FDA Compliance Statements

21 CFR § 820, 21 CFR § 11, ISO 13485 Compliance and IQ/OQ/PQ

May 2022

Dear Instron Customer,

Instron designs, manufactures and services advanced universal testing machines and software for a wide range of applications and uses. Please note that these instruments are not "Medical Devices" as defined under 21 CFR or by ISO13485 and consequently are not covered in the scope of these regulations.

Instron does provide a range of software compliance statements and IQ/OQ products that will enable customers to successfully validate their Instron software product in accordance with these regulations and standards.

21 CFR § 820 and ISO 13485:2012

Instron Corporation develops its products and procedures and measurement standards that meet or exceed the requirements of ISO9001, ISO 10012-1, ANSI/INCSL Z 540-1 and ISO17025 as applicable. Software developed by Instron for use in calibration of testing instruments is also verified and validated using the same procedures. These Procedures include product and data integrity verification and validation during the product design phase. Compliance is demonstrated by Instron's quality management system being registered to ISO9001:2008. Our certificate number is US95/0293. The certificate and most current revision of our quality manual is posted on our website (link below).

As the FDA does not recognize the newly created ISO9001:2008 standard as being harmonized or aligned with their Quality System Regulations, Instron cannot claim compliance with 21 CFR § 820, however to meet the need of customers who are seeking compliance, we can provide Software Verification Letters for specific software products to enable customers to fulfill the requirements of sections 820.70(i) or ISO 13485 Section 7.5.2.1.

Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)

Instron also offers a range of support options to assist with IQ/OQ/PQ. These services range from documentation packages to customized onsite IQ/OQ verification services.

21 CFR § 11

Many Instron customers use our products to generate electronic records in support of FDA compliance activities. Instron guarantees the integrity of the data generated from its products at the point the data is generated or output in ASCII format. Software Verification letters for specific software products are available on request.

When outputting data via ASCII, the data leaves the control of the Instron system and we are unable to maintain traceability on any additional amendments to these electronic records.

It is important to note that no product by itself can be 21 CFR § 11 compliant. The FDA requires both procedural controls (i.e. notification, training and SOPs) and administrative controls to be put in place and validated by the Lifescience Company in addition to the technical and data integrity controls that the vendor uses to ensure compliance with this regulation.

Bluehill Universal Testing Software's Traceability Module
Bluehill Universal's Traceability Module was introduced in 2020 to enable users to meet the audit requirements associated with FDA 21 CFR Part 11, ISO 17025, NADCAP, A2LA, and other accrediting bodies. Through seamless integration of electronic signatures and approvals, file revision history, and an automated, secure audit trail, this optional module provides data traceability required by the Lifescience Company.

Upon request, additional documentation can be provided to outline how the Traceability Module can help users meet the technical requirements of each section within FDA 21 CFR Part 11.

Best Regards,

Jeffrey L. Manney
Director of Quality

Instron®
The recognized world leader in advanced material and components testing instrumentation, support services and expertise for testing products, structures and materials.

Tel: +1 781 575-5585
jeffrey_manney@instron.com

Give us your feedback at: Quality@instron.com

It is Instron's intention that all supplied products and services fully satisfy our customers' expectations for safety, timeliness, performance, reliability, freedom from defects and suitability for their intended application.