

EQUIPMENT QUALIFICATION

Arnt Kern, Bruker AXS GmbH, Karlsruhe, Germany

Compliance with cGxP and 21CFR Part11 regulations is of the highest priority for regulated industries such as the bio-pharmaceutical industry as well as its suppliers. The scope of cGxP and Part11 requirements is wide reaching, including but not limited to hard- and software validation and the use of electronic records and signatures in lieu of paper records.

An important aspect of cGXP is equipment qualification, frequently broken down to design, installation, operation and performance qualification, i.e. the action of proving that any equipment works correctly and actually leads to the expected results.

This presentation will describe the fundamentals of design and alignment of modern diffractometers, the use of standards for verification of alignment, and tips on practical use. An instrument verification procedure will be discussed meeting the requirements of operation and performance qualification.