Validation of FTIR systems for the investigation of microorganisms

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At the end of 1960 the US FDA (Food and Drug Administration) uncover substantially irregularities in execution of investigations and their reporting. As consequence test rules for laboratories under the term Good laboratory practice (GLP) were defined with the goal to get a comparable quality standard and first guidelines regarding GLP were published in USA in the year 1978 [1].
The thought of the quality assurance for officially demanded laboratory tests was taken up by other industrialized export countries of the western world. It was very fast recognized that by GLP and later on by the Good manufacturing practice (GMP) the level of confidence for analytical results and pharmaceutical products could be significantly increased. Today GMP and GLP guidelines impact dramatically the daily work in pharmaceutical and chemical QC and R&D [2].
Accordingly, the proceeding to provide qualification of instrumentation in FTIR and Raman spectroscopy must be consistent with the standardized GMP/GLP practises. This process which has to be performed for each analytical system individually is usually realised by a step by step procedure within a validation plan.
This plan consists mostly following parts: Design qualification (DQ), Installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). Whereas DQ specifies the functional requirements, IQ assures that the intended equipment is received as designed and specified. OQ and PQ confirm that the equipment functions as specified and operates correctly upon installation and at regular intervals afterwards, respectively.
During OQ and PQ of FT-IR instrumentation automated tests are performed to check specified parameters like spectral resolution, sensitivity, linearity and wavelength accuracy independent from any sample. The benefit of these procedures for the user is that instrumental artefacts are prevented and that resulting data are suitable for calibration transfers. However, this instrument validation does not include aspects of sample preparation, data processing and data evaluation. It was found that for high throughput screening in microbial identification, the automated control of spectral data is essential.
In this paper the principle of instrument validation and its consequences for the user is discussed.

References

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