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## **Frequentz's Track and Trace System Meets and Exceeds Global Regulatory Standards Compliance**

*Three Critical Audit Areas Every Traceability Supplier Should Pass*

**Palo Alto, CA** – June 23, 2015 – Frequentz Inc., a global leader and champion of end-to-end visibility, encourages all businesses to proactively audit potential and existing traceability solutions suppliers to ensure their track and trace system fulfills the global regulatory and standards requirements. Audits are key to protecting companies whose brands, operations and bottom lines are at risk if they are not FDA or EU compliant. While at minimum, passing an audit means suppliers are able to help keep their clients running business as usual, Frequentz Inc. suggests three critical audit areas tracking software suppliers should not just pass, but excel.

"As a software auditor, I understand why there can be a lot of stress conjured just by the mention of an audit, no matter where you sit in the process. The stakes are high for everyone, especially in terms of compliance. However, doing your due diligence and conducting an audit will give you confidence you are working with a company with the best product and practices," said Mathew Thomas, Director of Quality & Compliance, Frequentz Inc. "Frequentz recently passed stringent supplier audits by major multi-national life sciences companies, validating that we offer a flexible, robust Quality Management System that can meet the needs of any company."

An audit helps ensure suppliers are in line with a company's requirements and expectations, covering areas such as coding processes, product design, and good testing and documentation practices. Although audit requirements vary by company and industry, there are three areas that are crucial for a supplier to prove themselves in:

**1. Quality Management System (QMS):** All information and documentation must be viewable in one location and meet various governing body standards.

- All Frequentz release software product lifecycle deliverables, SOPs and change control records are maintained within a validated, robust and Quality Management System in compliance with FDA/EU GMPs, ISO 13485 and



GAMP5 guidance on risk based approach to Computer Systems compliance. The QMS also holds the employee training records, supplier/vendor audits, internal audit reports and CAPA closeout reports.

**2. Security:** In this day and age, securing information is of the utmost importance.

- Frequentz product is validated and maintained in compliance with FDA guidance on Software Validation, GAMP5, Good Documentation Practice and GMPs.
- Frequentz QMS is validated and maintained in compliance with ISO 13485 and CFR Part 11.
- Frequentz suppliers and hosting providers are ISO 9001 QMS/ISO 27001 security certified, and comply with SSAE16 audit standards and provide SOC1 and SOC3 periodic reports on security and internal controls.

**3. Track Record:** A supplier should have a proven history of passing audits.

- Frequentz has passed stringent supplier audits by major multi-national life sciences companies, thereby providing further assurance on quality.

### **About Frequentz**

Frequentz is a global leader and champion of end-to-end visibility, offering comprehensive traceability, serialization and information management technologies. Their transformative tools bolster businesses and brand reputations by improving productivity, product quality, and profitability. To accomplish this, Frequentz provides valuable insight into end-to-end supply chains, and critical business processes by collecting, storing and analyzing serialized, life history data. Applications of its software are currently used in the life sciences, agricultural, fishery and sustainability, retail, and automotive industries worldwide and promote intelligent analytics and consumer safety. For more information visit [www.frequentz.com](http://www.frequentz.com).

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