

Audit Report: 21 CFR Part 11

MagIC Net 1.0 for ion chromatography



Metrohm Ltd.
CH-9101 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01
www.metrohm.com

Audit Date:	27.04.2006
Auditor:	Dr. Gerald Schwarzenbacher, Chemgineering Planung GmbH
Audit Target:	Compliance check of <i>MagIC Net 1.0</i> software for controlling ion chromatography devices against the requirements of 21 CFR Part 11.
Description:	<p>PC software for controlling ion chromatography devices. Creation of methods, carrying out determinations (chromatograms and measurements), data acquisition, evaluation, and archiving in a database.</p> <p>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 instruments.</p>
Investigation:	<p>The functions and properties of the above software system are audited with the requirements of 21 CFR Part 11 and the current interpretations.</p> <p>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.</p>
Operator Responsibility:	<p>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:</p> <ul style="list-style-type: none">• technical environment, data management• training• administration• SOP (Standard Operating Procedures)
Summary:	<p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">• 11.10 (b), (d), (e), (f), (g), (h)• 11.50, 11.70• 11.200 (a), 11.300 (a), (d) <p>The software is compliant to the following 21 CFR Part 11 requirements with support of the operator.</p> <ul style="list-style-type: none">• 11.10 (a), (c), (i), (j), (k)• 11.30• 11.100 (a), (b), 11.300 (b), (c), (e)