
STRENGTHENING COMPLIANCE AND MITIGATING LIABILITY FOR MEDICAL DEVICE MANUFACTURERS

The Growth of Data Demands Responsibility

As the implantable device industry growth surges to an estimated **\$153 billion by 2026**¹, so too has the growth of data managed by healthcare organizations, **increasing 900% since 2016**². Additionally, this growth is also accompanied by heightened regulatory and compliance requirements such as US HIPAA and HITECH regulations, new data guidelines from HHS and the FTC, and a number of broader, cross-industry regulations such as GDPR and CCPA. In this challenging environment, it's critical for medical device manufacturers to more fully grasp the detailed **data chain of custody** surrounding their business processes, tracking **precisely** how data is captured, used and secured over the data lifecycle. Given the mandate of new industry regulations, organizations must now plan to meet 100%, not 99.99% of data chain of custody requirements.

Within the medical device industry, two obvious examples come to mind illustrating the importance of data chain of custody. First, given the sensitive nature of personal health data, **protecting patient privacy** is of critical importance. Second, to **save human lives** and **reduce product liability risks**, the data associated with a device not performing as designed (how it performed in the field, how it was manufactured) must be **traceable** across that device's lifespan in a timely and rigorous manner.

Protecting Patient Privacy

Data breaches cost the healthcare industry **\$4 billion**³ in 2019. It is imperative to protect personal privacy data, which is what the data chain of custody does. The data chain of custody is founded on two principles: data lineage and data provenance. **Data lineage** is the ability to understand where data is coming from, where it is going, and what transformations are applied to it as it flows through multiple processes. **Data provenance** is the ability to understand data strictly in terms of how it was derived from the original data sequence in the original source databases. Understanding where the data came from, who has touched it, and who has access to it enables personal privacy protection measures.

Saving Lives and Reducing Product Liability Risks

Medical device recalls reached historic levels in 2018⁴. McKinsey estimates that manufacturers experience as much as a **10% decrease in share prices following a major recall**⁵, amounting to huge losses. Can you imagine the power to change this by identifying a device's in situ performance to understand if it is defective, or more importantly, if it was just this device or a whole series of devices? The ability to leverage the data chain of custody to understand root cause effects, whether they apply to one device or a batch, has huge implications on making the decision to recall one, many, or all devices currently in use. A wrong decision is a costly decision.

With the appropriate data privacy and traceability measures in place, a forensic approach can be taken to tracing data back to a single device and moment in time. For medical device manufacturers, these capabilities are critical to credibility and financial health.

What Cloudera Offers Medical Device Manufacturers

Cloudera's real-time streaming analytics platform helps medical device manufacturers easily capture, combine, secure, and drive insights on data feeds from device sensors, bio-monitors, and other connected IoT devices. This data is then stored, analyzed, and used to build machine learning models.

Cloudera helps build greater trust in your data through enhanced data security, compliance, and product traceability, allowing medical device manufacturers to:

DATA SECURITY AND COMPLIANCE	PRODUCT TRACEABILITY
<ul style="list-style-type: none">• Protect data assets by monitoring access and usage• Leverage enterprise knowledge• Create and view multiple dashboards, reports and summarizations of data providing the right data to the right people• Curate and group data based on different characteristics to provide the right data to the right people• Contextualize data by adding classifications and notifications• Mitigate product, financial, and legal risks	<ul style="list-style-type: none">• Understand sources and complete chain of custody for all data (lineage and impact)• Locate and catalog all data globally to produce one source of truth• Reduce risk through greater visibility into data lineage• Gain total visibility through product lifecycle: design, manufacturing, product performance, possible issues in the field• Mitigate product, financial, and legal risks thus increasing the value of medical devices and improved patient outcomes

Cloudera's next generation cloud, hybrid or on-prem data management platform drives AI, machine learning and predictive analytics, enabling organizations to make better decisions across historical and real-time patient health and device manufacturing data. Our solutions enable medical device manufacturers to comply with health and data regulations, protecting patients' health and privacy while mitigating potential liabilities. That's why **70% of the top 100 global manufacturers run on Cloudera.**

In other words, Cloudera can help turn challenges into opportunities and risks into rewards.

About Cloudera

At Cloudera, we believe that data can make what is impossible today, possible tomorrow. We empower people to transform complex data into clear and actionable insights. Cloudera delivers an enterprise data cloud for any data, anywhere, from the Edge to AI. Powered by the relentless innovation of the open source community, Cloudera advances digital transformation for the world's largest enterprises.

¹"Implantable Medical Devices Market Size US\$ 153.8 Bn by 2026." <https://www.acumenresearchandconsulting.com/implantable-medical-devices-market>. Accessed 28 Feb. 2020.

²"Organizations See 878% Health Data Growth Rate Since 2016." 8 May. 2019, <https://hitinfrastructure.com/news/organizations-see-878-health-data-growth-rate-since-2016>. Accessed 28 Feb. 2020.

³"Data Breaches Will Cost Healthcare \$4B in 2019, Threats ..." 5 Nov. 2019, <https://healthitsecurity.com/news/data-breaches-will-cost-healthcare-4b-in-2019-threats-outpace-tech>. Accessed 11 Mar. 2020.

⁴"Medical device recalls reach historic levels in 2018 with ..." 9 May. 2018, <https://www.fiercehealthcare.com/tech/medical-device-recalls-software-fda-cybersecurity>. Accessed 28 Feb. 2020.

⁵"The Business Case for Medical Device Quality - McKinsey." https://www.mckinsey.com/~media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_busine_case_for_medical_device_quality.ashx. Accessed 28 Feb. 2020.



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