Equipment Qualification for FT-IR / FT-NIR

Albrecht Rager

BRUKER OPTIK GMBH, Rudolf-Plank-Straße 27, D-76275 Ettlingen

Due to considerations of the Code of Federal Regulations (CFR), Title 21 part 11 the instrument handling, electronic spectra record and documentation has to fulfil a certain level. Today´s regulated laboratories must comply with these extensive regulatory requirements. Comprehensive instrument and software validation manuals provide the documentation and procedures to achieve systematic and cost effective compliance.

The procedures of validation and qualification are illustrated and the methodical pathways are described in illustrated ways.

References

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5. General Chapter <1225>, Validation of compendial methods, United States Pharmacopeia XXIII, National Formulary, XVIII, Rockville, MD, The United States Pharmacopeial Convention, Inc, 1995, 1710–1612
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