

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

Save batches. Improve yield.

Every biologics manufacturer runs batches that drift days before their MES sees it, investigates the same root cause across campaigns and sites without connecting it, writes CAPAs for events that were preventable, and never quite reconciles the dollar impact of drift 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.

01 Drift starts before your MES sees it

02 One root cause, hidden across campaigns and sites

03 CAPAs written for what could have been prevented

04 Drift costs absorbed, uncounted

The data is already in your building

You don't need new sensors, new instrumentation, or a new IT project. The signal that predicts each batch outcome exists days to weeks before the batch tells you — sitting in the same systems you already run.

PI HISTORIAN · EVERY PLANT

Density, complete

Every bioreactor run generates thousands of parameter reads per hour — pH, dissolved oxygen, cell viability, glucose, lactate, metabolite ratios. Structured, high-frequency, already logged.

MES BATCH RECORDS · EVERY CAMPAIGN

Genealogy captured

Materials, operators, equipment IDs, deviations, exceptions, in-process measurements — every batch's full genealogy structured and permanent in your MES.

LIMS · EVERY RELEASE

Outcomes measured

Assay results, purity, aggregate content, release-spec outcomes. The dependent variable of every campaign — waiting to be joined to what upstream drove it.

SENIOR OPERATORS · EVERY PLANT

Signal held in heads

Which supplier lots to distrust. Which equipment cycles run hot. Which environmental days breed contamination. 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.

Read it against your own plant

If you run **PI Historian, MES, 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. 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 write-off, a QC hold, a delayed release. Here is the same underlying batch drift, surfacing as four separate departments’ problems.

MSAT

The recurring investigation

A subtle upstream drift — supplier lot, environmental excursion, equipment variance — produces a downstream deviation. Root-cause takes weeks. The same investigation repeats next campaign, same conclusion, same delayed action.

Owned by: manufacturing sciences

QUALITY

The CAPA that arrives too late

CAPA compilation begins after the deviation is confirmed and the batch is already at risk or lost. Documentation is thorough. The batch it would have saved is gone.

Owned by: QA / QC

OPS

The batch write-off

Contamination, yield fall-off, or release-spec drift caught at harvest or downstream. Fully-loaded batch cost absorbed as scrap. The signal that would have flagged it was in the trajectory 48–72 hours earlier.

Owned by: operations

PROCURE

The supplier drift that reached your reactor

A media (or resin, or filter) supplier's CoA passes incoming QC — technically within spec, but subtly drifting. 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

03 — THE STRUCTURAL FRAGMENTATION

The batch is one process. You see many.

This is the core of it. A batch 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

HOW YOUR SYSTEM
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 — pool characteristics, feed schedule, agitation, temperature, media lot, environmental zone, operator, equipment cycle count.

Four disconnected signals.

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

MES sees a batch record.

Historian sees a trend.

LIMS sees a QC result.

MSAT 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.

Every system in that list is doing its job. MES records the batch. Historian trends the parameters. LIMS releases the outcome. Manufacturing sciences investigates the deviation. None of them is broken — and none of them is looking at the batch as one continuous trajectory. The next section is what that costs.

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. 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

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.

04

Yield variability absorbed as the cost of doing business

Campaign-to-campaign yield swings treated as inherent to biologics manufacturing. 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. Manufacturing scientists 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 Historian reporting is a rear-view mirror. The deviation is flagged after it happens. The release panel arrives after the batch is committed. 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. The spend is real and recurring; the coordination is not.

03 You absorb losses that were avoidable

Every CAPA cycle, every 483 response, every missed production target that traces to a signal readable days or weeks earlier. Losses that industry-wide are treated as inherent — and are, in fact, preventable.

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, entirely within your own systems.

THE UNIFIED BATCH SIGNAL

One batch, surfaced four ways the moment its trajectory shifts

RECOVERY 01 · PREDICTION

Cross-signal prediction

Every process parameter read simultaneously. The pattern flags drift 48–72 hours before harvest impact — before the deviation is visible to any single system.

RECOVERY 02 · BLUEPRINT

Gold Standard, reverse-engineered

Your best batches, reverse-engineered — specific parameter targets, timing windows, thresholds. Not “optimize pH.” Rather: “maintain pH X.XX from hour Y to Z.”

RECOVERY 03 · PREVENTION

Prevention over documentation

Ranked corrective actions delivered during the run — not CAPAs assembled after the batch is lost. The best CAPA is the one you never had to write.

RECOVERY 04 · NETWORK

Root cause, across your network

One drift signal, connected across campaigns and sites. One media lot, three campaigns, two sites — surfaced as one pattern, not three separate investigations. The connection a single-plant, single-system view genuinely cannot see.

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.**

One more thing. The same trajectory, read one degree differently, can push more of your batches into the high-potency tail — batch by batch, upstream. That’s not a claim we make in a white paper. It’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](#)

FyndEm Quality — Biologics is one variant within the broader FyndEm Quality suite. The **Solid Dose** variant covers small-molecule and biosimilar manufacturing; the **Cell Therapy** variant covers CAR-T and adjacent modalities. One platform, one architecture, tuned per modality.

CentroidAI · FyndEm Quality — Biologics

Industry references: BioPhorum CAPA and quality benchmarking; BioPlan Annual Report of Manufacturing Capacity; public FDA Form 483 cost studies. Multi-variate analysis and \$ quantification are produced from each manufacturer's own historical data and cost drivers.