

SOFTWARE TO RUN THE FLOOR

Decay-corrected batch records, conditional release, hot-cell ready.

V5 Ultimate is the AI-assisted operations platform radiopharmaceutical manufacturers use to run the shop floor end-to-end: electronic batching and weighing, in-line quality, lot & pallet traceability, OEE, labour, maintenance, document control, supplier portal — wired to your scales, printers, PLCs and ERP. Rapid onboarding in days, not months.

7-DAY FREE TRIAL

LIVE IN 14 DAYS

AI-ASSISTED

21 CFR PART 11 · 21 CFR PART 212 (PET) · USP <797> / <825> · EU GMP ANNEX 1 · EU GMP ANNEX 11 · ICH Q7 / Q10

One system for the whole radiopharmaceutical floor – not just MES.

V5 Ultimate replaces the patchwork of spreadsheets, paper batch sheets, standalone weighing PCs, separate QA tablets and bolt-on traceability apps with **one platform** that runs production, quality, traceability, maintenance, labour and supplier control from the same data spine. Built for radiopharmaceutical. Designed for the floor.

P

Production

Electronic batching, weighing, recipe execution, scheduling, OEE, downtime & labour — live on the floor.

Q

Quality

In-line checks, CCP/oPRP monitoring, NCRs, CAPA, allergen control, document control, audit-ready records.

T

Traceability

Lot, pallet, ingredient and finished-good genealogy. Recalls in minutes, not days.

Every module your floor needs

16 CORE MODULES · 1 PLATFORM

MAKE

Electronic Batching

Recipe-driven instructions, scale-locked weighing, sub-recipe nesting, scrap & yield in real time.

MAKE

Weighing & Dispensing

Native scale integration (Mettler, Sartorius, Avery, Wedderburn). Operator-proof tolerances.

MAKE

Scheduling & OEE

Drag-and-drop schedule, downtime reasons, live OEE per line, shift handover board.

MAKE

Labour & Shifts

Clock-in at the kiosk, skill matrix, line manning, productivity by team and SKU.

QUALITY

In-line QA Checks

Time/temp, weight, metal detect, X-ray, sensory. Auto-escalate fails. No paper.

QUALITY

HACCP / CCP / oPRP

Live monitoring with validation evidence. Auditor walks to a screen, not a binder.

QUALITY

NCR / CAPA

Auto-routed corrective actions with root-cause prompts and SLA timers.

QUALITY

Allergen & Contamination Control

Changeover validation, sequencing rules, cleaning verification photo evidence.

TRACE

Lot & Pallet Genealogy

Every ingredient, every output, every label. Backward and forward in seconds.

TRACE

Global Traceability

FSMA 204, EU 178/2002, DSCSA, MDR UDI, FSANZ — captured by the system, not the operator.

TRACE

Label & Print Control

GS1, SSCC, EU FIC, UDI, country-of-origin, retailer-specific. Printers controlled by V5.

TRACE

Mock Recall

One-click drill with timing and gap analysis. Retailer technical reviews pass.

RUN

Maintenance & CMMS

PMs, work orders, calibration. Linked to assets, scales and CCPs.

RUN

Supplier Portal

COAs, specifications, approval status, raw-material verification — all online.

RUN

Document Control

SOPs, work instructions, training sign-off — current version on every kiosk.

RUN

Reports & ERP

Live dashboards. SAP, NetSuite, Sage, MS Dynamics, Oracle — bidirectional.

Faster decisions. Faster go-live.

AI is woven through V5 — not bolted on. It triages quality issues, predicts yield drift, drafts CAPAs, summarises shifts and answers operator questions in plain English on the kiosk. And because the platform ships pre-configured for radiopharmaceutical, you go live in days.

AI INSIDE

Ask V5 — the AI co-pilot for your floor

Operators, supervisors and QA managers ask V5 in plain English. V5 answers from your real production data, your SOPs and your audit history — instantly.

- ▶ **Yield prediction** — flags the SKU/line/shift drifting toward a giveaway loss before it lands on the P&L.
- ▶ **QA triage** — auto-classifies in-line failures, suggests root cause, drafts the CAPA and assigns it.
- ▶ **Shift summary** — a one-page brief at every handover: production, downtime, NCRs, what's at risk.
- ▶ **Operator co-pilot** — "Where's my next changeover?" "What's the next step?" — answered at the kiosk.
- ▶ **Audit prep** — V5 assembles the audit pack from live records, mapped to your regulators and certification bodies.

Live in 14 days

RAPID ONBOARDING PROGRAMME

- Days 1–2 · Kick-off & data import**
SKUs, BOMs, recipes, suppliers, scales, printers, users — imported from your ERP and spreadsheets.
- Days 3–5 · Configure & connect**
Kiosks online, scales paired, printers calibrated, ERP link tested, QA templates loaded.
- Days 6–9 · Pilot line live**
One line on V5, end-to-end. Real batches, real labels, real traceability. Operators trained at the kiosk.
- Days 10–12 · Roll across the floor**
Remaining lines added. Daily standup with CSM. Reports tuned to your management cadence.
- Days 13–14 · Handover & audit-ready**
System owner trained. Mock recall passed. Evidence pack generated for your standards.

Audit-ready out of the box — globally

Evidence packs pre-mapped to the standards your regulators, customers and certification bodies require — across the UK, EU, North America, Australia & APAC.

US 21 CFR Part 11

US 21 CFR Part 212 (PET)

US USP <797> / <825>

EU EU GMP Annex 1

EU EU GMP Annex 11

ICH ICH Q7 / Q10

REG NRC / IAEA

AUDIT Nuclear safety

AUDIT Data Integrity ALCOA+

ISO ISO 9001

EU Euratom 2013/59

TRACE Batch genealogy

AUDIT GMP for short half-life

CA CNSC

UK MHRA / EA

AU/NZ ARPANSA

14d

AVERAGE GO-LIVE

7d

FREE TRIAL

16

CORE MODULES

<60s

MOCK RECALL

Run your floor on V5 – by next Friday.

Free 7-day trial on your own data and your own lines. No credit card. No commitment. Your CSM stands up a pilot line with you and your team on day one. If it doesn't run your floor better than what you have today, walk away.

START THE 7-DAY FREE TRIAL

BOOK A 30-MINUTE DEMO

V5ULTIMATE.COM · START YOUR 7-DAY FREE TRIAL – NO CREDIT CARD

WHY V5 ULTIMATE

Six things every radiopharmaceutical operator notices in the first week

01

Built-in isotope master

Pb-212, Ac-225, Lu-177, F-18, Tc-99m, Ga-68, I-131 and more — half-lives, decay modes, default shelf-lives all wired in. Decay correction $A(t) = A_0 \cdot e^{(-\lambda t)}$ at every read, no spreadsheets.

02

Calibration-time batch record

Every work order carries a calibration datetime. The BMR records activity AT calibration; every later read auto-decays from there.

03

Conditional release with forced close-out

Per 212.70(d) — release the dose for patient use before sterility testing completes, with a system-enforced retroactive sterility sign-off that ties back to the original batch and operator.

04

Patient unit-dose dispense

One synthesis, many patient doses. Each dose has its own calibration time, syringe ID, and decay-corrected activity at injection — captured live, signed by the dispenser.

05

AI does the busywork

Triages NCRs, drafts CAPAs, summarises shifts, predicts yield drift before it hits the P&L.

06

Your ERP gets clean data

Bidirectional with SAP, NetSuite, Sage, MS Dynamics, Oracle. No more midnight reconciliations.



V5 replaced three systems and a filing cabinet. Our last audit took half the time, and the auditor walked to a screen – not a binder.

TECHNICAL MANAGER

Global manufacturer · V5 Ultimate customer

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