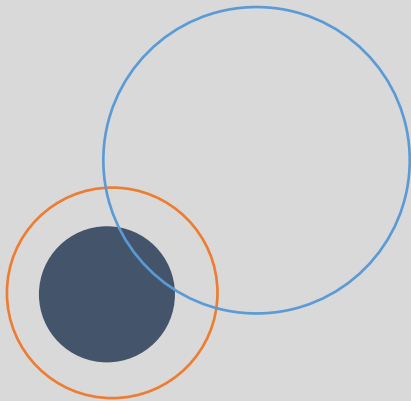




GALEN DATA

CLOUD CONNECTIVITY FOR MEDICAL DEVICES

Easy, Affordable, Compliant



1331 GEMINI AVE, SUITE 300

HOUSTON, TX 77058

888-372-9175

hello@galendata.com

www.galendata.com

GALEN ADVANTAGE

Galen Data provides a turnkey, configurable, scalable, and easy to use software platform allowing medical devices to centralize data and leverage cloud technologies. Our Galen Cloud platform collects and securely stores data as well as provides tools to visualize and analyze both patient and device data. Galen Data maintains and secures the Galen Cloud and ensures FDA and global regulatory compliance.



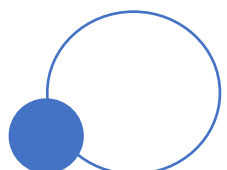
The Galen Cloud™



The Galen Cloud™ allows the increasing number of cloud-reliant medical device companies to focus their expertise on medical innovation without needing to become experts in software design, data storage infrastructure, cybersecurity, and global regulations. Galen Data products and processes are built to the needs of companies from start-ups to large med tech and pharma companies in clinical trials and commercial sales. Galen Data provides tremendous savings in terms of time to market, risk, and cost. Galen Data is FDA/CE Mark compliant, meets the requirements of HIPAA/GDPR, and is ISO 13485:2016 Certified. The Galen Cloud hosted on AWS is HITRUST certified.

GALEN VALUE

- Reduced development cost and time
- Reduced regulatory risk. Developed under ISO 13485 certified quality management system
- Track patient compliance
- Traceability of devices, mapping, full audit trail
- Scalable and secure data storage
- Fully regulatory (FDA, CE, Health Canada) audit support
- EHR / EMR Integration
- Proactive health alerts for clinicians, patients, and families
- Device diagnostic information for manufacturers
- Data repository for future device innovation, risk mitigation, cross device analysis, simulation, pattern recognition and predictive analysis
- Pay as you go approach with a low monthly fee



GLOBAL COMPLIANCE

Compliant to FDA, CE Mark, and Health Canada design controls.

Adheres to HIPAA, GDPR, and other privacy regulations

Designed under ISO 13485, IEC 62304, ISO 14971 compliant Quality Management System

SECURITY & PRIVACY

Operated under security controls certified by HITRUST for Galen Cloud on AWS

Configurable Access controls for various roles

Active Cybersecurity monitoring

Encrypted transfer and storage of data

Full Audit trail of changes

TURNKEY SOLUTION

Reduce development time from months to days with out-of-the-box configurable solution

Leave the infrastructure management to us and focus on your device innovation

24/7 access with 99.9% uptime guarantee, and technical support

VISUALIZATION

Create customized dashboards for different users

Visualize data in many insightful ways using our library of widgets

Anonymous and data masking of PHI

Instantly export data for analysis and reporting

CONFIGURATION

Customized branding to integrate your product end-to-end

Easily create workflows for data to allow for post processing

Setup push notifications for patients and clinicians

ANALYTICS

Incorporate your proprietary algorithms with security and scalability

Use our analytics tools to identify trends and patterns in your data

The Galen team has a combined 100+ years of experience providing compliant software to the medical device industry. We have designed, implemented, and deployed a broad range of solutions for FDA compliant Web connectivity. Our expertise includes medical technology connectivity, privacy and security, and regulatory compliance.

Let Galen Data help you succeed – offload your cloud connectivity and data regulatory needs to us.

