Certificate

chemgineering

Audit Report: ERES Assessment

MiraCal P Software 4.2.x

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Audit Date: 2020-05-29[1]

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Audit Objective: Compliance check against the ERES[2] requirements of 21 CFR Part 11 and EU GMP[3] Annex 11 for *MiraCal P Software 4.2.x*[4].

Description: PC software for controlling Raman spectroscopy devices:
Create operating procedures, libraries, and training sets, perform analyses (record Raman spectrum), data acquisition, evaluation against libraries and/or training sets, and archiving in a database.

MiraCal P Software is developed by Metrohm Raman USA in accordance with ISO 9001:2015 requirements.

Investigation: The functions and properties of the above software system are audited against the ERES requirements of 21 CFR Part 11 and EU GMP Annex 11 with 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: ERES compliance 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 ERES requirements:

21 CFR Part 11:	11.10 (b), (d), (f), (g), (h); 11.50, 11.70; 11.300 (a)
EU GMP Annex 11:	Paragraphs: 8, 9, 12, 14b, 14c

The software is compliant with the following ERES requirements with support of the operator:

21 CFR Part 11:	11.10 (a), (c), (e), (i), (j), (k); 11.100 (a), (b); 11.200 (a); 11.300 (b), (c), (d)
EU GMP Annex 11:	Paragraphs: Principles, 1 to 4, 6, 7, 10, 14a, 17

The software supports electronic signature.

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[1] This ERES certificate is based on an on-site audit performed January 12, 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 versions – including the current version – are not relevant with regard to ERES requirements, or comply with ERES requirements (see Release Notes 8.105.8023EN, 8.0105.8014EN, and 8.0105.8028EN). Therefore, this update does not require an on-site re-audit.
[2] Electronic Records, Electronic Signatures
[3] see EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines
[4] Version numbers below 4.1 are used for bug fixing only