



BrightInsight, Inc.
A trusted healthcare
technology leader.

The healthcare sector has emerged as one of the easiest targets for hacking due to weak and obsolete security systems.¹ In 2018, the Department of Health and Human Services' Office for Civil Rights (OCR) reported 351 data breaches resulting in the exposure of over 13 million healthcare records.²

In a time where healthcare hacks are in the headlines daily, you cannot afford a data breach. Besides the damage to a company's reputation and credibility, there are significant financial penalties associated with breaches.

Biopharma and medtech companies wouldn't accept a sub-par security, privacy, regulatory or quality system for their traditional drugs or devices, and the same rigor should be applied to their digital health offerings.

As the leading regulated Internet of Things (IoT) platform for biopharma and medtech, BrightInsight has achieved the upmost privacy, security, regulatory and quality certifications to minimize customer risk and protect sensitive health information.

BrightInsight, a Flex Company, provides the leading global regulated digital health platform for biopharma and medtech.

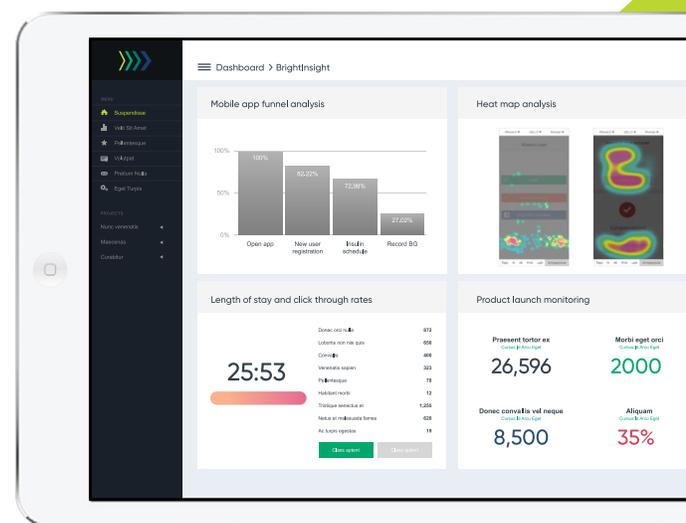
Our medical-grade IoT platform is built under a Quality Management System (QMS) to support and optimize regulated drugs, devices and software through integrated data and actionable insights to enable customers to drive increased patient adherence and engagement.

Our mission is to make digital health innovation easy for our customers through our end-to-end digital health capabilities and scalable, medical-grade platform. Together, our leadership team brings over 85 years of combined digital health experience in the biopharma and medtech industries.

Flex helps their customers transform ideas into intelligent products for a connected world. With approximately 200,000 employees in thirty countries, Flex provides innovative design, engineering, manufacturing, supply chain insights, and logistics services to a global customer base across every major industry, including healthcare.

For over 30 years Flex has worked with leading healthcare companies deploying over 100 regulated hardware and software medical products worldwide. Flex Health Solutions is audited an average of 15 times per month, or roughly every other day by its healthcare customers.

As a Flex company, BrightInsight taps into this regulated healthcare expertise.



1. <https://www.infiniteresearch.com/thoughts/top-5-healthcare-breaches-far>
2. <https://www.hipaajournal.com/largest-healthcare-data-breaches-of-2018>

BrightInsight™ Platform

A managed service IoT platform to minimize customer risk

The BrightInsight™ Platform uses software and services to capture, transmit and analyze data from CE-marked and FDA- regulated medical devices, combination products, apps and Software as a Medical Device, in compliance with security, privacy and regulatory requirements.

Deployed as a managed service, the platform accelerates the time to market for biopharma and medtech companies, reduces the cost of implementation and maintenance versus a custom solution, and scales across products and global markets.

BrightInsight is built from the ground up to securely manage highly regulated medical device data and personal health information and is designed to support up to Class III medical device and combination product intended uses.

Our products regularly undergo independent verification of quality, security and privacy controls and we have achieved and maintain the gold standard in industry certifications to meet our customers' requirements.



Quality

BrightInsight, Inc. is ISO13485:2016 certified, demonstrating that we operate a cutting-edge QMS for software development services. Our QMS is built to support up to Class III and combination product intended uses.

With experience launching digital health products for biopharma and medtech companies, the BrightInsight team is adept at navigating complex and evolving regulatory environments on a global scale. In the US, the BrightInsight Platform Device Master File has been accepted by the FDA, reducing the regulatory burden for our customers by directing any FDA questions related to the BrightInsight digital health platform to the BrightInsight team, not our customers.

As a result, our regulatory managed service helps relieve the regulatory headaches that digital therapeutics carry with them related to the software system.

In addition to scheduled audits and inspections by certification providers or regulatory bodies, we regularly respond to audits by our biopharma and medtech customers in these key areas:

- ▶ Management Responsibility, such as training and resource allocation
- ▶ Feedback and Complaint Management, such as support escalation and corrective action
- ▶ Design Controls, such as management of risk or software verification and validation testing



Security

The BrightInsight Platform is built from the ground up to securely manage and protect highly regulated medical device data and personal health information (PHI). The Platform applies the Security-by-Design principle and Defense-in-Depth best practices and built the entire BrightInsight software stack with security in mind for the whole software development lifecycle. Furthermore, the security framework applied to secure our platform leverages established global security standards and frameworks including over 350 technical and operational security and privacy controls to safeguard customer data.

Our managed service for data privacy includes robust privacy policies and procedures, implementation of automated processes to decouple sensitive personal information from other health data, operational procedures for protecting our customer's PHI, complemented with ongoing employee trainings to safeguard customer's information.

We regularly respond to audits by our biopharma and medtech customers in these key areas:

- ▶ Security Certifications, such as HITRUST
- ▶ HIPAA Compliance
- ▶ Cloud Security Strategy
- ▶ Incident Response



Privacy

Our managed service for data privacy includes privacy policies and procedures, implementation of automated processes to decouple sensitive personal information from other health data, operational procedures for protecting Personal Health Information (PHI), and monthly employee trainings to safeguard customer's information.

We regularly respond to audits by our biopharma and medtech customers in these key areas:

- ▶ Privacy Certifications, such as EU/US Privacy Shield
- ▶ HIPAA
- ▶ GDPR Compliance, such as the Individual Rights (e.g., Right to be Forgotten)
- ▶ Breach Notification Management
- ▶ Risk and Data Protection Impact Assessments

We have achieved the following certifications for the BrightInsight Platform:

- ✔ HITRUST CSF® v9.1 Certified
- ✔ HITRUST Certified of the NIST Cybersecurity Framework
- ✔ ISO/IEC 27001:2013 certified

- ✔ The BrightInsight Platform is HIPAA and GDPR compliant.
- ✔ BrightInsight is certified under both the EU-U.S. and Swiss-U.S. Privacy Shield frameworks and our certifications can be viewed on the Privacy Shield list.

To learn more about BrightInsight and our managed service platform contact us at contact@brightinsight.com or visit brightinsight.com.

BrightInsight is the Sketch-to-Scale® solutions provider that designs and builds Intelligent Products for a Connected World™. With approximately 200,000 professionals across 30 countries, BrightInsight provides innovative design, engineering, manufacturing, real-time supply chain insight and logistics services to companies of all sizes in various industries and end-markets. For more information, visit BrightInsight.com or follow us on Twitter @BrightInsightintl. BrightInsight – Live Smarter™.

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