



OsteoMeasureXP GLP Validation Package

OsteoMeasureXP v2.1.0.0 includes new features designed to implement CFR Part 11 requirements, including:

- Configurable OsteoMeasureXP user code and password combinations
- Context-sensitive electronic signature and audit trail of key system and individual biopsy events
- Data approval and modification tracking
- Automatic detection of external manipulation of data and calibration files

In order to comply with GLP requirements, the system must be installed and tested in a documented manner. Extensive documentation is required. The OsteoMeasureXP validation package available from OsteoMetrics includes:

- Validation Plan (includes risk assessment)
- User Requirements Specification
- Workstation Installation Qualification (IQ)
- Software IQ
- Software Operational Qualification (OQ) and Performance Qualification (PQ) Strategy
- OQ Test Scripts
 - Electronic Signature Setup
 - Calibration
 - Measurement Field Setup
 - Motorized Stage (1)
 - Motorized Stage (2)
 - Measurement Setup
 - Accuracy & Reproducibility
 - Electronic Records
 - Cancellous Bone Calculations
 - Cortical Bone Calculations
- Traceability Matrix
- Validation Report Template
- Upgrade & Maintenance Documentation
- User Training Documentation

The documents are provided in substantially complete form, ready for you to modify for compliance with institutional or sponsor policies, procedures, and document format requirements.



Validation assistance is also available on a fee for service basis from Think Bone Consulting.

Assistance can include:

- Working with you and your institutional QA to modify documents into compliance with institutional procedures
- Working with you and your sponsor QA to modify documents into compliance with sponsor procedures
- Development of supporting QA infrastructure and SOPs
- Performance of IQ, OQ and/or PQ and production of validation reports

For more information, please contact us or contact Think Bone at (360) 221-6723 or chris.jerome@thinkboneconsulting.com.