Product Note R36 - 09/16

BRAVO
More than compliance to Pharmaceutical regulations

Any analytical instrument being operated in the validated environment of the Pharmaceutical industry needs to comply with different regulations concerning various topics, ranging from performance specifications to requirements with respect to data integrity of records. For the realization of compliance it is left a broad scope of solutions to manufactures of analytical instrumentation to satisfy the needs of the Pharmaceutical manufacturing industry and official authorities. Bruker's handheld Raman spectrometer BRAVO comes up with many innovative functionality and concepts being more than conform to current regulations.

Validation concept

Bruker is well known as a leading supplier for analytical instruments to the Pharmaceutical industry. All FT-IR, FT-NIR and Raman spectrometers are managed by the software suite OPUS, which is designed for and proven in validated environments. Of course, the same holds for BRAVO: The handheld Raman spectrometer is operated by its own on board software, but the system's memory is only accessible via the OPUS platform using a verified communication. Consequently, BRAVO is considered in operation as a standalone system, which is fully encapsulated into the OPUS software sharing all validation relevant information like user management, GMP/GLP, and 21 CFR Part 11 settings (see Fig. 1).

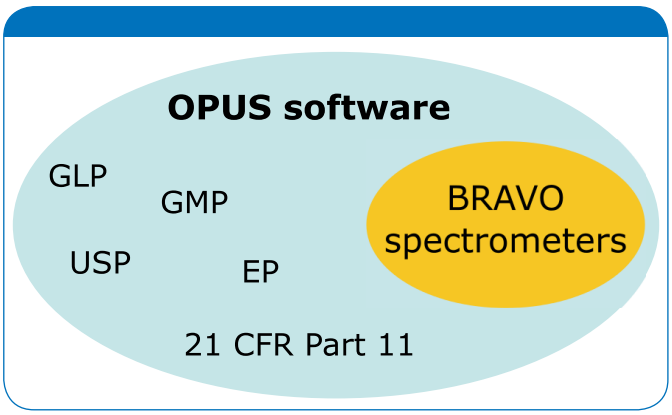

Figure 1: BRAVO is fully encapsulated into the framework of the OPUS spectroscopy software to be operated fully validated in compliance to current regulaions as 21 CRF Part 11.

System specifications – USP 1120, EP 2.2.48 and beyond

With BRAVO Bruker challenges current regulations setting a new benchmark for handheld Raman instruments being operated in the Pharmaceutical industry. Exemplarily, chapters EP 2.2.48 and USP 1120 of the European and United States Pharmacopeia define minimum system specifications for Raman instrumentation, respectively. The recently revised chapter 2.2.48 of the European Pharmacopeia 8.7 for the

first time considers especially handheld Raman analyzers, but in a way that the requirement for the Raman shift accuracy is softened towards conventional benchtop spectrometers. The optics of BRAVO has been designed to achieve highest standards in accuracy, which allows matching the specifications applicable for benchtop instruments [1]. Anytime, the performance of the system can be challenged by the operator with comprehensive system tests according to current regulations making data and test reports available for documentation.

Data integrity

Data integrity is a very important aspect especially as nowadays electronic records are getting more and more established. Usually the desired information is not readily available from the original data which in case of Raman spectroscopy is the raw data recorded by the detector. To obtain the desired results comprehensive methods including mathematical data pretreatments are applied. It is emphasized that BRAVO's result files include, next to the processed data, as well raw data of the individual lasers at sequentially shifted excitation (SSE™) and of course all relevant acquisition and instrument parameters are available [2]. The most comprehensive information stored in every result file being protected from manipulation by our OPUS software and a complete Audit-Trail including all relevant user actions ensure that everything is traceable back to its origin.

Validation Package

The validation and qualification package for BRAVO provides all necessary building blocks to operate the system in a validated environment: The software package for compliance to regulations like GMP/GLP and 21 CFR Part 11, reference standards according to ASTM 1840 for comprehensive system tests as specified by the USP and EP regulations, and a comprehensive validation manual including certificates and step by step instructions for IQ, OQ and PQ procedures. Of course, there are validation and other comprehensive services available to ensure the most effective operation of the BRAVO analyzer.

With innovative solutions and new technologies Bruker offers the state-of-the-art handheld Raman analyzer dedicated for the Pharmaceutical industry. Be confident that our experienced sales, service and application teams offer an efficient support being based in offices all over the globe. As Bruker is aware of continuous adaptions of current regulations with our experienced validation support and in-house development we can ensure compliance to all future developments and account for new trends at the earliest stage.

References

[1] Bruker Product Note, "Accuracy is crucial: The starting point for a robust transfer of methods"

[2] Bruker Product Note, "Efficient mitigation of fluorescence in Raman Spectroscopy using SSE™"