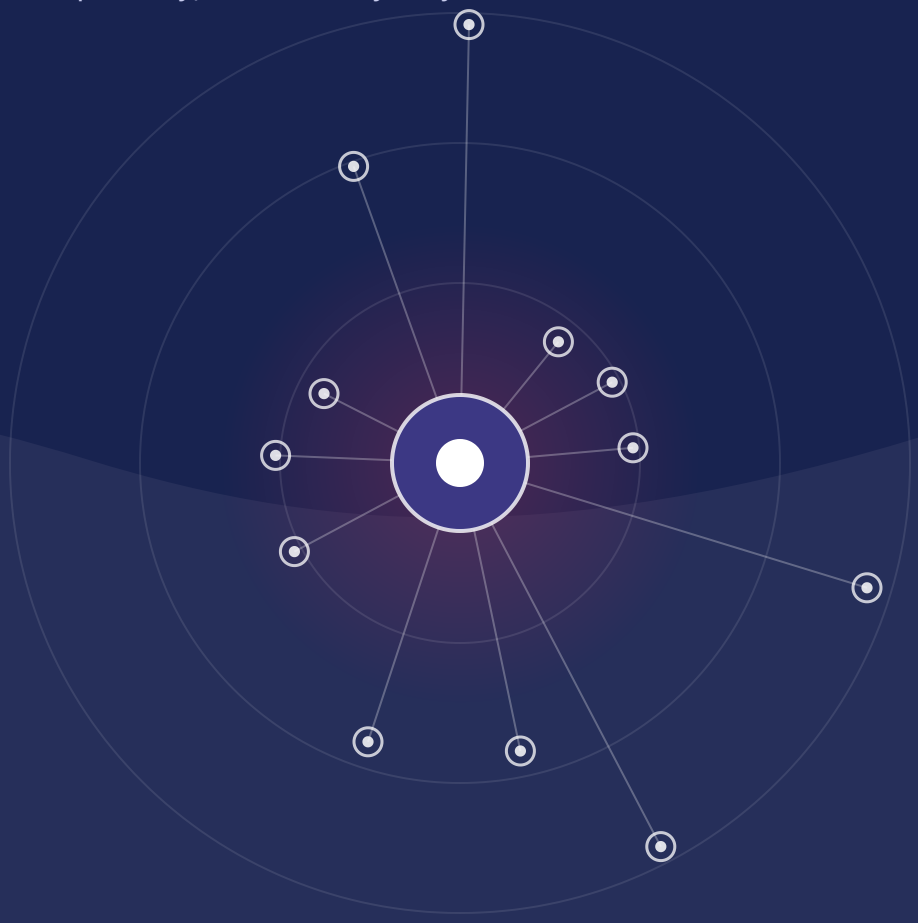
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ARTICLE

Enabling Real-Time Transparency in External Manufacturing Partnerships

Why real-time batch, quality and inventory data — not another status slide — is the foundation of sponsor transparency, and the only way to react in time to protect supply.



Joe Miles · Member of the Board of Advisors – Global GTM, Collabrix Inc. · 11-Nov-2026 **Collaborate for life.**

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The Visibility Gap at the Heart of Outsourcing

External manufacturing is no longer a supplement to in-house capacity. The global CDMO market was estimated at $136.6 billion in 2024 and is forecast to reach $191.6 billion by 2029, and sponsors now depend on networks of partners across small molecules, biologics and cell and gene therapies for both clinical and commercial supply.

Yet the way sponsors see what happens inside those partner sites has barely changed. Batch status arrives in weekly calls. Certificates of analysis arrive as PDFs. Inventory positions arrive in a monthly spreadsheet. By the time a sponsor learns that a batch has slipped or a deviation has been raised, the window to do anything about it has often closed.

The argument of this article is simple. Real-time and near real-time manufacturing data — batch, quality and inventory — is not an IT convenience. It is the foundation of sponsor transparency, the basis of trust in the CDMO relationship, and the only way a sponsor can react quickly enough to protect delivery dates and the availability of critical materials.

Why Late Data Is the Real Problem

The core issue is not that sponsors lack data. It is that the data arrives late by construction. What typically crosses the company boundary is a status slide and a PDF, produced by hand, on request and after the batch is complete. Problems are reviewed when they can no longer be influenced.

Late data also carries risk of its own. Regulators hold the sponsor accountable for operations performed on its behalf, under FDA quality agreement guidance and EU GMP Chapter 7. Information that crosses company boundaries by email and is re-keyed by hand is difficult to defend against expectations, and a transcription slip can become a quality finding in its own right.

The burden falls on CDMOs too. A partner serving many sponsors is asked to reshape the same batch and quality data into each sponsor's template, request by request. Where integrations exist, they are usually bespoke point-to-point interfaces, so cost grows with the number of sponsors multiplied by the number of partners. Neither side wins under this model.

Batch, Quality and Inventory: What Real-Time Visibility Looks Like

Batch data. Instead of receiving the batch record once the batch is complete, the sponsor sees it while the batch runs. Milestones such as equipment reservation, raw material receipt, material release and manufacturing start are tracked with target, expected and actual dates. Critical process parameters, in-process test results, material consumption, yield and batch genealogy arrive as they

are recorded. Standards such as ISA-95 and ISA-88 give each value its context — site, unit, operation, phase — so it can be joined to the sponsor's own records and trended across campaigns.

Manufacturing data standards. The principle that already applies to orders and inventory — define the exchange once, reuse it everywhere — applies equally to manufacturing. Rather than invent a new vocabulary, manufacturing messages build on two established standards. ISA-95 (IEC 62264) defines how production schedules, production performance, material lots and consumption, equipment and quality operations are exchanged between business systems and manufacturing operations. ISA-88 (IEC 61512) defines the physical, procedural and recipe models of batch manufacturing and the structure of batch production records.

Using these models, every message carries its data within a recognized hierarchy: site, plant, product and recipe, unit, unit procedure, operation and phase. A batch status, an in-process test or a process parameter (target and actual) therefore arrives in the context of the batch it belongs to. A lot, a unit operation or a parameter is described the same way whether the batch is made in the sponsor's own plant or at a partner's.

Crucially, the standards govern the structure of the data, not its format, and they are not a requirement on anyone's systems. ISA-95 was written for exchange between enterprise systems and the shop floor, and its XML implementation, B2MML, already describes batch status and material consumption. The hierarchy is a superset in which levels are optional: a partner running a paper batch record may report an operation and a phase without a unit procedure. Nothing here asks a partner to adopt an MES. The standards also bring a shared vocabulary in which terms such as lot and batch have agreed meanings, and they keep batch context intact when a sponsor loads partner data into its data lake. Quality exchanges draw instead on BioPhorum's work on digital certificates of analysis and deviations.

The vocabulary differs by modality — synthesis, granulation and coating for small molecules; cell culture, harvest, purification and fill-finish for biologics; patient-specific batches under chain of identity for cell and gene therapies. A shared canonical model carries the common structure, with modality-specific detail as defined extensions.

On this foundation, around twenty standard messages cover the batch from execution to release:

Table 1. Standard messages for manufacturing and quality (illustrative)

Group	Standard Messages	Typical Source
Batch progress	Batch status updates; product QA status; QA release for shipment	MES, QMS
Process and execution	Batch execution process parameters (CPPs); batch process data in batch context; in-process quality control results	MES, historian, LIMS
Materials and output	Material input and charge; material consumption; product output by stage; batch yield; batch genealogy	MES, ERP
Equipment	Equipment used for the batch	MES
Quality and release	Release analysis for intermediates and finished product; deviation reporting; change control; certificates of analysis, conformance and manufacture	LIMS, QMS
Batch record	Electronic batch record — or the executed paper record, digitized	MES / EBR, documents

Each message specification defines its fields, data types, source and destination systems, push or pull, trigger frequency, validation rules and GxP classification. The fields are fixed; only the delivery varies by partner. A CMO whose MES publishes batch status sends the message directly, while one that issues a certificate of manufacture as a PDF has the same message populated through AI-assisted digitization. Downstream, the sponsor's systems receive the same message either way. BioPhorum's DISCO program is extending its standard message catalogue from inventory and purchase orders into manufacturing and quality collaboration.

Quality data. Deviations, investigations, CAPAs and change controls become one shared record rather than an email thread. Each organization keeps its own QMS as the system of record, but both work against the same event, with documents, tasks and queries attached. AI-assisted digitization extracts fields from deviation reports and certificates, with confidence scores and human review of exceptions, so quality staff assess data rather than re-enter it.

Inventory data. Sponsor-owned stock held at partner sites becomes visible daily rather than monthly, reconciled against goods receipts, shipping notices and consumption. That turns inventory from a quarter-end reconciliation exercise into a live planning input.

The Evidence from Live Deployments

Two deployments of the Collabrix platform show what this looks like in practice.

Year one at a global biopharmaceutical sponsor. Between October 2025 and October 2026, the platform became the system of record for external manufacturing purchase orders:

- 7,034 POs across 11 CMO sites, used by 118 people.
- 2,566 batches were tracked across 9 CMO sites, and 99.7% reached production complete and CMO QC release with that progress visible to the sponsor.

- Batch allocations written back to SAP reached 3,637 across 2,017 POs, with some biologics partners averaging 12 to 20 batches per PO, each reconciled individually.
- Lot mismatches, once caught by hand against paper, surfaced on about 1 batch in 50.
- Collaboration itself moved onto the record: 13,928 CMO documents digitized and 12,177 sponsor–CMO exchanges tied to the PO they concern.
- 72% of POs written back to SAP closed without a planner decision.

A medium-maturity CMO. A second sponsor connected a partner that still ran largely on PDFs and spreadsheets, without asking it to build an interface. Approximate results:

Table 2. Measured outcomes at a medium-maturity CMO (approximate)

Metric	Before	After
Inbound delivery processing time (sponsor target: 20 minutes)	~30 minutes	~5 minutes
Manual effort per transaction	~1 hour	~5 minutes
Transactions fully automated (no human intervention)	—	40%
Inventory visibility frequency	Monthly	Daily
Extraction accuracy (after validation)	—	98.4%
Documents processed	—	More than 3,000 per month
Time to onboard the partner	—	3–4 weeks

The lesson from both is consistent. Where sites follow the model, it works: one partner site cut receipts posted outside the platform from 10.5% to 0.5%.

Time to React: Turning Visibility into Supply Protection

The strategic value of real-time data lies in the time it buys. A sponsor sits at the center of an ecosystem the CDMO cannot see: alternative manufacturing sites, inventory held at other partners and distribution centers, raw material suppliers, logistics providers and its own demand plan. Every day of earlier warning widens the set of moves available.

Consider a deviation raised at transfection because viable cell density exceeded the batch record's upper limit. In the traditional model, the sponsor might learn of it when the final deviation report arrives a week or more later. With the deviation visible as a shared record the day it is raised, the sponsor's quality and supply teams can engage while the investigation is open. Likewise, an assay result trending below threshold on a campaign release map, or a milestone slipping on a production gantt chart, becomes a signal rather than a surprise.

With that signal in hand, a sponsor can:

- Re-balance sponsor-owned inventory across sites and markets to cover a delayed batch.

- Pull forward or reallocate capacity at a second qualified CDMO.
- Expedite critical raw materials or components to the affected partner.
- Re-prioritize batch allocations toward the highest-risk markets and patients.
- Adjust logistics, including expedited shipping, before a delivery date is missed.

None of these levers work when the news arrives after the batch is closed. Real-time data turns supply risk from something reported into something managed.

Transparency as the Basis of Trust — and Competition

Transparency changes the nature of the relationship. When both parties see the same batch status, the same deviation record and the same inventory position, conversations shift from “what happened?” to “what do we do next?”. McKinsey’s recent analysis of the CDMO market makes the commercial point: partners that improve transparency and responsiveness will be best positioned to win share. For CDMOs, publishing batch and quality data once, in one standard form, for every sponsor is both a cost saving and a differentiator built on quality and reliability rather than price alone.

Scaling this across a network depends on standards. BioPhorum’s DISCO program has identified more than 100 manufacturing messages and is extending its catalogue into manufacturing and quality collaboration. A standards-based hub lets each partner connect once, through the model that fits its maturity: structured spreadsheets, AI-assisted document exchange or full ERP-to-ERP integration. Low- and medium-maturity partners can be onboarded in weeks; high-maturity integrations in two to three months.

The question for sponsors and CDMOs is no longer whether to share manufacturing data in real time. It is how quickly they can make it the default — because the partner that sees a problem first is the one that can still protect the patient’s supply.

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