

Purchase Agreement

Agreement governing the purchase of software and equipment

The Norwegian Government's Standard Terms and Conditions for IT Procurement SSA-K

Tender for delivery of an Automatic Blister Cutting and Packaging Machine for the Hospital Pharmacies Enterprise – South Eastern Norway

K Appendix 5: Approval test

Customer: Sykehusapotekene HF

Contractor: <Contractor name>

Case number: 2019/0010



This appendix should not be filled out by the Contractor upon submission of proposal.



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1. Introduction

This appendix describes the validation and acceptance test(s) for the delivery of the solution (Customer acceptance test).

2. Clause 2.2.2 of the agreement

2.1 Separate approval test

Validation and Testing

All new equipment must be validated and tested. The result of this validation and testing will form the basis for the Customer's approval of the delivery (accepted customer acceptance test), upon which the production may be initiated. An overview of the validation and testing process and responsibilities is provided in table 5.1.

Sykehusapotekene HF (SAHF) will, in collaboration with the Contractor, validate and test the solution in accordance with the following standards:

- EU Guidelines to good manufacturing practice for medicinal products for human and veterinary use vol 4; annex 1 Manufacture of sterile medicinal products
- PIC/s Guide to good practices for the preparation of medicinal products in Healthcare establishments
- Good Automated Manufacturing Practice – (GAMP) – GAMP 5 – A risk-based approach to compliant GxP computerised systems
- EU Guidelines to good manufacturing practice for medicinal products for human and veterinary use vol 4; chapter 4: Documentation

Table 5.1. An overview of the validation and testing process, documentation and responsibilities

Documents	Information	Responsible	
		SAHF	Contractor
Before validation			
Validation Plan (VP)	A plan describing testing and validation scope, organization and a general overview of the work; typically the documents to be prepared progress plan etc.	X	
Validation Report (VR)	A report describing the results of validation and testing according to validation plan.	X	
Risk Analysis	A risk analysis should be part of the validation and typically a part of the VP.	X	
Validation documents (stages)			
User Requirement Specification (URS)	General, functional and technical requirements are specified in a tender competition and together constitute user requirements.	X	
Design Qualification (DQ)	Systematic review of projected solutions to show that premises, technical solutions and equipment are adapted to URS and GMP. Often contains a traceability matrix that shows where the requirement is tested (IQ, OQ, PQ / PV etc.)	X	
Factory Acceptance Test (FAT)	Documentation confirming that the equipment has been tested at the factory, and is produced in accordance with applicable user requirements before delivery to customer.		X



Site Acceptance Test (SAT)	Documentation that the equipment has been tested after transportation and installation at a customer and complies with applicable user requirements. A separate test protocol is not required, and this can be done as a SAT-IQ/OQ.		X
Installation Qualification (IQ)	Documentation verifying that the equipment complies with approved design and supplier recommendations.		X
Operational Qualification (OQ)	Documentation verifying that the equipment work as intended within the specified range of functions, including efficiency and reproducibility. IQ should be approved and signed before the start of OQ. In some cases, IQ and OQ may be combined.		X
Performance Qualification (PQ)	Documentation verifying that the equipment can work together efficiently and reproducibly, based on approved processes and product specifications. OQ should be approved and signed before the start of PQ. PQ should always be performed by pharmacy staff. PQ is often combined with PV in SAHF	X	
Process Validation (PV)	Documentation ensuring that the processes, within established management parameters, can effectively and reproducibly deliver a product that meets predefined specifications and quality objectives. PV should always be performed by pharmacy staff. PV is often combined with PQ in SAHF	X	
Documentation			
(Test-) protocol	<p>A protocol is a document specifying how to perform the validation, what to test, and the acceptance criteria.</p> <p>The respective protocol for each validation process/stage shall be prepared and approved prior to the validation. It may be prepared as a non-completed report, called "protocol/report".</p>	X	X
(Test-) report	<p>A report is the results of the validation/testing in accordance with the test protocol. The report must be complete with all testing performed and contain a conclusion. Test documentation shall be included as attachments to the report. "Protocol/Report" may be used.</p> <p>The test report shall include:</p> <ul style="list-style-type: none"> • Who, when and what controls were conducted • What equipment/system is tested • The location of the equipment and system tested • How the test was performed • References to the Norwegian standard, European standard, ISO etc. (if applicable) • Copy of valid calibration certificate for used test equipment (if applicable) • Values and results • The defined acceptance criteria. The report shall offer an opinion on whether or not the relevant test/inspection has met the acceptance criteria. • Documentation of deviations if acceptance criteria are not met • Other comments and/or observations <p>Examples of test documentation may be:</p> <ul style="list-style-type: none"> ○ Test results (prints, registered results, raw data etc.), signed and dated by the one who has tested. 	X	X



	<ul style="list-style-type: none"> ○ List of persons signing the qualification and validation documentation. ○ Calibration documentation for measuring instruments used. ○ Drawings e.g. of equipment or samples. ○ Deviation logs and forms. ○ Risk analyses in case of non-conformance, change control, testing and temporary use. ○ Training documentation. 		
Other documentation part of the validation process			
Training and Training documentation	Must be provided prior to PQ/PV can start, and normally included as a part of OQ, Training of the pharmacy staff should be carried out. The Contractor is responsible for the training, and should provide documentation for training (in cooperation with the pharmacy staff if desired)	(X)	X
Necessary licenses and maintenance agreement	All necessary licenses and a maintenance agreement should be documented before starting production.	X	X
User manual and internal Procedures.	Internal procedures shall be approved by SAHF before the PQ/PV is started. User manuals should be delivered as a part of IQ (or sooner), and the Contractor is responsible for providing user manuals.	X	X

If either parties needs support to fulfill their responsibility, the other party shall be of assistance within reasonable limitations.

The documentation has to be approved by the Customer before implementation/testing starts. The documentation shall be submitted to the Customer's validation/test manager in due time prior to the scheduled start of the validation activity. Updated and finally approved editions of the documentation shall be available to the validation manager before the activity begins.

2.2 Definition of errors

Errors shall be defined in accordance with clause 2.2.2 of the Agreement.

2.3 Acceptance Criteria

All acceptance criteria shall be specified in their respectable validation and test protocols.

The Customer acceptance test is completed when all individual protocols are approved, all implementation activities have been completed and approved by the Customer, and the equipment is ready for operation.

2.4 Deadline for approval

In accordance with clause 2.2.2 of the Agreement.