

E TECH GROUP

Smarter Compliance.
Stronger Quality.
Real Time Traceability.

Standardized Systems. Reliable Data. Audit Ready Operations.

Integrated Solutions for End to End Medical Device Compliance

E Tech Group's end to end compliance solutions help medical device manufacturers strengthen quality, improve traceability, and maintain consistent regulatory alignment across their operations.

We design and integrate **validated digital systems, quality and manufacturing platforms, and secure automation technologies** that connect seamlessly with equipment, processes, and enterprise applications. Our solutions unify **MES and MOM, SCADA, quality systems, and data integrity controls** to support analytics, automated workflows, and informed decision making. With centralized records, environmental and utility monitoring, and secure data lifecycle management, organizations reduce compliance risk while improving efficiency and product release timelines.

Whether digitizing Device History Records, modernizing legacy systems, enhancing environmental monitoring, or deploying validated platforms across multiple facilities, E Tech Group delivers scalable, future ready solutions that strengthen quality, consistency, and regulatory performance.

With **E Tech Group**, operations become smarter, more traceable, and more efficient to support long term compliance and continuous improvement.

Tangible Benefits

- **Reduce compliance risk with automated, validated workflows that eliminate manual gaps**
- **Improve audit readiness through centralized records, traceability, and real time visibility**
- **Shorten investigations, deviations, and CAPA cycle times with integrated quality data**
- **Decrease operational delays caused by paper processes and disconnected systems**

Use Cases

- **Medical device manufacturing and assembly operations**
- **Regulated cleanrooms and controlled environments**
- **Quality and production systems across multi-site enterprises**
- **Laboratories, test facilities, and validation environments**

Proven Results, Measurable Impact

- **Reduce compliance issues through standardized, validated digital processes**
- **Improve audit outcomes with complete traceability and centralized records**
- **Shorten investigations and CAPA cycles with integrated quality and production data**

Beyond Automation and Control

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Key Areas of Expertise:

Data Integrity and Digital Records

- Strengthen data accuracy and traceability across production and quality systems
- Replace paper based logs with secure, electronic batch and device history records
- Support audit trails, access control, and lifecycle data management

Cybersecure OT Architecture

- Implement segmented, hardened networks aligned with regulated environment needs
- Protect systems and records from cyber threats with secure access and authentication
- Support secure integrations between OT, IT, and cloud environments

Regulatory Compliance System Design

- Develop advanced platforms for building and power management
- Enable real time monitoring and control of HVAC, utilities, and electrical systems
- Integrate sensors, metering, PLCs, and networks for seamless data flow

Turnkey Validated System Deployment

- Deliver full lifecycle solutions from design to commissioning and validation
- Standardize architectures and documentation across multiple facilities
- Ensure scalability for future systems, upgrades, and regulatory changes

Environmental and Utility Monitoring

- Implement continuous monitoring of critical parameters in cleanrooms and controlled areas
- Enable alarm response, excursion tracking, and automated reporting
- Reduce manual checks to support accuracy, readiness, and operational efficiency

Compliance Analytics and Reporting

- Consolidate data from MES, SCADA, QMS, and lab systems
- Provide actionable insights for assessments, trending, and quality decisions
- Support long term planning and readiness with complete traceability