COMPLIANCEQUEST

# Production finished.
# So why isn't your product ready to ship?

Most medical device manufacturers measure production efficiency. Few measure what accumulates after production is complete. **Your bottleneck may no longer be manufacturing — it may be the batch record.**

### WHERE TIME, RISK AND COST ACCUMULATE AFTER PRODUCTION


## THE PAPER TAX NOBODY TALKS ABOUT

On paper, documentation looks inexpensive. In reality, it creates costs across your entire operation.

UP TO
**10 hours**
of productivity lost per day*

**Hundreds of hours**
spent on documentation every month

**Thousands of labor hours**
dedicated to paperwork instead of production

**For a facility with 20 operators**

**Manufacturers report operators spending 10–30 minutes per day searching for documents, completing paperwork, or managing production records.*

## THE REAL HIDDEN COSTS OF PAPER BATCH RECORDS

### 1 RELEASE DRAG

Quality teams spend days reviewing signatures, inspections and production records before a lot can be released. Manufacturing is complete — revenue generation isn't.

**The real cost:**
Delayed shipments, higher inventory holding costs, longer cash conversion cycles.

### 2 QA REVIEW BURDEN

Every page, every signature and every entry is reviewed manually — hunting for missing approvals, incomplete records and data-entry mistakes.

**The real cost:**
Quality resources consumed by paperwork rather than prevention.

### 3 PAPER-SPEED INVESTIGATIONS

When an audit finding, complaint, deviation or recall lands, answering "what happened?" means searching files, spreadsheets, binders and disconnected systems.

**The real cost:**
Slower root-cause investigations, longer CAPA cycles, higher compliance risk.

### 4 LATE DISCOVERY OF ERRORS

Handwritten entries, transcription errors, missing signatures, wrong lot numbers, skipped steps — most are found after production is finished. **The real cost: more deviations, rework, investigations and nonconformances.**

### 5 TRIBAL KNOWLEDGE DOESN'T SCALE

Experienced operators compensate for documentation gaps — until production expands, a second site opens or work is outsourced. **The real cost: execution varies by shift, site and operator.**

## THE COMPLIANCE REALITY

Medical device manufacturers must maintain Device History Records for each batch, lot or unit, demonstrating the device was manufactured according to approved requirements (21 CFR 820.184).

FDA's QMSR now aligns more closely with ISO 13485:2016, increasing focus on controlled, traceable and auditable manufacturing processes.

**Paper proves what happened. Electronic batch execution enforces and captures evidence while it happens.**

*Source: FDA.gov, law.cornell.edu*

## FROM DOCUMENTING TO PREVENTING

### TRADITIONAL APPROACH

CAPTURE → REVIEW → FIND ERRORS

Errors are found late. Rework is inevitable. Release is delayed.

VS

### MODERN EBR APPROACH

GUIDE → VERIFY → FLAG EARLY → REVIEW BY EXCEPTION

Issues are prevented early. QA focuses on what matters. Release is accelerated.

## THE BUSINESS IMPACT

**50–80%**
FASTER BATCH REVIEW

**50–90%**
LESS QA REVIEW EFFORT

**35–70%**
SHORTER RELEASE CYCLES

**15–40%**
FEWER DEVIATIONS

**60–75%**
FASTER INVESTIGATIONS

**80–100%**
REDUCTION IN MANUAL ERRORS

*Outcomes vary based on process maturity, product complexity and level of automation.*

**The biggest cost of paper records isn't paper.**

- It's delayed releases.
- It's investigation time.
- It's quality resources tied up in reviews.
- It's execution problems discovered after production is complete.

The manufacturers gaining the greatest advantage aren't simply replacing paper.

**They're turning batch records into a real-time manufacturing control system.**

COMPLIANCEQUEST

**How much is paper really costing your operation?**

Discover how BatchQuest helps medical device manufacturers accelerate batch review, improve traceability, reduce deviations, and release products faster through real-time batch execution.

REQUEST A DEMO