

21 CFR Part 11

DIFFRAC.SUITE PART11

The Solution for your Compliant Lab

DIFFRAC.SUITE Part11 defines a new benchmark for X-ray powder diffraction data acquisition and interpretation of one- and two-dimensional XRD data in cGxP / 21 CFR Part 11 regulated environments, including the following modules:

- MEASUREMENT PACKAGE
- EVA
- DQUANT

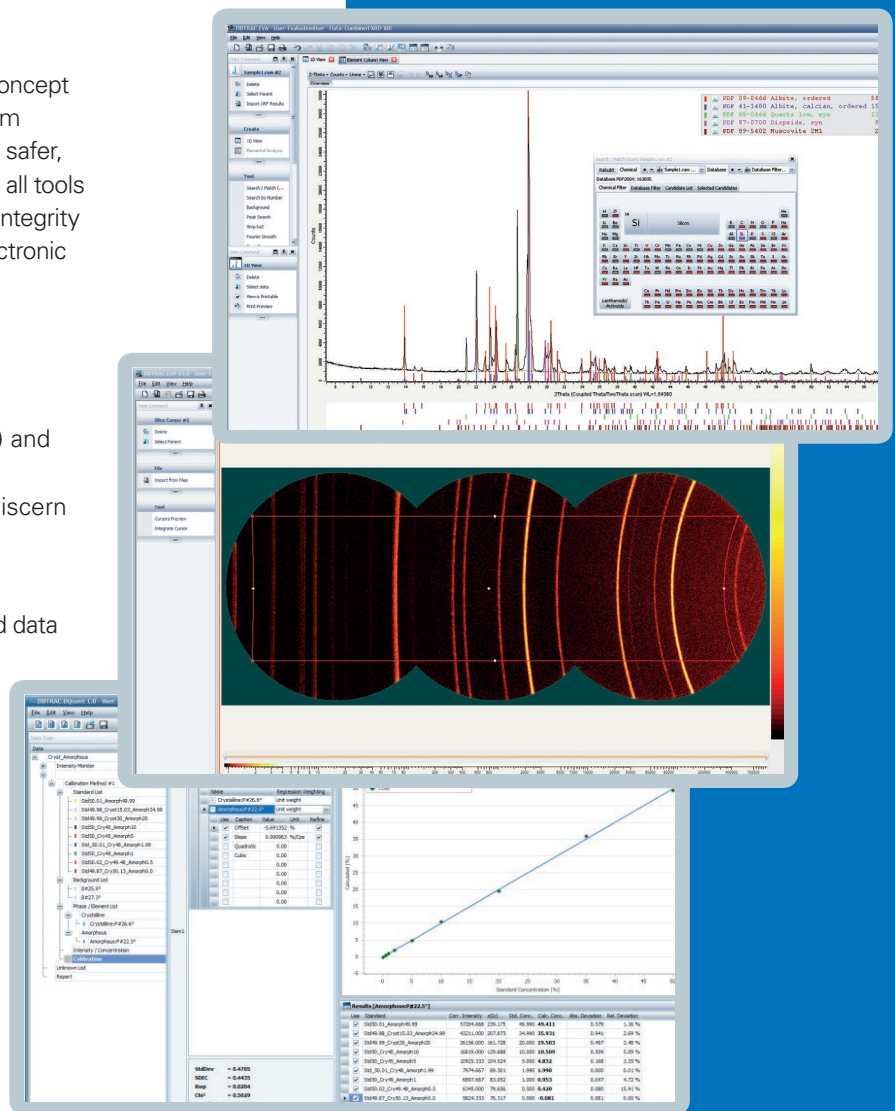
The new and innovative design and operation concept of DIFFRAC.SUITE Part11 provides for maximum simplicity and flexibility, making compliant work safer, easier and faster than ever. The software offers all tools required to provide and guarantee authenticity, integrity and confidentiality of electronic records and electronic signatures including

- Secure system log-ins
- Automatic audit trail generation
- Electronic signatures with reports and data
- Network security with Windows XP (32 bit) and Windows 7 (32 & 64 bit)
- Tamper proof data files with the ability to discern invalid or altered records

DIFFRAC.SUITE Part11 enables fully automated data acquisition and interpretation and perfectly integrates into multi-user environments. The software can be installed on individual computers or a networked computer infrastructure. Authorized users have any-time access to both the software and the diffractometer. New samples, measurement and evaluation tasks can be added at any time, and can be prioritised by higher authority users.

The new DIFFRAC.SUITE Part11 supports the full range of the [D2 PHASER](#) and [D8 diffractometer family \(D8 ENDEAVOR, D8 ADVANCE, and D8 DISCOVER\)](#).

- Acquisition and interpretation of 1-D and 2-D data sets - easier, faster, and more accurate than ever
- Simultaneous phase identification and quantification for automated phase analysis
- Full support of multi-user environments



DIFFRAC.SUITE Part11 is being developed by applying a formal design process and product development life cycle according to Bruker AXS's ISO9001 certified product development procedures, based on cGAMP. Written standards exist such as coding standards, configuration management, programmer qualifications, software version control, maintenance, formal testing of software/hardware, incident reporting and tracking, and disaster recovery.

A white paper detailing BRUKER AXS 21 CFR Part 11 policy as well as the implementation of the 21 CFR Part 11 requirements in DIFFRAC.SUITE Part 11 is available on request (document number DOC-M88-EXX241).

Bruker AXS also offers tools and expertise to help meeting the requirements of equipment qualification EQ (including design qualification DQ, installation qualification IQ, operation qualification OQ, and performance qualification PQ) for system validation according to 21 CFR Part 11, §B11.10a.



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