

# Elevating Quality Assurance and Quality Control in Labs and Manufacturing Operations

The Foundation of Your Success

At Elemental Machines, our pursuit of excellence is a character trait, and it's driven by our commitment to quality. With a watchful eye on the critical roles of QA/QC in labs and manufacturing ecosystems, we help you transcend traditional data siloes and derive maximum benefit from our leading-edge, fully integrated connectivity solutions. Our seamless connectivity from instruments to your system of record avoids needless errors, ensuring data integrity and traceability from the source to your LIMS, ELNs, or any other system of record.

Quality and compliance are paramount to your operations, and we are dedicated to supporting these needs. Our mission: to equip you with the industry's most reliable and compliance-supporting tools — essential for groundbreaking discoveries and operational success.

# **Supporting Compliance and Precision**

- **ISO 17025 certified sensors:** Out-of-the-box accuracy, meeting the stringent demands of the scientific community
- Connectivity solutions for GxP environments: Our Elemental Insights platform helps you stay aligned with FDA regulations and CFR compliance requirements from research labs to production floors:
  - 21 CFR Part 11B
  - 21 CFR Part 58D, 58E, and 58G
  - 21 CFR Part 1271
- **ISO-9001 certification:** This underscores our dedication to maintaining the highest quality management systems

# The Elemental Advantage

- **NIST-traceable standards:** Calibration guarantees the integrity of your data and the reliability of your critical operations
- Rigorous quality and validation framework: Our system embodies a holistic approach to quality and validation, setting unparalleled standards for operational excellence and compliance



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# **Empowering Operations With Comprehensive Integration**



Elemental Machines sets a new standard by seamlessly integrating diverse systems, ensuring your operations are not only compliant but also poised for future innovation:

- **Diverse system integration:** Covering systems ranging from LIMS, ELNs, QMS, and CMMS, as well as both new and legacy instruments, we bridge every component of your operational ecosystem
- **Enhanced traceability:** From real-time monitoring to historical analysis, our integrations ensure that all data points are accessible and accountable; this eliminates manual transcription and recording errors, while supporting data integrity and accuracy
- Complete audit readiness: Our solutions capture, store, and retrieve every data point, enabling a clear audit trail with automated logging, timestamping, and secure data storage; this simplifies regulatory audits, allowing you to quickly pinpoint data origins, track changes, and verify authenticity, ensuring compliance with stringent requirements
- **Electronic signatures:** We support electronic signatures, ensuring that all signed records are compliant with 21 CFR Part 11, including user authentication and secure access controls; this ensures that only authorized personnel can access and interact with the system

By prioritizing seamless integration and adapting to your specific workflows, Elemental Machines amplifies your current capabilities and ensures your infrastructure is robust and agile enough to meet the challenges of tomorrow.

### Core Elements of Our Quality Promise to You



#### Reliable and innovative design:

Engineered for optimal performance and nonintrusiveness, addressing the nuanced needs of varied environments



#### Scalable solutions:

Ready to grow with your ambitions, adapting to your expanding operational demands with zero compromises on quality



#### Data integrity and security:

Robust data management, ensuring the protection and sanctity of your data — pivotal for trust and operational success

# Connectivity at the Core of QA/QC Excellence

Step confidently into the future of quality assurance and quality control in labs and manufacturing with Elemental Machines. Our industry-leading suite of connectivity solutions guarantee precision, reliability, and security, simplifying your GxP and GMP compliance efforts and safeguarding your progress.

Ready to enhance your operations? Discover more at <u>elementalmachines.com</u> or <u>connect with our team</u> to find solutions designed for your success.

**Explore Our Commitment to Quality** 



#### **About Elemental Machines**

Elemental Machines' Intelligent Operations Platform leverages the best of Internet of Things (IoT) technology and custom hardware/software solutions, delivering actionable insights to operators in life sciences, biopharma labs, biobanks, analytical labs, and manufacturing facilities. By connecting the physical and digital worlds, the platform simplifies, optimizes, and augments operations. Leaders in science, facilities, and technology trust Elemental Machines' ecosystem for insights that accelerate innovation, predict outcomes, and shift from reactive to proactive management. With scalable solutions from incubator to enterprise, custom integrations to fit each operation's unique needs, and a wide ecosystem of partnerships, Elemental Machines ensures operational excellence and the future-proofing of lab and manufacturing processes.