

WHITE PAPER

Bridging Life Sciences and Manufacturing

CGTO · ICSM · MES · BRH on SAP S/4HANA

How the world's most specialised SAP life sciences and manufacturing solutions converge — and the architecture principles that make the integration work

Cell & Gene Therapy · Clinical Supply · Batch Release · MES Execution · Warehouse Automation

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28 years · 7 full implementations · Automotive · Life Sciences · CGT · Chemicals · Oil & Gas

Executive Summary

SAP has built a portfolio of highly specialised solutions — CGTO, ICSM, BRH, SAP Digital Manufacturing, and EWM with MFS — that individually address some of the most complex operational challenges in pharmaceutical and industrial manufacturing. The strategic opportunity — and the architectural challenge — is designing these solutions to operate as a unified model on a single S/4HANA instance, governed by SAP BTP.

This white paper addresses the cross-domain integration architecture that bridges life sciences processes (clinical supply management, chain of identity, batch release) with manufacturing processes (shop-floor execution, warehouse automation, quality management). It draws on direct programme experience delivering these solutions across a major UK automotive S/4HANA transformation, the world's first global ICSM and BRH implementation at a Top 5 pharmaceutical company, and commercial-scale cell and gene therapy CDMO programmes.

Central argument: Organisations that treat CGTO, ICSM, BRH, and MES as separate workstreams — connected by interfaces added in later phases — consistently discover that retrofitting integration is significantly more expensive than designing it from the start. Cross-domain architecture is not a phase 2 activity.

Ten process flow diagrams and a cross-domain data ownership matrix illustrate the architectural principles.

1. The Two Domains and Why They Converge

1.1 Life Sciences Domain — CGTO, ICSM, BRH

Three SAP solutions define the life sciences domain on S/4HANA:

- ICSM (Intelligent Clinical Supply Management) manages the complete lifecycle of investigational medicinal products — from study master configuration and patient demand forecasting through global supply pooling, manufacturing preparation, cold-chain distribution, returns, and accountability reconciliation. It integrates natively with IRT/RTSM platforms and S/4HANA inventory management.
- CGTO (Cell and Gene Therapy Orchestration) addresses personalised medicine manufacturing — maintaining the chain of identity (COI) and chain of custody (COC) for each individual patient's biological material from leukapheresis collection through manufacturing, batch release, cold-chain shipment, and clinical infusion. One patient order drives one unique manufacturing batch.
- BRH (Batch Release Hub) digitises pharmaceutical batch release — automatically assembling the batch dossier from S/4HANA, SAP Digital Manufacturing, QM, and external quality systems, then routing it electronically for Qualified Person review and 21 CFR Part 11 / EU Annex 11 compliant electronic signature.

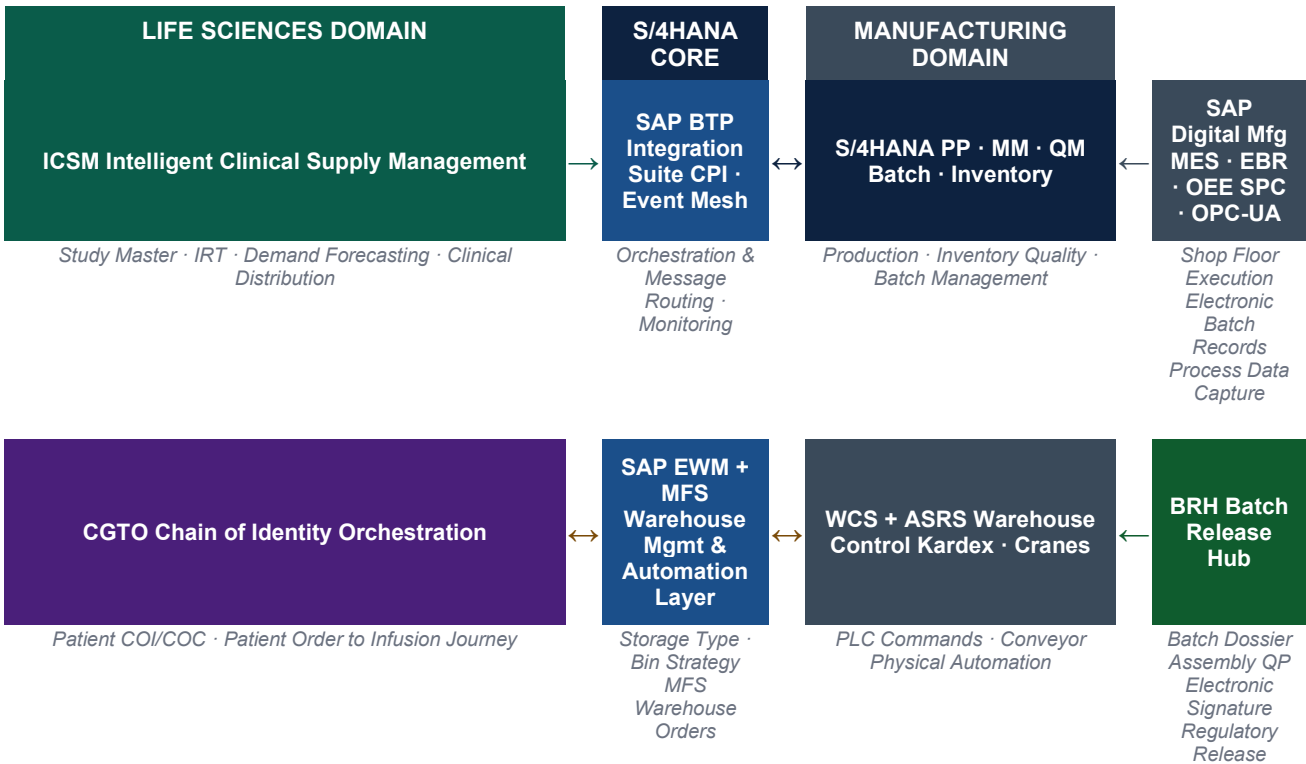
1.2 Manufacturing Domain — SAP Digital Manufacturing and EWM

- SAP Digital Manufacturing (formerly SAP ME/MII) provides the MES layer — Electronic Batch Records (EBR), in-process quality checks, Statistical Process Control (SPC), OEE tracking, and integration with PLC/SCADA systems via OPC-UA. In regulated environments it produces the electronic batch record that flows into BRH for release.
- SAP EWM with Material Flow System (MFS) manages automated warehouse operations — ASRS integration, Kardex Vertical Lift Modules, conveyor systems, and robotics. MFS is the SAP layer that translates warehouse orders into physical machine commands sent to the Warehouse Control System (WCS).

1.3 The Convergence Architecture

The following diagram shows how these six solutions connect on a single S/4HANA platform, with SAP BTP acting as the integration orchestration layer between the life sciences and manufacturing domains.

Figure 1 — Convergence Architecture — Life Sciences and Manufacturing on S/4HANA + BTP



Integration Principle: All cross-domain message flows are routed through SAP BTP Integration Suite. No point-to-point connections. Every interface is monitored, logged, and includes explicit error handling and retry logic.

SAP BTP Integration Suite routes all cross-domain messages. No direct point-to-point connections exist between solutions. Every interface is monitored, logged, and includes explicit error handling.

2. Data Ownership — The Foundation of Cross-Domain Integration

2.1 Why Data Ownership Must Be Resolved First

Cross-domain integration is fundamentally a data architecture challenge. Each solution requires the same foundational master data, but each may define, own, and update it differently. The most common cause of post-go-live integration failures is dual ownership — two systems updating the same data element with conflicting values.

Architecture rule: No data element may have more than one system of record. Before any blueprint session begins, the cross-domain data ownership matrix must be formally approved by all workstream leads. Changes to this matrix after configuration begins are extremely expensive.

Figure 7 — Cross-Domain Data Ownership Matrix

Data Element — Who Is the Master?	S/4HANA ERP	MES / SAP DM	ICSM	CGTO
Material Master & Bill of Materials	✓ MASTER	○ Read	○ Read	○ Read
Production Order / Process Order	✓ MASTER	○ Read	—	○ Read
Electronic Batch Record (EBR)	○ Read	✓ MASTER	—	○ Read
QM Inspection Lot & Usage Decision	✓ MASTER	○ Read	—	○ Read
Study Master & Protocol Configuration	○ Read	—	✓ MASTER	—
Clinical Supply Demand Forecast	○ Read	—	✓ MASTER	—
Chain of Identity (COI) — Patient ID	—	○ Read	—	✓ MASTER
Batch Release Dossier	○ Read	○ Read	○ Read	○ Read
Cold Chain Shipment & TM	✓ MASTER	—	○ Read	○ Read
Serial Number / ATTP Track & Trace	✓ MASTER	○ Read	—	○ Read
Storage Bin & Warehouse Order (EWM)	✓ MASTER	—	—	—
OEE & Machine State	—	✓ MASTER	—	—
IRT Randomisation & Kit Assignment	○ Read	—	✓ MASTER	—

Legend: ✓ = system of record for this data element — only this system creates or updates it. ○ Read = consumes this data, never writes back. — = no direct relationship with this data element.

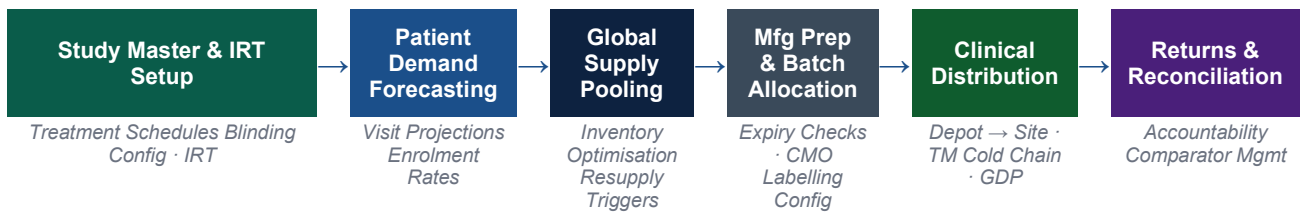
14 critical data elements mapped across 4 systems. ✓ MASTER = sole system of record. ○ Read = consumes only. — = no relationship. Dual ownership of any row is a programme risk.

3. ICSM — Clinical Supply Chain Architecture

3.1 End-to-End Clinical Supply Flow

ICSM manages the complete lifecycle of investigational medicinal product (IMP) through six distinct stages. Each stage generates transactions in both ICSM and S/4HANA core. IRT integration is bidirectional and active across all six stages.

Figure 2 — ICSM Clinical Supply Chain — End-to-End Six-Stage Flow



IRT randomisation and kit dispensing events drive ICSM supply responses in real time. Each stage transition updates S/4HANA inventory, batch management, and QM simultaneously.

3.2 Study Master — The Architectural Foundation

The ICSM study master is the architectural foundation from which all clinical supply decisions derive. A precisely configured study master eliminates the majority of downstream supply failures. Three configuration decisions carry the highest risk:

- **Blinding Alignment:** Blinding configuration must be exactly aligned with the IRT setup. If ICSM believes a patient is in treatment arm A but the IRT has randomised them to arm B, the supply consequences are serious and difficult to unwind in a live trial. The IRT-ICSM reconciliation check at each randomisation event is the control that prevents this.
- **Shelf-life Logic:** Shelf-life calculations must factor in both the manufacturing shelf-life and the patient visit window. A batch with six months remaining may be unsuitable for a patient scheduled in five months if the visit window and transit time are not fully accounted for in the ICSM allocation logic.
- **CMO Structure:** CMO integration requires S/4HANA to manage the CMO as an external storage location, with inter-company or intra-company stock transfer orders governing material movement. CMO goods receipt, quality release at the CMO site, and transfer to depot must all be explicitly designed in the S/4HANA plant structure.

4. CGTO — Chain of Identity Architecture

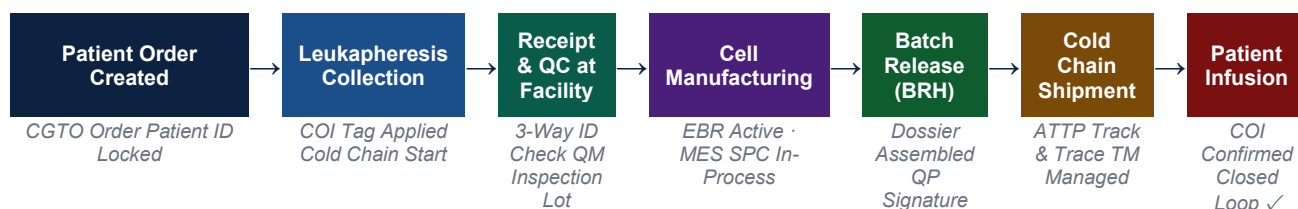
4.1 Why CGT Manufacturing Is Different

Cell and gene therapy manufacturing inverts the fundamental assumption of pharmaceutical production. One patient order produces one unique batch — manufactured from that patient's cells, processed according to their specific protocol, and released for administration to that patient only. No two batches are interchangeable. A single COI failure can result in the wrong therapy being administered to the wrong patient.

This creates an integration challenge that is categorically different from any other SAP programme. The chain of identity must be maintained as a hard constraint across every system in the technology stack — CGTO, SAP Digital Manufacturing, EWM, BRH, SAP TM, and any external cold-chain or logistics platform.

4.2 Patient Journey — Chain of Identity Maintained End-to-End

Figure 3 — CGTO Chain of Identity — Patient Journey from Leukapheresis to Infusion



Each of the 7 stage transitions requires explicit COI verification before the next stage is unlocked. CGTO orchestrates the journey. MES records the execution. BRH releases the batch. SAP TM manages cold-chain custody.

4.3 Multi-Site CGTO — The Additional Complexity

Commercial CDMOs operate across multiple manufacturing sites. The CGTO architecture must maintain COI across site-to-site material transfers, where physical handoffs between facilities create the highest COI risk. Three specific design requirements apply:

- Inter-site stock transfer orders in S/4HANA must carry the CGTO patient identifier as a batch classification attribute. The COI tag travels with the material through every inter-company and intra-company transfer, regardless of which site's EWM instance manages the physical movement.
- Cold-chain continuity across site transfers requires integration between CGTO, SAP TM, and external temperature monitoring platforms. The continuous temperature log must be associated with the patient's batch identifier and presented as part of the BRH batch release dossier.
- Manufacturing variance management — when a patient's cells fail an in-process specification — must be orchestrated by CGTO without losing the patient identity linkage. CGTO must manage the failed batch disposition, the re-collection request, and the restart of manufacturing, maintaining the patient's COI throughout.

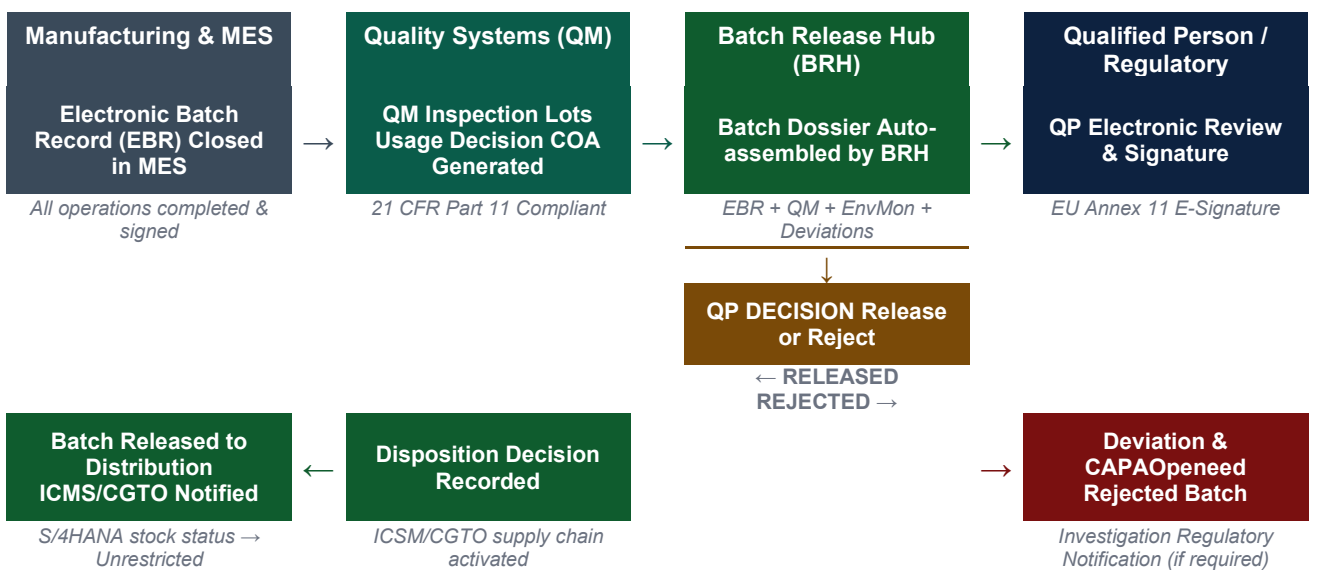
5. BRH — Batch Release Hub Architecture

5.1 The Digital Batch Release Challenge

Pharmaceutical batch release is the regulatory certification by a Qualified Person (QP) that a manufactured batch meets all applicable specifications before it is released for distribution or patient administration. BRH digitises this process — replacing manual paper dossier assembly with automated collection, assembly, and electronic routing.

5.2 BRH Process Flow — Manufacturing to Release

Figure 4 — Batch Release Hub — From Manufacturing Complete to Regulatory Release Decision



BRH assembles the complete batch dossier from four source systems automatically. The QP's electronic signature triggers the S/4HANA stock status change and activates distribution in ICSM or CGTO. The entire process is 21 CFR Part 11 and EU Annex 11 compliant.

5.3 The Four Integration Dependencies That Determine BRH Quality

BRH quality is entirely determined by the quality of data it receives. Four integration points must be precisely designed:

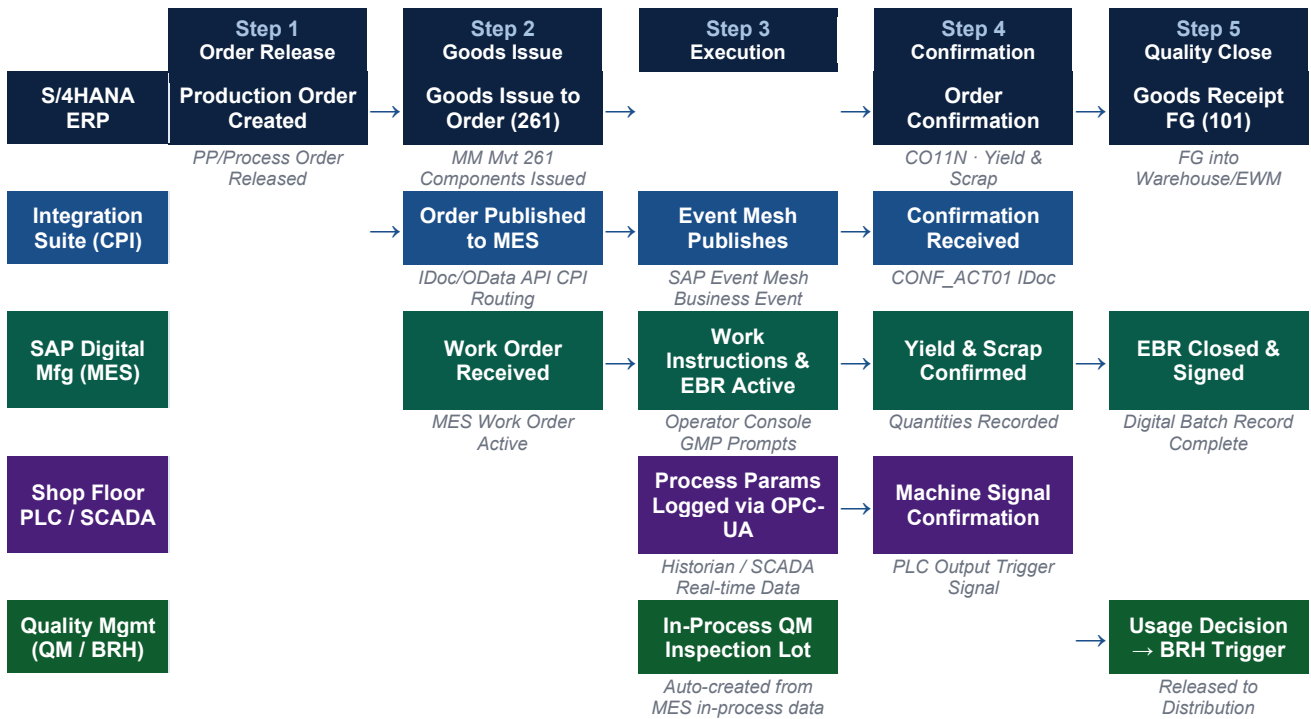
- **EBR:** MES / EBR integration: The Electronic Batch Record must be complete, all operations signed, and no open in-process deviations before BRH can assemble the dossier. BRH must read the EBR closure status as a prerequisite — not assume it.
- **QM:** QM integration: All inspection lots related to the batch must have a final usage decision recorded. BRH reads QM to confirm incoming material, in-process controls, and release testing are all within specification. A single open inspection lot blocks release.
- **Environmental:** Environmental monitoring integration: Temperature, humidity, and particle count records for the manufacturing period must be within GMP specification. This data comes from building management systems and must be integrated via CPI into the BRH dossier.
- **Deviations:** Deviation management integration: Any deviations raised during manufacturing must be formally closed with a disposition decision. BRH must integrate with the deviation management system — typically a standalone QMS platform — to confirm all deviations are resolved before routing for QP review.

6. MES Integration — Manufacturing Execution Architecture

6.1 Production Execution Swimlane

The production execution swimlane illustrates the full scope of interactions between S/4HANA, the CPI integration layer, SAP Digital Manufacturing (MES), the shop-floor PLC/SCADA layer, and quality management across five execution steps. This architecture applies to both pharmaceutical and industrial manufacturing — the GxP regulatory overlay differs, but the integration structure is identical.

Figure 5 — Production Execution Swimlane — Five Systems · Five Steps · Full Bidirectional Flow

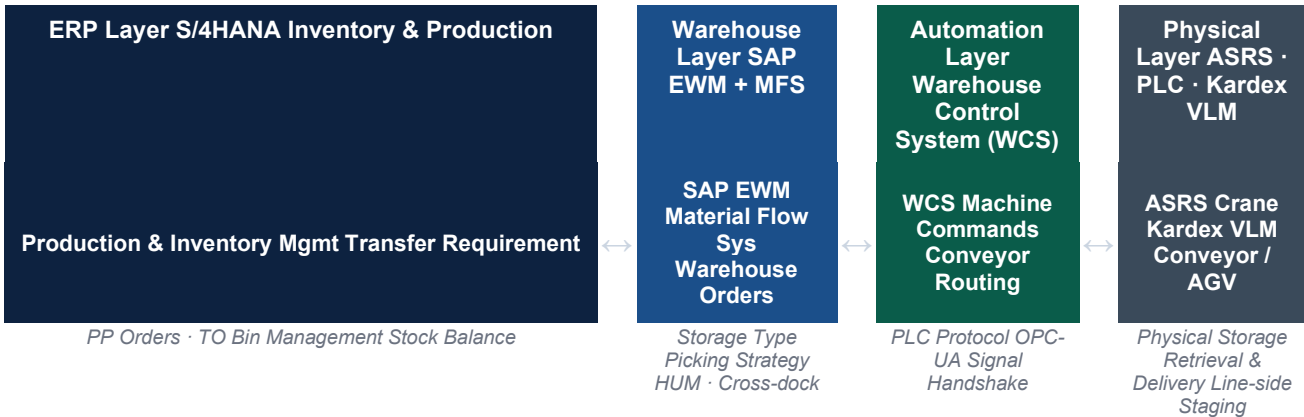


Every arrow in this diagram represents a designed, tested, and monitored interface with defined error handling. In GxP environments, every data exchange must generate a permanent audit trail entry.

6.2 ASRS and Warehouse Automation — The Four-Layer Stack

Automated Storage and Retrieval Systems represent the most technically complex integration boundary in any S/4HANA warehouse automation programme. The ASRS operates at millisecond machine speeds — fundamentally different from the second-scale transactional world of SAP EWM.

Figure 6 — ASRS / EWM / MFS — Four-Layer Integration Stack and Design Boundary



⚠ Critical Architecture Boundary — EWM / WCS Ownership:

EWM owns: logistics logic — what to move, from which source bin, to which destination, in what priority sequence. **WCS owns:** physical execution — which machine receives the command, conveyor routing, crane selection, bin opening. This boundary — particularly bin management ownership and conflict resolution — must be formally documented in an Architecture Decision Record before EWM configuration begins. Discovering it during UAT adds weeks to the programme.

EWM owns logistics logic. WCS owns physical execution. The design boundary between these two layers — particularly bin management conflict resolution — must be formally documented before any configuration begins.

6.3 GxP Overlay — The Five Additional Requirements in Regulated Environments

In pharmaceutical manufacturing, five requirements apply that do not exist in automotive or industrial programmes:

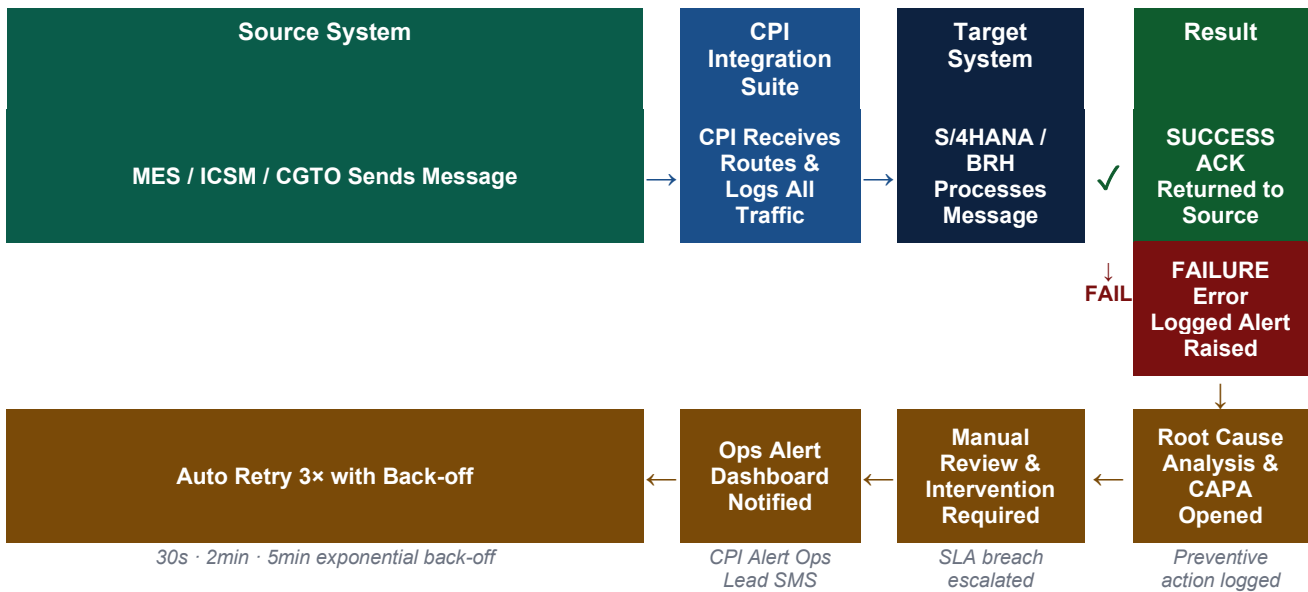
- **e-Signature:** Electronic signatures: Every operation, in-process check, and deviation resolution must be electronically signed with operator credentials and a validated timestamp. 21 CFR Part 11 and EU Annex 11 both require this and both are audited by regulators.
- **Audit Trail:** Audit trail: Every data entry and change in the MES must generate an unalterable audit trail capturing original value, new value, user, date/time, and reason. Deletion of audit trail entries is a critical GxP violation.
- **CSV:** Computer system validation (CSV/GAMP 5): The MES integration with S/4HANA must be formally validated with documented requirements, design specifications, IQ/OQ/PQ test protocols, and formal validation reports signed by QA.
- **Change Control:** Change control: Any configuration or interface change must pass through formal change control before deployment to the production environment. Emergency changes require retrospective documentation and QA approval.
- **Data Integrity:** Data integrity and backup: EBR data must be backed up on a validated schedule with restoration testing at defined intervals. Loss of EBR data for a released batch is a serious regulatory non-compliance event.

7. Error Handling — The Integration Reliability Architecture

7.1 Error Handling Is an Architectural Requirement

In a highly integrated environment where CGTO, ICSM, BRH, MES, and EWM/MFS are all exchanging messages through SAP CPI, a single interface failure at a critical moment can halt a production line, delay a patient's therapy, or create a regulatory non-compliance. Error handling must be as carefully designed as the success paths.

Figure 8 — Integration Error Handling — Detection, Retry, Escalation, and Resolution



Shift-End Reconciliation: Automated comparison of MES-confirmed quantities vs S/4HANA posted quantities at every shift end. Any variance >0.1% triggers an investigation report distributed to plant manager, QA lead, and IT. In GxP environments this is a mandatory regulatory control, not optional.

Three-tier retry logic with exponential back-off. CPI monitoring dashboard provides single-pane visibility across all interfaces. Shift-end reconciliation is a mandatory GxP control in regulated environments.

7.2 Interface Criticality Classification

Figure 9 — Interface Criticality Classification — Three Tiers with Response Requirements

Tier	Interface	Failure Impact	Response Target	Examples
T1 CRITICAL	COI validation · Patient batch release · CGTO stage transition · EBR closure handoff	Patient safety risk. Regulatory non-compliance. Manufacturing halt. Cannot be resolved without incident report.	Alert ≤60 sec. Architect on-call within 5 min.	CGTO→BRH · COI Check · EBR→S4HANA
T2 HIGH	Production order confirmation · Goods issue · QM usage decision · Batch status update	Production delay. Inventory discrepancy. Shift-end reconciliation failure. Requires same-shift resolution.	Alert ≤5 min. Ops lead within 15 min.	CO11N · MM 261 · MIGO 101 · QM lot
T3 STANDARD	OEE data · Environmental monitoring · Process historian · Analytics feeds	Analytics gap. No immediate operational or regulatory impact. Can span one shift.	Alert ≤30 min. Resolved next business day.	OEE stats · EnvMon sensors · KPI feeds

Tier 1 interfaces carry patient safety or regulatory non-compliance risk. Tier 2 interfaces affect production continuity. Tier 3 interfaces affect analytics and reporting. Error handling design must be proportional to the tier.

8. The Ten Architecture Decisions That Determine Outcomes

In a combined CGTO, ICSM, BRH, MES, and EWM/MFS programme, ten decisions consistently determine whether the integration succeeds or requires expensive rework. Every one of these decisions must be made and documented in the blueprint phase.

Figure 10 — Ten Architecture Decisions — What Must Be Resolved in Blueprint

#	Decision	Options	Recommendation
1	Integration middleware	P2P IDoc vs SAP CPI vs native BTP API	SAP Integration Suite / CPI for all cross-system message flows. No point-to-point connections.
2	COI enforcement — who validates patient identity	CGTO only vs CGTO+MES vs all systems	CGTO is master COI authority. MES validates but never writes COI. Hard constraint — not a warning.
3	EBR master — system of record for batch record	MES/SAP DM vs paper hybrid vs S/4HANA QM	SAP Digital Manufacturing as EBR master. QM inspection lots are the S/4HANA representation.
4	EWM/WCS bin management boundary	EWM master vs WCS master vs shared	EWM owns bin assignment logic. WCS owns physical execution. Document in ADR before configuration.
5	Batch number alignment across all systems	Single SAP number vs system-specific vs hybrid	Single SAP batch number as master across S/4HANA, MES, CGTO, BRH. Patient ID as cross-reference.
6	BRH trigger event	Manual trigger vs QM usage decision vs MES EBR closure	Automated: MES EBR closure + QM usage decision = BRH dossier assembly triggered automatically.
7	IRT integration entry point	ICSM direct vs S/4HANA middleware vs manual	CPI middleware with ICSM as receiving system. S/4HANA batch updated as secondary step.
8	Error handling ownership	IT only vs plant ops vs shared model	Shared: CPI monitoring owned by IT. Business impact triage owned by operations. Tier 1 = joint response.
9	Cold chain data — temperature excursion handling	Manual review vs automated API vs CPI	CPI integration from monitoring platform to CGTO. Automatic batch hold on excursion — no manual step.
10	Go-live strategy — all at once vs phased	Single go-live vs ICSM first vs MES first	Design and validate together. If phased, run both in parallel for minimum 4 weeks before cutover.

All ten decisions must be formally made, documented in Architecture Decision Records, and approved by both workstream leads before configuration begins. Deferring any of these to the build phase adds cost and risk.

9. Lessons from the Field

9.1 What Works

- Resolving data ownership in the first blueprint workshop, not after configuration has begun. Every hour spent on ownership design saves ten hours of reconciliation rework in system testing.
- Designing COI validation as a hard constraint in CGTO — an error that prevents the stage transition, not a warning that operators override under production pressure.
- Building the BRH dossier template from a real batch record reviewed by the QP who will sign it. The gap between what BRH assembles automatically and what the QP actually needs is where implementations succeed or fail.
- Running MES-to-S/4HANA interfaces under load test conditions equivalent to peak production volume before UAT. An interface that works at test volumes may fail at production rates. Discovering this in load testing costs days. Discovering it in go-live costs weeks.
- Establishing the CPI monitoring dashboard before go-live, not after. The first week of production generates the highest interface error rate. Without a monitoring dashboard, errors are discovered by plant operators making phone calls to IT.
- Involving the WCS vendor in the EWM/MFS boundary design session. The WCS vendor's technical constraints on what it can and cannot receive from SAP EWM are not in the SAP documentation — they are in the vendor's integration guide, which must be obtained and reviewed in the blueprint phase.

9.2 What Does Not Work

- Treating MES integration as a phase 2 activity. Production order structure, batch classification schema, and QM inspection plan design — made in phase 1 — have direct consequences for MES integration that cannot be easily changed after go-live.
- Allowing CGTO and MES workstreams to develop integration specifications independently. They will make incompatible assumptions about batch number format, status codes, and event triggers unless they work from a shared interface specification from day one.
- Underestimating the computer system validation effort. In a GxP environment, MES integration validation is a regulatory requirement with formal documentation, independent testing, and QA approval. Organisations that discover this in the testing phase face significant programme delays.
- Going live without a tested cutover plan that explicitly addresses how CGTO patient records, ICSM study data, and MES historical data will be synchronised with the live S/4HANA system at the moment of cutover. Data gaps at go-live in a regulated environment are difficult and expensive to remediate.
- Treating BRH as a document management system rather than an integration solution. BRH's value is entirely dependent on the quality of data flowing in from MES, QM, environmental monitoring, and deviation systems. Without those interfaces working correctly, BRH produces an incomplete dossier that cannot be released.

About the Author

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Ram is a Senior SAP Solution Architect with 28 years of end-to-end programme delivery across the complete SAP supply chain and manufacturing stack. He has delivered seven full S/4HANA implementations and supported over twelve clients across automotive, life sciences, cell and gene therapy, chemicals, and oil and gas.

His unique profile spans both domains covered in this paper: he has led MES integration and ASRS/EWM automation architecture on a major UK automotive OEM's S/4HANA programme, and simultaneously delivered CGTO solution architecture for a commercial-scale global biopharmaceutical CDMO operating across three continents. Previous engagements include the world's first global ICSM and BRH implementation at a Top 5 pharmaceutical company, and major S/4HANA programmes at global specialty chemicals and biopharmaceutical organisations.

TOGAF · GxP Computer Validation (FDA / EMA) · S/4HANA EWM · IATF 16949 aware · ISO 9000/14000

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