WHITEPAPER · FIELD LIBRARY VOL. 01

ERP Strategies to Navigate Compliance in MedTech

From clinical trials to approval to launch

SUMMARY

The ERP features fast-growing MedTech companies need for market readiness, and why software designed specifically for MedTech is non-negotiable.

AUDIENCE

Lean startups approaching commercialization and SMEs scaling production

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CHAPTER 01

Your pathway to FDA approval

There are three regulatory pathways depending on risk class. Class I (low risk) products like non-electric wheelchairs typically don't require Pre-Market Approval. Class II (moderate risk) such as syringes and catheters usually does. Class III (high risk) — pacemakers, implants — is subject to PMA under Part 814.

Average development takes 36 months for standard devices and up to 114 months for complex ones. PMA review can take up to 180 days. Every month of delay is lost market opportunity.

CHAPTER 02

What to include in your submission

- Clinical trials data — inclusion criteria, study period, device failures, statistical analyses
- Documentation — device descriptions, manufacturing processes, facilities, and controls
- Labeling — copies of all proposed labeling and installation instructions

CHAPTER 03

Traceability and audit trail

Every process must be carefully documented and controlled by authorized personnel to ensure it doesn't deviate from Good Manufacturing Practices. Your ERP should provide full forward and backward traceability of serialized and lot-controlled items, from raw material receipt to a finished product's final destination.

Automatically recording activity with time stamps and user IDs lets you prove GMP was followed — and surface any deviation instantly.

CHAPTER 04

Essential ERP features for MedTech

- Full forward & backward lot/serial traceability from raw material to patient
- Automatic audit trail with time stamps, user IDs, and references

- Built-in quality modules (SOPs, CAPA, NC, 8D, CoA/CoC) pulling live production data
- Surgical kit / consignment tracking with unique IDs and expiration management

CHAPTER 05

Why Expandable checks every box

Expandable ERP was developed specifically for the MedTech industry. The features above ship as standard — no custom code, no workarounds that undermine GMP. One click reveals exact part origin and patient receipt; every transaction is audit-ready by default.

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.