A STRATEGIC ARCHITECTURE PERSPECTIVE

Batch Release and Cold Chain in the CGT CDMO

Why the Operating Model Needs to Evolve

A perspective on SAP Batch Release Hub and Cold Chain architecture for Cell & Gene Therapy Contract Development and Manufacturing Organisations.

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Executive Summary

The Cell and Gene Therapy contract manufacturing sector is moving from specialist niche to industrial scale. The operating models that served the early stage of the industry — manual batch release, paper-based quality oversight, spreadsheet-tracked cold chain — are now structural liabilities. CDMOs that cannot demonstrate digitally orchestrated batch release and real-time cold chain governance are increasingly being deselected by sponsor pharma for late-stage and commercial supply partnerships.

This whitepaper sets out a strategic architecture perspective on SAP Batch Release Hub (BRH) and Cold Chain digitalisation in the CGT CDMO context, drawing on direct co-innovation experience with SAP product development during the lighthouse customer phase.

Five takeaways for CDMO operations and IT leadership

1. **Legacy operating models are now a commercial liability.** Sponsor pharma quality audits are becoming the gatekeeper for commercial supply partnerships. Manual release cannot pass that bar.

2. **CGT batch release breaks every assumption of traditional pharma release.** Single-patient batches, days of shelf life, multi-system data dependencies, and accelerated regulatory pathways demand a different operating model.

3. **SAP BRH was designed for large pharma but fits CGT CDMO complexity well.** Centralised data aggregation, configurable workflows by product type, and exception-based review map directly to CGT operational pain points.

4. **Cold chain is part of release, not a downstream concern.** Architecting BRH and cold chain orchestration together — including IoT integration and ICSM/CGT Orchestration coupling — creates end-to-end operational visibility that sponsor pharma values.

5. **Five architectural decisions shape long-term value.** Tenancy model across geographies, LIMS/MES integration depth, BTP extensibility strategy, QP authorisation across the network, and implementation sequencing each have major downstream consequences.

Done well, the resulting digital operating platform becomes a commercial asset on equal footing with the CDMO's manufacturing capability.

1. The Operational Reality CDMOs Face Today

Contract Development and Manufacturing Organisations serving the Cell and Gene Therapy sector operate in a uniquely demanding environment. A single CAR-T batch may represent a single patient's only treatment. Viral vector production for a commercial gene therapy may support thousands of patients globally. A temperature excursion during cold chain transit can invalidate weeks of manufacturing work and delay a patient's therapy by months.

Yet most CDMOs still run batch release and cold chain oversight on systems and processes designed for small-molecule or traditional biologics manufacturing — systems that assume larger batch sizes, longer shelf lives, and a degree of forgiveness in temperature handling that advanced therapies simply do not permit.

As the CGT market matures, this gap between legacy operating models and actual operational complexity is becoming a competitive issue. CDMOs that cannot demonstrate rigorous, digitally orchestrated batch release and cold chain governance are increasingly being passed over by sponsor pharma companies for late-stage and commercial supply partnerships. The manual, paper-based, Excel-tracked release process that was acceptable five years ago is becoming a commercial liability.

> *The operating model gap between specialist CDMOs and industrial-scale sponsor pharma expectations is the defining commercial issue of the next five years for this sector.*

2. Why Batch Release is Fundamentally Different in CGT

In traditional pharma, batch release is a well-defined process: manufacture the batch, run the Quality Control tests, have the Qualified Person review the results, release for distribution. The batch sizes are large, the products are stable, the timelines allow for deliberate review.

In CGT manufacturing, every one of those assumptions breaks down.

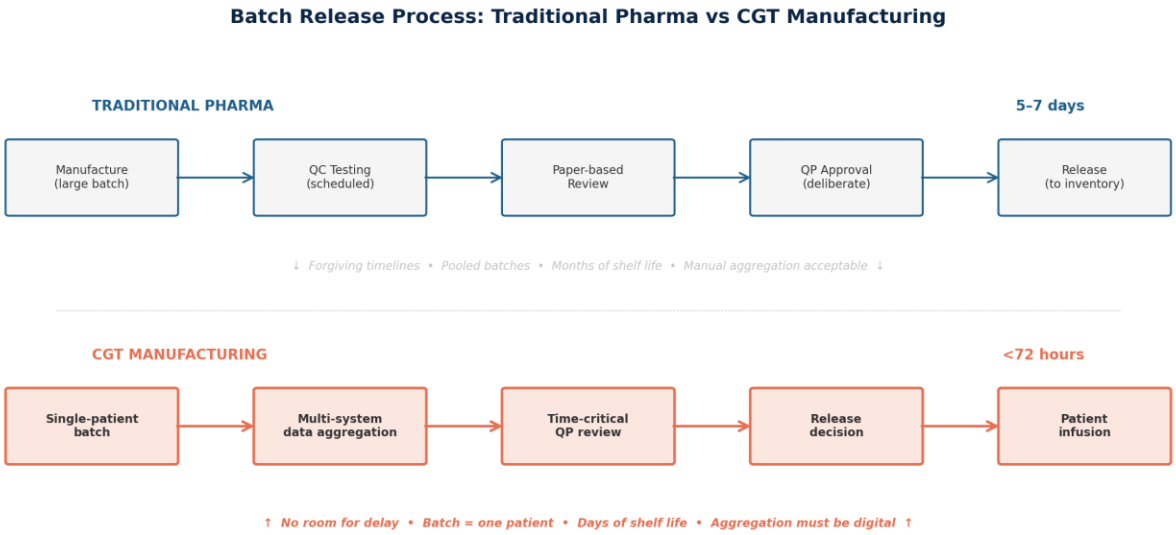

Figure 1: Batch release process in traditional pharma vs CGT manufacturing — a structural shift, not an incremental change.

Batch sizes are small and patient-specific. For autologous cell therapies, each "batch" may be a single patient. There is no pooling, no averaging, no ability to recover from a release delay by drawing from inventory. The batch either releases on time for the patient, or the patient waits.

Shelf lives are short. Many cell therapy products have shelf lives measured in days rather than months. A batch release process that takes 72 hours consumes a significant proportion of the product's usable life. Every hour saved in the release cycle is an hour the product is available for patient infusion.

Release decisions are data-heavy. A CGT batch release requires review of cell viability data, potency assays, sterility results, endotoxin testing, identity confirmation, vector copy number, mycoplasma results, and more. The data originates from LIMS, MES, shop floor quality systems, and external testing laboratories. Aggregating this data manually for QP review is time-consuming and error-prone.

Regulatory scrutiny is intense. CGT products are frequently manufactured under accelerated approval pathways with heightened post-market surveillance. Release documentation must be audit-ready, traceable, and defensible. A release decision made on a summary spreadsheet does not meet the bar of modern regulatory expectations.

3. The Case for SAP Batch Release Hub

SAP Batch Release Hub for Life Sciences is a cloud-native application built on SAP Business Technology Platform, designed specifically to digitise and automate the batch release decision process. While the product was developed with large pharma as lighthouse customer, its architecture lends itself particularly well to CGT CDMO operational complexity. Five capabilities map directly to CGT pain points.

Centralised data aggregation for release review

BRH aggregates quality, manufacturing, and regulatory data from multiple source systems into a single review context for the Qualified Person. For a CDMO releasing a cell therapy batch, this means the QP sees cell viability, sterility, potency, identity, and associated documentation in one place rather than logging into six different systems. For high-volume release operations, the cycle time reduction alone is substantial.

Configurable release workflows by product type

A CDMO manufacturing viral vectors, autologous cell therapies, allogeneic cell therapies, and plasmid DNA for the same client portfolio needs different release processes for each. BRH supports multiple release workflow templates that can be configured by material type, regulatory jurisdiction, and release scenario. This flexibility is essential for a contract manufacturer whose product portfolio changes as the client base evolves.

Exception-based review

One of BRH's core design principles is that routine releases should process with minimal human intervention, while exceptions are surfaced for QP attention. In a CGT CDMO context, this means the QP focuses on the 10% of batches with deviations rather than spending equal time on the 90% that are nominal. This is how lean QA organisations scale with volume.

Full audit trail and compliance documentation

Every release decision in BRH is documented with its supporting evidence, reviewer comments, and approval chain. For a CDMO preparing for FDA, EMA, or other regulatory inspections, this is the kind of documentation quality that significantly reduces inspection anxiety.

Integration with SAP S/4HANA and non-SAP systems

BRH is designed to integrate with SAP ERP backbones and external systems like LIMS, MES, and quality management platforms. A CDMO running S/4HANA with third-party LIMS can architect BRH as the central release orchestration layer without forcing rip-and-replace of specialised quality systems.

4. Reference Architecture

The architectural intent is straightforward: BRH sits as the orchestration hub between data sources (LIMS, MES, quality systems, external labs) and the downstream operational systems (ICSM for clinical supply, CGT Orchestration for chain of identity, ATTP for serialisation, cold chain monitoring for temperature data). The S/4HANA backbone provides master data and core ERP capability. The Qualified Person decision layer sits above, with dashboards, exception management, audit trail, and regulatory reporting.

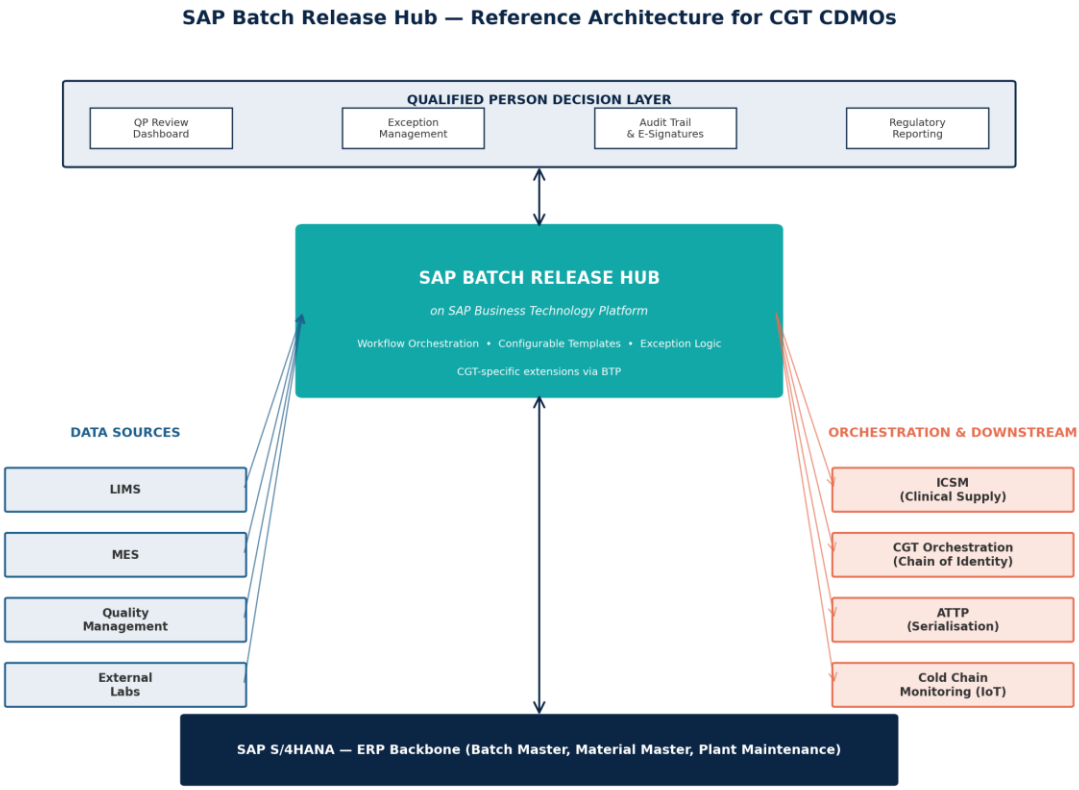

Figure 2: SAP Batch Release Hub reference architecture, showing data sources, orchestration components, downstream systems, and the QP decision layer.

What makes this architecture work for a CDMO specifically is the BTP extensibility layer. CGT-specific release logic — for example, the relationship between vector copy number, viability, and release decision for a viral vector batch — is not in the standard BRH product. It can be built as a BTP extension that plugs into the standard workflow templates without modifying the core. This is the architectural pattern that allows the CDMO to absorb client-specific requirements without forking the platform.

5. The Cold Chain Dimension

Batch release in CGT does not end when the QP approves the batch. For temperature-sensitive products — which most advanced therapies are — the release decision must account for the complete cold chain from manufacture through distribution to patient infusion. This is where the architectural conversation becomes interesting, and where most CDMOs have significant unmet needs.

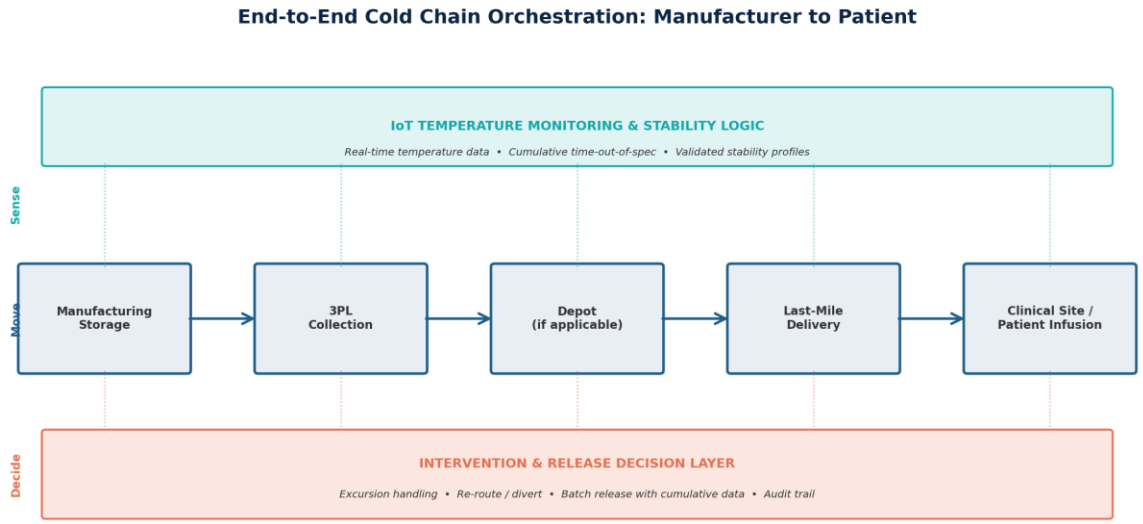

Figure 3: Cold chain orchestration as a sense-move-decide loop. Real-time temperature data, validated stability logic, and intervention capability operate as one integrated layer over the physical chain of custody.

Temperature excursion handling at release. If a batch shows a temperature excursion during manufacturing storage, the release decision needs to account for cumulative time-out-of-specification, the phase of product lifecycle when the excursion occurred, and the validated stability data for the product. Doing this analysis manually is slow and inconsistent. Embedding the logic in BRH release workflows, with integrated IoT temperature data feeds, enables consistent, documented, defensible decision-making.

Cold chain continuity from manufacturer to clinical site. For clinical trial supply managed by ICSM in combination with BRH, the cold chain handover between CDMO, 3PL, depot, and clinical site is a critical control point. An architecture that integrates manufacturing release data with downstream distribution temperature monitoring creates end-to-end visibility that neither the CDMO nor the sponsor currently has through traditional systems.

Real-time intervention on in-transit excursions. When a shipment shows a temperature excursion in transit, the decision to divert, re-route, or accept the product needs to be made quickly. A digitised cold chain orchestration layer — combining IoT data, product stability logic, and release workflow — supports this in a way that email-and-phone escalation cannot.

Integration with SAP CGT Orchestration. For autologous therapies specifically, CGT Orchestration manages the needle-to-needle chain of identity and chain of custody. When BRH release decisions, cold chain data, and CGT Orchestration scheduling are architected together, the CDMO gains a unified operational view that makes them a genuinely differentiated partner for sponsor pharma.

6. Architecture Decisions That Shape the Implementation

Five architectural decisions shape the long-term value of any BRH and cold chain digitalisation programme in a CDMO setting. Each has significant downstream consequences. Each is best made deliberately, early, and with the operating model in mind.

Decision	What it shapes
BRH tenancy model	Whether the CDMO runs a single global BRH tenant consolidating release data, or multiple regional instances. Has implications for data governance, cross-jurisdiction QP authorities, and decision speed.
LIMS / MES integration depth	What data flows into BRH, at what granularity, and with what master data governance. Determines whether BRH is the central release orchestrator or just another system asking the same questions.
BTP extensibility strategy	Where CGT-specific release logic, bespoke cold chain integrations, and non-standard regulatory reporting are built. Defining this upfront prevents costly retrofitting later.
QP authorisation model	How global, regional, and site-level QP roles map to BRH's Quality Department concept. Get this wrong and either QPs have approval power across sites they don't know, or release bottlenecks form when the right QP is unavailable.
Implementation sequence	Whether to digitise one product family first or attempt multiple in parallel. Phased delivery is almost always faster, less disruptive, and cheaper than the alternative.

7. Implementation Roadmap

Most CDMOs benefit from a phased approach that delivers value early, builds operational confidence in the platform, and avoids the disruption of attempting to digitise all release workflows for all product types simultaneously. A typical 18 to 24 month horizon looks as follows.

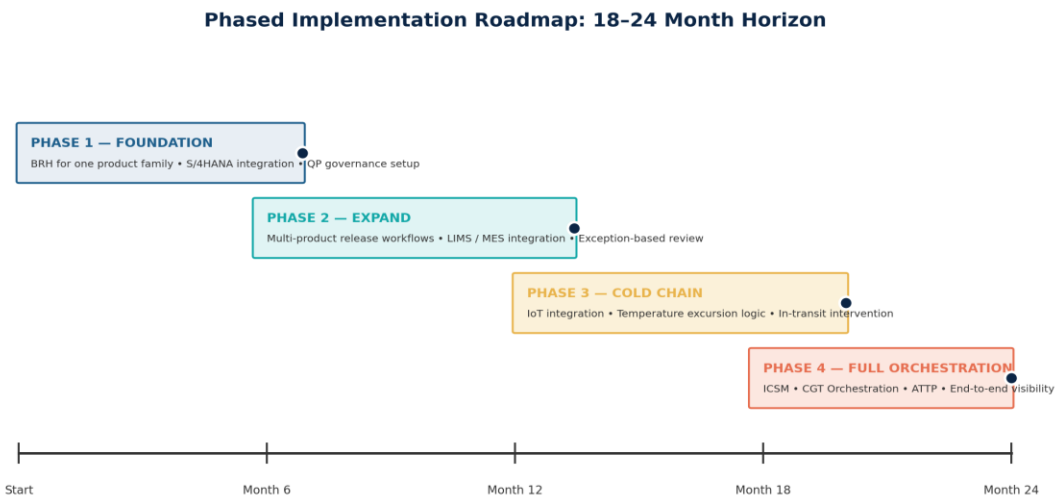

Figure 4: Phased implementation roadmap. Each phase delivers operational value before the next begins, reducing risk and allowing the operating model to absorb each capability.

Phase 1 — Foundation. BRH for one product family with full S/4HANA integration. QP governance setup, release workflow templates, audit trail. Goal: prove the operating model.

Phase 2 — Expand. Multi-product release workflows. LIMS and MES integration. Exception-based review fully operational. Goal: scale the operating model.

Phase 3 — Cold Chain. IoT temperature data integration. Excursion handling logic embedded in release workflows. In-transit intervention capability. Goal: extend the operating model end-to-end.

Phase 4 — Full Orchestration. ICSM for clinical supply, CGT Orchestration for chain of identity, ATTP for serialisation, all coupled to BRH. Goal: unified operational platform that becomes a commercial differentiator.

8. Commercial Implications

The commercial case for BRH and cold chain digitalisation in a CGT CDMO rests on four arguments, each with measurable business impact.

Faster release cycle times translate directly to competitive advantage. A CDMO that can reliably release batches in 24 hours versus 72 hours becomes more attractive to sponsor pharma for time-sensitive products. For clinical supply, this means patient enrolment is not delayed. For commercial supply, this means inventory carrying costs are lower.

Audit readiness becomes a sales asset. Sponsor pharma increasingly conducts thorough quality audits before committing to commercial supply partnerships. A CDMO whose release process demonstrates digital rigour, complete audit trails, and consistent exception handling inspires materially more confidence than one relying on spreadsheets and email approvals.

Cold chain reliability reduces batch loss. The cost of a lost batch in CGT is measured in hundreds of thousands to millions. Even modest improvements in cold chain oversight and in-transit intervention capability pay back the digitalisation investment quickly.

Scalability as the business grows. The CGT market is growing rapidly. CDMOs serving this market need operational platforms that scale. Manual processes that work at 50 batches a month break at 500. BRH and cold chain orchestration scale with volume in a way that people and spreadsheets do not.

> *Operational excellence in CGT is no longer a quality compliance question. It is a commercial proposition.*

9. Closing Perspective

The CGT CDMO sector is moving from its early-stage specialist niche toward industrial-scale operations. The CDMOs that thrive over the next decade will be those that industrialise their operating models without losing the scientific agility that made them successful in the first place.

Batch Release Hub and Cold Chain digitalisation are not technology upgrades. They are enabling infrastructure for a different operating model — one where release decisions are fast and consistent, cold chain oversight is real-time and intervenable, and the CDMO's operational capability becomes a visible differentiator when sponsor pharma is choosing partners.

For CDMOs evaluating these investments, the strategic question is not whether to digitise, but how to architect the digitisation so that it scales with the business and integrates with the broader SAP life sciences ecosystem — ICSM for clinical supply, CGT Orchestration for advanced therapy workflows, ATTP

for serialisation, and S/4HANA for core operations. Done well, the CDMO's operational platform becomes as much of a competitive asset as its manufacturing capability.

About the Author

Ram Kumar K is a Senior SAP Supply Chain Architect with 29 years of experience designing end-to-end warehousing, logistics, and supply chain solutions across life sciences, automotive, and oil & gas.

From 2019 to 2024 he worked directly with SAP's product development teams as a co-innovation partner during the design, build, and deployment of SAP Batch Release Hub for Life Sciences, Intelligent Clinical Supply Management (ICSM), and Cold Chain solutions, with Roche as the lighthouse customer. During this period he led Roche's global template design and rollout for SAP LE, EWM, TM, ATTP, and GTS across multiple countries and regulatory jurisdictions.

His current focus is regulated industry transformation architecture — particularly in life sciences and CGT supply chain — and the broader SAP Life Sciences cloud suite, including ICSM, CGT Orchestration, EWM, ATTP, and BTP integration, for pharma, biotech, and CDMO clients.

He began his career as an instrumentation engineer commissioning fertilizer and petrochemical plants, and later as a maintenance engineer at PDO in Oman. He holds an MSc in Oil & Gas Business Management (Distinction) from Robert Gordon University, with multiple certifications from SAP and TOGAF. He is fluent in three languages and is based in Cambridge, United Kingdom.