SYKEHUSAPOTEKENE

Purchase Agreement

Agreement governing the purchase of software and equipment

The Norwegian Government's Standard Terms and Conditions for IT Procurement
SSA-K 2018

Tender for delivery of Blister Unit Dose Dispensing and Packaging Machine

SSA-K Appendix 5 Approval test

Case number: 2022/510

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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 costumer 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. The Contracting Authority 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 oPIC/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	
		Contracting Authority	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 could be combined with PV.	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.	X	
Documentation			
(Test-) protocol	A protocol is a document specifying how to perform the validation, what to test, and the acceptance criteria. 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".	X	X
(Test-) report	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. The test report shall include: • 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.	X	X

	• Documentation of deviations if acceptance criteria are not met • Other comments and/or observations Examples of test documentation maybe: • Test results (prints, registered results, raw data etc.), signed and dated by the one who has tested. • 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 the Contracting Authority 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

2.2. Definition of errors

Level	Category	Description
A	Critical error	-Any error that results in downtime of dispensing or production of unit doses with an output/input capacity decrease at least of 25%, and all loss of data. - Documentation being incomplete or misleading, causing Customer to being unable to use the system or functionality that is critical to Customer.
B	Serious error	- Any related errors to the unit-dose solution that results in an increase of rejects higher than 4%, and which it is time consuming or expensive to avoid.
C	Less serious error	- Any related errors that is possible to work around with relative ease by the Customer but affects individual functions not working as intended. - Documentation being incomplete, imprecise or easily misunderstood.

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.