November 2018, Bassersdorf, Switzerland

Rotronic Validation Guide V1.3.1

Release Documents: All Release Documents are provided free of charge. These documents describe the RMS, certify validation and refer to the Qualification Documents.
Qualification Documents: We will sell the Qualification Documents in the validation package.

Release Documents	
Validation & Compliance Declaration, **RMS-CD-V131-EN.pdf**	Rotronic certification of validation. RAG certificate
eCompliance White Paper (WP), **RMS-WP-V131-EN.pdf**	FDA requirement: - USA, EU instruction How we fulfill the statutory requirements with the RMS
Validation Plan (VP), **RMS-VP-V131-EN.pdf**	"Example Document" Procedure and planning of a validation, including releases
Change Log (CL), **RMS-CL-V131-EN.pdf**	Description of all modifications to the RMS software. From V1 including declaration of all known errors
Functional Specification (FS), **RMS-FS-V131-EN.pdf**	Description of all functions of the RMS software. Individual parts of this FS are used in the system validation. For creation or review of the User Requirements Specification (URS)
EudraLex The Rules Governing Medicinal Products in the European Union, **annex11_01-2011_en.pdf**	European instruction
Comparison of FDA's Part 11 and the EU's Annex 11 **Comparison of FDA Part 11 and EU Annex 11.pdf**	Comparison of FDA Part 11 (21 CFR Part 11) and the EU's Annex 11 (EUDRALEX The rules governing medicinal products in the European Union)
eCFR — Code of Federal Regulations, U.S. Government Publishing Office, **Code of Federal Regulations *(Link)***	Link to USA

Qualification Documents	
Validation Master Plan (VMP), **RMS-VMP-V131-EN.docx**	Detailed RMS master plan for the validation procedure. Instruction, timeline, release, etc.
Qualification Documents – Specification	
User Requirements Specification (URS), **RMS-URS-V131-EN.docx**	User requirements specification, customer requirements, description of system
Risk Assessment (RA), **RMS-RA-V131-EN.docx**	System-related risks are declared, with references to resolution methods
Functional Requirement Specification (FRS), **RMS-FRS-V131-EN.docx**	Configuration, settings to the RMS software and instruments. Alarms, intervals, users, etc.
Configuration Specification (CS), **RMS-CS-V131-EN.docx**	System configuration and installation Server, database, operating system, etc.
Requirement Traceability Matrix (RTM), **RMS-RTM-V131-EN.docx**	Matrix showing, beginning with the URS, where what is described
VSS (Validation Script Specification), **RMS-VSS-V131-EN.docx**	Which FS specifications are tested with scripts. Script output = OQ test report
Qualification Documents – Verification	
Performance Qualification (PQ), **RMS-PQ-V131-EN.docx**	Results of the URS tests
Operation Qualification (OQ), **RMS-OQ-V131-EN.docx**	Results of the FRS tests
Installation Qualification (IQ), **RMS-IQ-V131-EN.docx**	Results of the CS tests

Annexes:

UserImport.csv	Template for importing from users
DeviceImport.csv	Template for importing from device