

Audit Report: 21 CFR Part 11

MagIC Net 1.1 for ion chromatography



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- Audit Date:** 08.04.2008¹
- Auditor:** Yvonne Zurbuchen, Chemist FH, Chemengineering AG
- Audit Target:** Compliance check of *MagIC Net 1.1* software for controlling ion chromatography devices against the requirements of 21 CFR Part 11.
- Description:** PC software for controlling ion chromatography devices. Creation of methods, carrying out determinations (chromatograms and measurements), data acquisition, evaluation, and archiving in a database.
The above software was developed and manufactured in accordance with the requirements demanded by the ISO 9001 quality system regarding the design, manufacture and servicing of Metrohm Ltd.
- Investigation:** The functions and properties of the above software system are audited with the requirements of 21 CFR Part 11 and the 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:** The compliance with the requirements of 21 CFR Part 11 can only be met together with the operational environment. The requirements for such an environment are:
- technical environment, data management
 - training
 - administration
 - SOP (Standard Operating Procedures)
- Summary:** The software is compliant to the following 21 CFR Part 11 requirements:
- 11.10 (b), (d), (e), (f), (g), (h)
 - 11.50, 11.70
 - 11.200 (a), 11.300 (a), (d)
- The software is compliant to the following 21 CFR Part 11 requirements with support of the operator.
- 11.10 (a), (c), (i), (j), (k)
 - 11.30
 - 11.100 (a), (b), 11.300 (b), (c), (e)

¹ A physical audit has been performed on the base of the Version MagIC Net 1.0 on the 27.04.2008. According to Metrohm Ltd., the implemented changes in the current version are not relevant regarding 21 CFR Part 11. Therefore, the initial physical audit has been renounced, this is scheduled for december 2008.

Yvonne Zurbuchen