

5 Forces Reshaping Regulated Life Sciences Operations

Medtech and biotech answer to different regulators — the same operational math is catching up with both.



1

Regulatory burden is growing

The paperwork isn't just longer — it's the first place a submission stalls in review.

3,000+
IDE PAGES

2

EUDAMED is now mandatory

A hard EU deadline for traceability data most teams still track by hand.

4 of 6
MODULES MANDATORY

3

Supply-chain disruption hits the P&L

One weak link in the chain can quietly erode margin for years to come.

25%
OF EBITA AT RISK

4

Production is the moment to build it right

The processes you build now decide how fast — and how cheaply — you scale later.

38%
FASTER TECH-TRANSFER

5

Manual processes don't scale

What works by hand at pilot scale breaks down the moment volume multiplies.

45,000
MANUAL ENTRIES

THE PATTERN Five different pressures, one shared cause: complexity is outrunning manual operations.

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