

Automated Compliance Reporting for Global Medical Device Operations

How Elekta transformed regulatory reporting and de-risked global operations with automated compliance intelligence from Peraison



Executive Summary

Elekta, a global leader in cancer care solutions, operates in one of the most tightly regulated industries in the world. Their medical equipment is deployed across hospitals in multiple jurisdictions, each governed by rigorous frameworks.

Before partnering with Peraison, Elekta relied on manual processes to prove device compliance, generate mandated reports and detect emerging risks. Peraison delivered an automated compliance monitoring platform that transformed weeks of manual effort into real time compliance intelligence. The impact was immediate: reduced audit risk, faster issue resolution, and a step change in confidence across the business.

Medical device manufacturers face intense scrutiny. To remain in market, Elekta must comply with:

- EU Medical Device Regulation (EU MDR) requirements
- US FDA regulation and quality system expectations
- ISO 13485 quality management standards
- MDSAP audits

Non-compliance in any region could result in equipment shutdown across all client sites. All devices deployed at client site generate continuous logs and event alerts. Demonstrating compliance meant manually aggregating large volumes of operational data. The manual process was inefficient, difficult to scale and carried reputational and financial risk.

Elekta needed a proactive and automated way to monitor device performance, detect early warning signs and generate mandated regulatory reports without relying on manual spreadsheets or fragmented workflows.

The Challenge



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The Solution

Peraison built and operates a compliance monitoring platform that:

- Consolidates logs and issue alerts from all deployed machines
- Generates automated KPIs that show the compliance status of each device
- Detects early indicators of potential compliance failures
- Produces regulatory PDF reports, removing manual effort entirely
- Embeds data governance and consistent definitions across teams

By replacing Excel based workflows with governed analytics, Elekta gained a controlled and reliable compliance environment. Peraison continues to host and support the platform, acting as an extension of Elekta's internal teams and ensuring the system remains stable, scalable and audit ready.

The Impact

- **Weeks of manual work reduced to near zero** through full automation of compliance reporting.
- **Lower audit and regulatory risk** due to consistent, governed data and transparent lineage.
- **Proactive risk identification** enabling issues to be resolved before they threaten compliance.
- **More time for high value work** as internal teams are freed from manual administration.

Elekta now manages compliance with confidence, supported by real time insight that keeps vital medical equipment safely in operation across the world.



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