Cyclotron Department ERP High Level Requirements

1) Purpose & Scope (HLD Summary)

This High-Level Design (HLD) defines a full ERP for a radiopharmaceutical manufacturing facility covering: **online ordering (hospital/clients) → planning → batch production → QC batch release → dispensing into patient doses → pack/ship → financials & compliance**.

In-scope (functional)

- **Online ordering portal**: client ordering, **reservations for future delivery (capacity windows + optional time slots)**, order tracking, notifications
- **Capacity control basis**: reservations consume **dispensing/production time capacity (minutes)**
- Order-to-cash (client orders, invoicing, AR)
- Procure-to-pay (materials, services, supplier quality, AP)
- Inventory & warehousing (radioactive & non-radioactive, controlled storage)
- Manufacturing execution (batch records, routing/steps, yields, deviations)
- Quality management (sampling, lab results, out of spec/trend, **batch-level** release/hold)
- Dispensing & patient-dose fulfillment (**always post-batch release**)
- Logistics (packing, shipping docs, carrier handoff)
- Radiation safety records (waste, decay-in-storage, survey logs — configurable)
- Finance & costing (WIP, batch costing, variances)
- Reporting & audit (traceability, genealogy, audit trail)

Clarifications incorporated

1. **Patient identifiers**: ERP stores **only a pseudonym / hospital order reference** (no direct patient identifiers/details).
2. **Batch granularity**: a **single batch can cover multiple patient doses**.
3. **Dispensing gate**: dispensing occurs **only after batch release**.
4. **QC scope**: QC disposition is **batch-level** (DoseUnits inherit release status).
5. **Reservations model**: **both** capacity windows **and** optional **fine-grained time slots**.
6. **Capacity unit**: reservations and availability are managed in **minutes** on the **dispensing/fulfillment bottleneck resource**.

2) Functional Modules (ERP Capability Map)

2.1 Online Ordering & Engagement

1. **Client Ordering Portal** – Place orders, manage reservations, track status, role-based portal access.
2. **Availability & Slot Management (Minutes-based)** – Maintain ResourceCalendar; publish DeliveryWindows/Slots; enforce minute capacities.
3. **Order Reservations (Minutes-based)** – Reserve capacity; compute minutes via TimeStandard; convert to orders; prevent overbooking.
4. **Notification & Messaging Service** – Event-driven notifications (email/SMS/in-app), templates, subscriptions, delivery logs.

2.2 Foundation/Core

1. **Master Data (MDM)** – Products, recipes/BOM, routes, equipment, locations, customers, suppliers, price lists.
2. **Workflow & Approvals** – Approvals for release, deviations, PO, master-data changes.
3. **Security/IAM & Audit** – RBAC (role based access control), segregation of duties, immutable audit log, e-signature.

2.3 Commercial

1. **Hospital Order Management** – Orders, dose requests, cancellations/replacements.
2. **Contracts & Pricing** – Contract pricing, billing rules, credit limits.

2.4 Supply Chain

1. **Procurement** – RFQ/PO, supplier evaluation, receiving, readiness for 3-way match.
2. **Inventory & Warehouse** – Quarantine/released/expired status, bin control, cycle counts.

2.5 Manufacturing

1. **Planning (MPS/MRP-lite + capacity minutes)** – Production scheduling, material requirement planning, Batch planning + visibility into reserved/committed dispensing minutes.
2. **Batch Manufacturing Execution (eBR)** – Batch records, step execution, parameter capture, yields, deviations.
3. **Engineering Change Control** – Versioning for recipes/routes with effective dates.

2.6 Quality

1. **Quality Management (QMS/LIMS-lite)** – Sampling plans, test specs, results, OOS handling.
2. **Release Management (Batch-level)** – Hold/Release/Reject with e-signature.

2.7 Dispensing & Fulfillment

1. **Dose Dispensing (post-release)** – Create DoseUnits only from released batches; label integration.
2. **Logistics & Chain-of-Custody** – Packing, shipment, custody events, returns/incidents.

24.8 Safety & Waste

1. **Radiation Safety & Waste** – Waste records, decay-in-storage, disposal, safety logs.

2.9 Finance

1. **Finance Core (GL/AP/AR)** – Invoicing, receipts, supplier invoices, posting.
2. **Costing** – Batch costing, WIP, variances.

2.10 Analytics

1. **Reporting & Analytics** – KPIs: reserved vs committed minutes, utilization, release lead time, yield, OTIF.

3) Integration Architecture (high level)

- **Portal ↔ ERP APIs**: availability, reservations, orders, status, notifications.
- **Notification Channels**: Email/SMS gateways; optional Teams for internal alerts.
- **Labeling Systems**: Label print integration (ZPL/PDF) using DoseUnit data.
- **Instruments/Lab**: Optional import of lab results into TestResult.
- **Identity Provider**: SSO/MFA for portal + internal users.
- **Finance**: payment files/reconciliation.

Pattern: **event-driven** (domain events) + **API gateway**; all inbound messages validated and audited.

4) Non-Functional Requirements (NFRs) – concise baseline

- **Availability**: 99% for portal ordering + dispense + ship workflows.
- **Performance**: <2s for common transactions; genealogy query <10s typical.
- **Security**: RBAC, SoD, MFA/SSO, encryption at rest/in transit; tenant isolation by HospitalAccount.
- **Data Integrity**: Immutable audit trail; e-signatures for batch release, deviations, critical changes.
- **Traceability**: end-to-end genealogy from supplier lots to shipped DoseUnits.

5) Phase Roadmap (suggested)

MVP (Phase 1)

- Portal ordering + tracking
- Availability windows (**minutes-based**) + basic reservations
- QC testing + batch release workflow
- Dispensing (post-release), Logistics, AR/AP/GL
- Notifications (email + in-app), audit/e-sign

Phase 2

- TimeStandard (simple minutes per product/dose form)
- Order Mgmt, MDM, Inventory, Batch Mfg (basic eBR)
- Fine-grained DeliverySlots + slot-level minute enforcement
- Advanced capacity planning (finite scheduling)
- Advanced analytics (utilization trends, bottleneck analysis)

Phase 3

- Instrument integrations
- Supplier quality, CAPA
- Full EAM/maintenance
- HR/time
- IoT/machine data
- Optimization