MESvantage DESIGNED AGAINST 21 CFR PART 11 · BUILT IN AN ISO 13485 PLANT · ORTHOPAEDIC IMPLANTS

The manufacturing intelligence platform for medical device CDMOs.

Built inside a live 250,000-knee-a-year orthopaedic plant in Ireland, and validated there for that site's intended use under their ISO 13485 quality system. Not a pilot and not a demonstration — the system that plant runs on.

250,000
KNEE SYSTEMS A YEAR
The plant it was built in

74
MODULES
Six domains, as sold

226 / 226
VALIDATION TESTS PASSED
March 2026, at the founding customer

175 / 175
REQUIREMENTS TRACED
In the traceability matrix

PLATFORM MODULES — SIX DOMAINS

DOMAIN 01
Quality
FAI, FPY, SPC, DHR, NCR, CAPA, Incoming Inspection, Customer Quality Portal. Every record electronically signed and audit-ready.

DOMAIN 02
Production
Real-time OEE, scheduling, and in-process documentation. Paper travellers eliminated. Shift handover in one screen.

DOMAIN 03
Metrology
Automatic CMM parsing from Renishaw, Hexagon, and Zeiss. Tolerance failures flagged before the part leaves the machine.

DOMAIN 04
Training
Operators can only run what they are trained on. Competency expiry, trainer sign-off, and enforcement automated.

DOMAIN 05
Intelligence
CEO dashboard: machine utilisation, quality trends and energy spend, with threshold alerting. No BI team or data analyst required.

DOMAIN 06
Platform
Mobile PWA, digital signage, audit trail, e-signatures, role-based access. The regulated infrastructure layer.

WHY MESVANTAGE

Purpose-built for CDMOs

Not a generic MES retrofitted to medical. Every workflow — DHR, FAI, CMM, OEE, NCR — was designed for regulated contract manufacturing.

Validation you execute

IQ/OQ/PQ executed at our founding customer's site under their quality system. You still own validation — no supplier can discharge it. We supply protocols, scripts, the traceability matrix and executed reference evidence so your team executes rather than authors.

Production-grade from day one

Running daily in an orthopaedic plant that is FDA-registered and ISO 13485-certified — the plant's credentials, not ours. Every feature in the validated scope has run on a real production floor — not a lab, not a sandbox.

OUR COMPLIANCE POSITION

FDA 21 CFR Part 11

Full audit trail on every record change. Electronic signatures with intent capture. Access control and session management built in.

ISO 13485

DHR, traceability, incoming inspection, CAPA, and document control aligned to ISO 13485 quality management requirements.

Siloed SaaS

Each customer has their own compute, database, and storage. No data co-mingles across customers — a compliance feature, not a limitation.

IMPLEMENTATION TIMELINE — FIRST SIGNED TRAVELLER IN 10–14 WEEKS

Weeks 1–4	Environment provisioned. Data migration from ERP (M1, SAP, Plex, Infor). Quality module configured. Staff onboarding begins.
Weeks 5–10	Production, OEE, and training modules live. CMM integration connected to existing metrology hardware. Parallel run vs. legacy system.
Weeks 11–13	Intelligence and reporting live. Legacy system retired. IQ/OQ/PQ documentation package delivered. Go-live sign-off.

FOUNDING CUSTOMER

> *"We spent two years looking for an MES that understood a knee. Everything we found was a QMS pretending to be an MES, a platform we would have had to build ourselves, or a two-year programme priced for a company ten times our size. So we built it, we validated it, and we ran our plant on it."*
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> **Patrick Byrnes, CEO — Croom Medical · ISO 13485 · FDA 21 CFR Part 11 · 250,000 knee systems/year**