



Ph21 Services Ltd's Quality Management Products

Ph21 Services Ltd. offers an extended range of supporting quality management products of its Ph21 laboratory software system. These products will significantly increase the productivity of the customer's in-house system validation efforts and decrease the timespan between installation of the system and taking the system into production. The QM packages will also greatly support FDA inspections at the customer's site.

The QM product comes in the following 'Package':

- All software validation test suites and reference reports of the current 'Standard' software version
- Extract of the change control database since the last revision change
- Declaration of compliance to 21CFR-11
- Requirement Specification
- All software validation test suites and reference reports of the current 'Extended' software version
- Risk Analysis
- A copy of the lifecycle database contents (change requests, review results, release approvals)

The documentation package will be distributed as a web download containing at least the above listed documents, mostly in Adobe® PDF file format. All copies of software validation test suites are signed and thus be compliant to current 21CFR-11 requirements. Prerequisite for an order of one of the QM-packs is a Ph21 R4 software license. Each QM pack carries a unique serial number which corresponds to the Ph21 software system license serial number. A QM pack **must not** be used with a software license carrying another serial number than the one stamped to the QM pack's documents!

G. A. Loeffler

Director Ph21 Services Ltd, February 2010