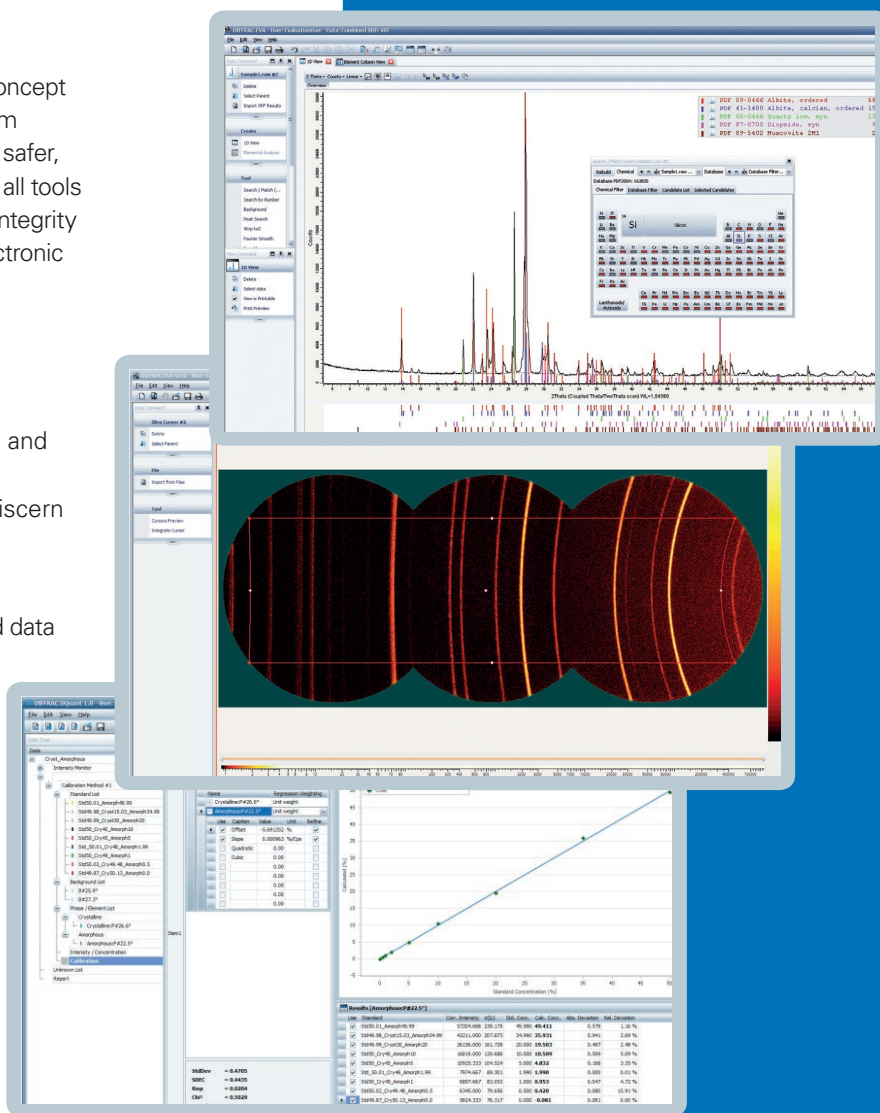


The Solution for your Compliant Lab



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.



Bruker AXS GmbH

Karlsruhe · Germany
Phone +49 721 50997-0
Fax +49 721 50997-5654
info.baxs@bruker.com

www.bruker.com