SOFTWARE TO RUN THE FLOOR

Every device ships with a complete, signed Device History Record.

V5 Ultimate is the AI-assisted operations platform medical device 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

ISO 13485:2016 · 21 CFR PART 820 / QMSR · EU MDR · EU IVDR · ISO 14971 · IEC 62304

01 · THE PLATFORM

One system for the whole medical device floor — not just MES.

01

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 medical device. 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.

02 · AI & RAPID ONBOARDING

Faster decisions. Faster go-live.

02

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 medical device, 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

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

ISO ISO 13485:2016 · US 21 CFR Part 820 / QMSR · EU EU MDR · EU EU IVDR · ISO ISO 14971 · IEC IEC 62304 · US 21 CFR Part 11 · AUDIT MDSAP · UK UK MDR · AU/NZ TGA · CA Health Canada MDR · JP PMDA · BR ANVISA · AUDIT UDI / EUDAMED · ISO ISO 11607 (Sterile) · AUDIT Design History File

14d	7d	16	<60s
AVERAGE GO-LIVE	FREE TRIAL	CORE MODULES	MOCK RECALL

03 · START THIS WEEK

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 medical device operator notices in the first week

01
Self-building eDHR
Every serialized unit gets a signed, immutable record of materials, operators, equipment, and in-process checks — assembled in real time.

02
Hard-gated routings
Operators cannot advance to the next step until the prior step is signed, in-spec, and within design control limits.

03
UDI at point of build
DI + PI captured and printed at the workstation; reconciles to FDA GUDID.

04
Training enforcement
Operators are blocked from steps they aren't currently certified for. Training records ride with the DHR.

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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