



Case Study 6: Compliance vs. Shortcuts in ECG Monitor Manufacturing

Two companies—Company A and Company B—manufactured portable ECG monitors. Company A partnered with Compliance Insight to implement and maintain a robust quality system aligned with 21 CFR Part 820. Company B, in contrast, took shortcuts to reduce costs.

Initially, Company B's strategy seemed effective. But two years post-launch, their devices were recalled due to malfunctions. The fallout included customer complaints, negative press, and an FDA inspection that uncovered severe compliance failures—missing records, incomplete CAPAs, and systemic gaps. The result was a 483 followed by a warning letter.

Company A, supported by Compliance Insight, demonstrated consistent performance, passed their FDA inspection without issue, and earned strong market credibility.

Key Takeaway: Cutting corners in quality management leads to long-term failure. With Compliance Insight's support, adherence to 21 CFR Part 820 ensures reliability, customer satisfaction, and regulatory success.