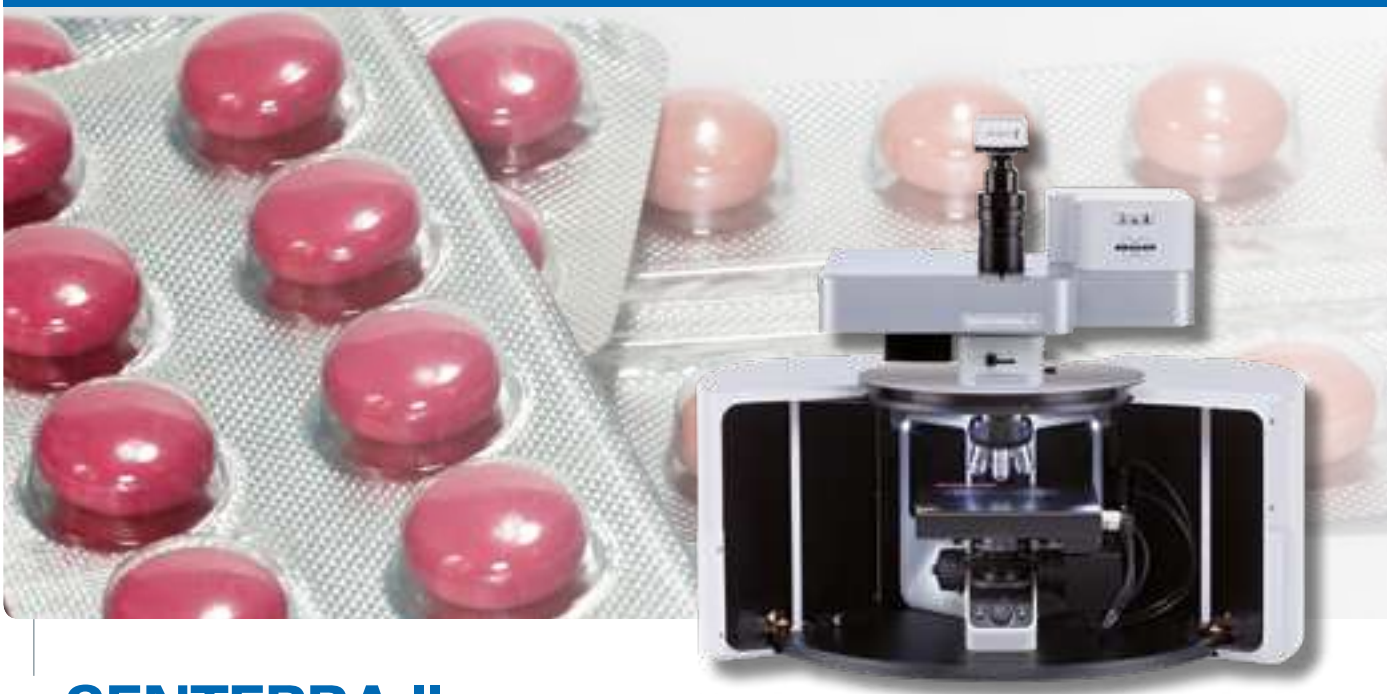

SENTERRA II Full Compliance to Pharmaceutical Regulations

Compliance is key. Numerous norms, standards and regulations must be followed by the pharmaceutical industry. This may concern requirements with respect to data integrity of records or performance specifications of any kind. Manufacturers of analytical instruments are left with the task of providing compliant devices to satisfy the demands of the pharmaceutical industry and official authorities.

Bruker's Raman microscope SENTERRA II is failsafe, fully automated, conforms to current regulations and offers an incomparably efficient workflow.

The OPUS software is the answer to 21 CFR part 11 requirements and fully complies to Good Practices (GxP).

When OPUS is paired with the SENTERRA II Raman microscope, they ensure accuracy, reliability and data integrity.

Comprehensive Instrument Qualification

- Bruker offers an extensive *System Validation Manual* for design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) of hardware and software.
- Our fully automated instrument tests for operational and performance qualification of the SENTERRA II
- The failsafe instrument test procedures comply with USP 1120, PhEur 2.2.48, ASTM E1840 and E2529-06
- Validation plate with certified ASTM based standard materials:
  - Acetaminophen for wavenumber accuracy & precision test
  - Polystyrene for photometeric precision test
  - Calcium carbonate for testing the spectral resolution

Absolute Data Security, Integrity, Traceability and Compliance

- A Protected Data Pool safeguards electronic records against deletion or loss
- The *Global Audit Trail* is comprehensive and offers filtering for smart audit trail review
- Our *User and Signature Management* offers consistent separation of user responsibilities. Two independent signatures are necessary for review and release and password complexity for users can be configured individually.
- Compliance to FDA's Data Integrity guidelines and cGMP requirements e.g. 21 CFR Part 11

The ALCOA+ Principle

OPUS spectroscopic data records are Attributable, Legible, Contemporaneously recorded, available in Original format, Accurate and hence securely measured and maintained (see table 1). The complete workflow, every evaluation and operation is accurately recorded into a single electronic file. In short, this means consistent evaluation, quick review and smart archiving.

Support and Validation Services

Bruker is at your side when it comes to validation and offers many support options based on your individual needs. We offer installation and qualification of instruments as well as annual certification by Bruker's factory trained and certified service engineers.

Figure 1: Screenshot of the activated data integrity mode (top) and the SENTERRA II validation plate (right) for automated instrument qualification.

ALCOA	Explanation	Implementation in OPUS
Attributable	▪ Who performed which activity, i.e. measured and evaluated the spectra	▪ Audit Trail with Date & Time Stamp and User ID
Legible	▪ Permanent storage of data, protection against deletion, renaming and loss	▪ Protected Data Pool
Contemporaneously recorded	▪ Spectrum must be recorded at the time of generation or data evaluation	▪ By design of OPUS software
Original	▪ Spectra are ´Dynamic Data` ▪ Origin spectrum and format are preserved	▪ GLP Mode (original data saved) ▪ OPUS Format
Accurate	▪ Complete and consistent evaluation workflow ▪ OVP: OQ and PQ status and validity	▪ History Data Block ▪ OPUS Validation Program

Table 1: The ALCOA+ Principle.

Bruker Optics is ISO 9001 and ISO 13485 certified.

Laser class 1 product.