

From Prototype to Production

How to scale your MedTech manufacturing business

SUMMARY

What SMEs (10–250 employees) need to move from prototype to full-scale production in an innovative, compliant, and sustainable way.

AUDIENCE

Startups approaching commercialization and SMEs scaling production

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CHAPTER 01

MedTech market drivers

The U.S. is projected to generate the highest revenue in the global medical technology market. Around 6,500 medical device manufacturers are operating today — from global incumbents to seed-stage startups.

Worldwide MedTech revenue is expected to surge from ~\$681B in 2025 to nearly \$955B by 2030. In 2023, the FDA approved a record 124 devices and processed 19,100 submissions.

Aging populations, chronic disease prevalence, preventative healthcare, and the consumerization of medicine are driving sustained demand. AI, IoT, 3D printing, and robotics are reshaping what's buildable.

CHAPTER 02

The opportunity for SME manufacturers

Smaller manufacturers have agility, fast decision-making, and founder hunger on their side. What they often lack are established workflows, skilled teams, and the technology needed to fulfill orders while meeting FDA and ISO standards.

With centralized data, clear document management, and automation, SMEs can move at speed and mitigate scale-up risk — staying lean while competing globally.

CHAPTER 03

Top challenges for medical device manufacturers

- Regulatory compliance — FDA, EU MDR, UKCA
- Design for manufacturability and process development
- Quality assurance through every production stage
- Supply chain — material flow and supplier relationships
- Scalability — production volumes without losing compliance

CHAPTER 04

Tools for the job

Beyond CAD and CAM, the missing piece for most SMEs is a system that manages production and business processes efficiently — removing paper push and automating compliance and quality workflows.

Quality control becomes less error-prone with a centralized ERP data layer. Buyers and planners can forecast accurately. Reporting supports continuous improvement at every level, from shop floor micro-efficiencies to diversification strategy.

CHAPTER 05

Why Expandable

Expandable ERP supports innovation and compliance with proven, industry-specific functionality. Real-time performance data drives better decisions; embedded compliance reduces risk; and a modular footprint grows as you do.

WANT A WALKTHROUGH?

We map these capabilities to exactly where you are in your FDA journey. No slides — just your process. Visit expandable.com/contact.