



SOFTWARE TO RUN THE FLOOR

An electronic batch record an inspector could sign off on.

V5 Ultimate is the AI-assisted operations platform pharmaceutical 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 210/211 · EU GMP ANNEX 11 · ICH Q7 · ICH Q9 · ICH Q10

One system for the whole pharmaceutical 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 pharmaceutical. 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

H MAKE

Electronic Batching

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

M MAKE

Weighing & Dispensing

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

C MAKE

Scheduling & OEE

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

P MAKE

Labour & Shifts

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

Q QUALITY

In-line QA Checks

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

S QUALITY

HACCP / CCP / oPRP

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

C QUALITY

NCR / CAPA

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

A QUALITY

Allergen & Contamination Control

Changeover validation, sequencing rules, cleaning verification photo evidence.

T TRACE

Lot & Pallet Genealogy

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

C TRACE

Global Traceability

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

M TRACE

Label & Print Control

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

C TRACE

Mock Recall

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

M RUN

Maintenance & CMMS

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

H RUN

Supplier Portal

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

D RUN

Document Control

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

L 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 pharmaceutical, 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 210/211

EU EU GMP Annex 11

ICH ICH Q7

ICH ICH Q9

ICH ICH Q10

WHO WHO TRS

ISO ISO 9001

US FDA DSCSA

EU EU FMD

EU EU GDP

AUDIT MHRA / EMA / PMDA

US ANVISA

AUDIT Data Integrity ALCOA+

AUDIT GAMP 5 / CSA

ISO ISO 22716

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 pharmaceutical operator notices in the first week

01

Immutable MBR, live BMR

Approved master records snapshot into every work order. The batch record is the master — executed and signed live.

02

Two-signature approvals

Preparer + independent reviewer e-signs on every approved formula, per 211.186 / 111.205.

03

Forward & backward genealogy

From API CoA to finished pack, in seconds. Recall scope in one query.

04

ALCOA+ data integrity

Every record is attributable, legible, contemporaneous, original, accurate — and complete, consistent, enduring, available.

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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