is a reason the gap stays open. The right move is to buy the capability layered on top of your existing SAP MES, not to fund a build you cannot staff.

04 You forfeit upside within reach

Higher yields left on the table. Drifting batches lost that could have been preserved. Faster campaigns delayed because a signal was read at week three instead of week one. The upside was there — the mechanism to capture it wasn’t.

06 — ONE SIGNAL, FOUR RECOVERIES

Read the trajectory **once**

Here is the shift. The same batch trajectory — read once, from data you already own — surfaces across all four problems at the same time. Not four tools. One reading, four uses, sitting alongside your SAP MES without touching it.

THE UNIFIED BATCH SIGNAL

**One batch, surfaced four
ways the moment its
trajectory shifts**

RECOVERY 01 · PREDICTION

Cross-signal prediction

RECOVERY 02 · BLUEPRINT

Gold Standard, reverse-engineered

Every process parameter read simultaneously — API lot signature to compression outputs, or cell-line signature to purification profile. The pattern flags drift days before final assay or comparability testing.

Your best batches, reverse-engineered — specific parameter targets, timing windows, thresholds per product. Not “optimize the process.” Rather: “hold parameter X in range Y from hour A to hour B.” The blueprint of what “right” looks like, empirically.

RECOVERY 03 · PREVENTION

Prevention over documentation

Ranked corrective actions delivered during the run — not investigations assembled after the batch is committed. The best failed batch is the one that never happened.

RECOVERY 04 · PORTFOLIO REACH

One platform, across the portfolio

Same architecture across your solid-dose portfolio — immediate-release, modified-release, injectable dose forms. Patterns learned in one product family transfer to related ones. The same platform extends to biosimilars and cell therapy — where the batch signals shift, but the architecture stays.

Today you pay four teams to chase four versions of this signal, and none of them sees the other three. **The recovery is not new instrumentation. It is reading the trajectory you already have — once, and together, across every plant and every modality.**

One more thing. For biosimilars, potency-to-reference is the entire regulatory game — every batch must land inside a tight similarity envelope. Missing it means rejected batches and regulatory scrutiny. The same trajectory reading, inverted, predicts which campaigns are at risk of falling outside — and surfaces the levers that keep them inside. Same math, inverted framing. That’s a conversation we’d love to have.

THE PLATFORM

A conversation we would welcome

CentroidAI's FyndEm Quality is a predictive intelligence platform for pharmaceutical manufacturing yield improvement — built to provide the intelligence, lead time, specific actions you can take and the \$ quantification, to improve yield and save the batch. How this is done, the data sources, the deterministic models and confidence levels, is a conversation we would welcome.

YOUR CENTROIDAI CONTACT

Raj Subramanyam

Founder & CEO, CentroidAI · raj@centroid-ai.com

[Contact Us](#)

CentroidAI · FyndEm Quality — Solid Dose & Biosimilars

Industry references: FDA Form 483 and warning-letter cost studies; ISPE and PDA process-performance benchmarks; biosimilar comparability guidance (FDA, EMA). Multi-variate analysis and \$ quantification are produced from each manufacturer's own historical data and cost drivers.