

## Validation in the NIR World

This class is open to individuals with prior validation experience, current responsibility for validating a FOSS NIRSystems instrument, or with approval of the instructor. Confused by the Code of Federal Regulations? Come and hear the major NIR instrument manufacturer's approach to addressing the issues. See and discuss what FOSS NIRSystems has done and suggests to address such issues as Electronic Records and Signatures, Vision software validation, FOSS NIRSystems hardware validation and User Application Validation.

Part Number: **XT-1110**

### Agenda

- Overview of Validation: Code of Federal Regulations, Title 21
- Overview of CFR Part 11, Electronic Records and Signatures
- The three major elements of validation
  - Software
  - Hardware
  - User Application
- Vision Software Validation
  - Software “Life Cycle” Validation Method
  - Difference between “validated software” and “application validation”
  - Tools for proof of software validation
- Hardware Validation
  - Optical Standards – a tool for proving optical response
  - Wavelength Standards
  - Photometric Standards
  - Sequence of ongoing hardware testing and qualification
- User Application Validation
- Validation: Putting it all together
- Discussion and Questions

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