

Audit Report: 21 CFR Part 11



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## Mira Cal Software 3.1

- Audit Date:** 13.10.2017<sup>1</sup>
- Auditor:** Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
- Audit Target:** Compliance check against the requirements of 21 CFR Part 11 for *Mira Cal Software 3.1* which is used to control devices for Raman spectroscopy.
- Description:** PC software for controlling Raman spectroscopy devices: create operating procedure, library and training set, perform analysis (record Raman spectrum), data acquisition, evaluation against library and/or training set, and archiving in a database. *Mira Cal Software* was developed under the supervision of the Metrohm AG in accordance with its ISO 9001 requirements – Metrohm Raman USA itself developed *Mira Cal Software* based on an inhouse QMS which currently runs through the ISO 9001:2015 certification process.
- Investigation:** The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations.  
During the audit the following items were examined:  
validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.
- Operator Responsibility:** Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding:
- technical environment, data management
  - training
  - administration
  - Standard Operating Procedures (SOP).
- Summary:** The software is compliant with the following 21 CFR Part 11 requirements:
- 11.10 (b), (d), (f), (g), (h)
  - 11.50, 11.70
  - 11.300 (a)
- The software is compliant with the following 21 CFR Part 11 requirements with support of the operator:
- 11.10 (a), (c), (e), (i), (j), (k)
  - 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d)
- The software supports electronic signature.

  
Sieghard Wagner

<sup>1</sup> This 21 CFR Part 11 certificate is based on an on-site audit performed January, 12<sup>th</sup> 2017. Subject of this audit was the software version 3.0 with all compliance features enabled. According to Metrohm AG management (development and QA) all implemented changes in the following version 3.1 are not relevant with regard to 21 CFR Part 11 or 21 CFR Part 11 compliant (see Release Notes 8.105.8023EN). Therefore, this update does not require an on-site re-audit.