SYKEHUSAPOTEKENE

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 Unit Dose Dispensing and Packaging Machine for the Hospital Pharmacies Enterprise – South Eastern Norway

K Appendix 1: Customer requirement specification

Customer: Sykehusapotekene HF
Contractor: <Contractor name>

Case number: 2019/0009

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

Contents

1 Introduction

This appendix is the Customer requirement specification in respect of the deliverables. The Contractor's proposed solution for delivery of the Unit Dose Dispensing and Packaging Machine, including necessary software, training and documentation will be referred to as the "Offered Solution".

2 The Agreement, clause 1.1 Scope of the Agreement

The Offered Solution shall function together with the Customer's current technical platform, which is stated "K Appendix 3 Customer technical platform".

3 The Agreement, clause 2.1.2 Customizations and installation, etc.

The Contractor is responsible for implementation activities for the Offered Solution. Implementation should cover activities necessary for the Customer to use the Offered Solution as intended, including; transportation, installation, validation/testing and programming the Offered Solution for use.

4 The Agreement, clause 2.1.4 Documentation and training

The Contractor shall help provide the necessary training for the Customer's personnel, and all relevant documentation shall be made available for the Customer. See requirements in chapter 9.

5 The Agreement, clause 2.2.2 Duty to examine

Validation and testing of the Offered Solution (Customer's acceptance test) will be conducted. See "K Appendix 5 Approval test" for further description and requirements.

6 The Agreement, clause 2.7 External legal requirements

The Contractor shall comply with all laws, regulations, rules, and guidelines. In particular, the Contractor shall ensure that the proposal complies with Good Manufacturing Practice ("**GMP**"), as published in EudraLex Volume 4. Furthermore, the proposal must enable the Customer to comply with GMP, as packing of pharmaceuticals is defined as "manufacturing".

7 The Agreement, clause 4.3 Free software

If parts of the Offered Solution are based on free software, including customizations and further developments of the free software, the Customer shall be granted the rights necessary to distribute the results further under the relevant free software license, or under a compatible free software license if this is specified.

The Customer needs to be able to distribute the results of the deliverables that are covered by a free software licence: YES [x] or NO [ ]

8 Instructions for answering the requirement specification

8.1 Instructions for answering requirement

The requirements shall be answered in “K Appendix 2 Contractor description of the deliverables”.

8.1.1 Importance of requirements

Obligatory requirements (“O”) must be fulfilled or the proposal will be rejected. “O” requirements will therefore not be graded. The other requirements will be graded according to their high, medium or low importance. The table below lists up the applicable classifications:

Type of requirement	Description	Highest possible grade score
O	Obligatory. All obligatory requirements must be satisfied	N/A
H	High importance	6
M	Medium importance	4
L	Low importance	2

8.1.2 Description of requirements

D = Description
Requirements that has a “D” included in the describe-column, indicates that the Contractor shall provide an in-depth description of how the Offered Solution responds to the requirement.

8.1.3 Confirmation of requirements

Some requirements will oblige a confirmation from the Contractor and shall be answered with a “confirm” OR “does not confirm” only. Confirmation is made using the dropdown menu as shown in table 1 below.). Should the dropdown menu for some reason not appear, the Contractor shall insert “confirm” or “does not confirm” in the intended cell.

8.1.4 Requirement respond form

No.	Requirement	Importance (O/H/M/L)	Describe
G 3	*Description of the requirement*	H	D
The Tenderer's description:			
	The Tenderer's confirmation:		

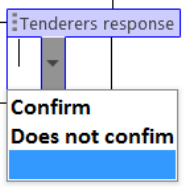

Table 1 Example of a requirement respond form (Tenderer = Contractor)

A requirement can require either a confirmation OR a description only, or both a confirmation AND a description.

8.1.5 Chapter and requirement numbers

The different requirement categories that are stated below is separated by chapters in their respective appendixes. Requirements are also identified by requirement numbers;

- "O(nr.)" for Obligatory requirements
- "G(nr.)" for the general requirements
- "F(nr.)" for functional requirement

9 Obligatory requirements regarding the delivery of the Offered Solution

No.	Requirement	Importance (O/H/M/L)	Describe
O 1	The Contractor shall, in K Appendix 2, confirm that the offered solution is suitable for installation in classified rooms (Class D) in accordance with EU GMP (Annex 1, general §4), with controlled ventilation.	O	
O 2	The Contractor shall in K Appendix 2, confirm that the offered solution meets formal requirements for validation according to EU GMP (Annex 1, general §4), EU GMP Annex 11: "Computerized Systems" and established industry standards.	O	
O 3	The Contractor shall, in K Appendix 2 confirm if that the offered solution is compliant with GDPR (The EU General Data Protection Regulation).	O	

No.	Requirement	Importance (O/H/M/L)	Describe
O 4	The Contractor shall, in K Appendix 2, confirm that the offered solution is able to dispense and pack unit doses and patient specific unit doses.	O	
O 5	The Contractor shall in K Appendix 2, confirm that the offered solution can operate within the assigned work area (including ceiling height), described in K Appendix 3. This area includes the area needed for the operator and maintenance operations. See figure 1 in K Appendix 3 for a drawing of the work area.	O	
O 6	The Contractor shall in K Appendix 2, confirm that the offered solution will not exceed the load bearing capacity of the floor in the work area stated in K Appendix 3.	O	
O 7	The Contractor shall in K Appendix 2, confirm that the software application and database must be able to manage letters distinctive to the Norwegian alphabet (Æ, Ø, Å).	O	
O 8	The Contractor shall, in K Appendix 2 confirm the that the unit dose label as a minimum include the following; • dispensing pharmacy • medicinal product name, strength and form; • administration and dosing instructions; • warnings and storage instructions as applicable; • expiry date of the medication • batch identification number to ensure full traceability; • active substance • drug manufacturer • Contracting Authority's article number as a barcode	O	
O 9	The Contractor shall, in K Appendix 2 confirm that the offered solution can print at least the following information on patient specific unit dose packages: • patient's name and date of birth • dispensing pharmacy; • ward name or ward ID • medicinal product name, strength and form; • quantity of medicinal products; • administration and dosing instructions; • date and time of medication use; • identification number to ensure full traceability in the form of a barcode (regular barcode and/or 2D barcode)	O	
O 10	The Contractor shall in K appendix 2 confirm that the offer contains product samples. (ref. F41/42).	O	

10 General requirements regarding the delivery of the Offered Solution

10.1 Contractor's understanding of the scope of the mission and underlying preconditions

10.1.1 Purpose of the contract

No.	Requirement	Importance (O/H/M/L)	Describe
G1	The Contractor shall, in K Appendix 2, provide a general description of their understanding of the scope of the mission and contract purpose, and how the offered solution will contribute to achieve the mission and contract objectives. Details regarding production and workflow can be found in K appendix 3.	H	D

10.1.2 The Contractor's understanding of the scope of the mission

No.	Requirement	Importance (O/H/M/L)	Describe
G 2	The Contractor shall, in K Appendix 2, confirm that the offered solution is a standard proven validated model. The Contractor shall, in K Appendix 2, describe any special adaptations or additional functions that are included in the offered solution.	H	D
G 3	The Contractor shall, in K Appendix 2, describe its future commitment to the development of the offered solution and their vision of development in the next 5 years. If applicable, the Contractor shall, in K Appendix 2, provide a overview of the current development plans for the solution for the next five (5) years.	H	D

10.2 Specification of Offered Solution (equipment and software)

10.2.1 Offered Solution

No.	Requirement	Importance (O/H/M/L)	Describe
G 4	The Contractor shall, in K Appendix 2, specify the expected life time when producing unit doses at max capacity, 2600 hours/per year (10 hour a day, 5 days a week and 52 weeks a year). Preconditions for service and maintenance should be described.	H	D
G 5	The Contractor shall, in K Appendix 2, present an overview of the solution offered. The summary should include specifications of all relevant components, equipment, spare parts and software, including version numbers.	H	D
G 6	The Contractor shall, in K Appendix 2, specify any other relevant equipment and software that is a precondition for the offered solution to work as intended for the Customer.	H	D
G 7	The Contractor shall, in K Appendix 2, confirm that they have the necessary authorizations, rights, etc. in relation to the offered equipment and software to be used.	H	
G 8	The Contractor shall, in K Appendix 2, specify any requirements for third-party software and associated licenses if the offered solution requires these.	H	D

10.2.2 Delivery time

No.	Requirement	Importance (O/H/M/L)	Describe
G 9	The Contractor shall in K Appendix 2, describe the delivery time for the offered solution from date of ordering.	H	D
G10	The Contractor shall in K Appendix 2, confirm that the tentative timetable in K appendix 4 is possible. If the Contractor have any deviation from this time schedule, or can expedite the delivery date, this shall be described. The customer would like the delivery date to be as soon as possible.	H	D

10.3 General security requirements

No.	Requirement	Importance (O/H/M/L)	Describe
G 11	The Contractor shall, in K Appendix 2, confirm that it is the Contracting Authority's understanding of requirements; implied by laws, regulations, rules, instructions and guidelines by the Contracting Authority in its capacity as a member of the Norwegian health sector, that are to be followed under this agreement and the maintenance agreement (SSA-K and SSA - V with appendices).	H	
G 12	The Contractor shall, in K Appendix 2, confirm that they in cooperation with the Contracting Authority will implement changes with respect to the relevant laws, regulations and regulatory requirements which affects the use of the offered solution no later than 6 months before the date the amendment takes effect, unless otherwise agreed upon in writing with the Contracting Authority. The Contractor shall in K Appendix 2, describe their procedures and methodology for change management.	H	D
G 13	The Contractor shall, in K Appendix 2, confirm that the Contractor shall comply with the Contracting Authority's standard security solutions for remote access (if applicable).	H	

10.4 Training

No.	Requirement	Importance (O/H/M/L)	Describe
G 14	The Contractor shall, in K Appendix 2, confirm that training of the pharmacy staff is part of the implementation of the offered solution. The scope of the training should be sufficient for the pharmacy staff to operate the offered solution.	H	
G 15	The Contractor shall, in K Appendix 2, give a brief overview of the training that will be part of the implementation of the offered solution. If there is different levels (training courses) of training given to the pharmacy staff, this should be specified.	H	D

10.5 Documentation

No.	Requirement	Importance (O/H/M/L)	Describe
G 16	The Contractor shall, in K Appendix 2, confirm that any form of documentation and training course material from the Contractor, shall be made available in an electronic format for the Contracting Authority, and should be editable if the Contracting Authority requires it.	H	
G 17	The Contractor shall, in K Appendix 2, confirm that all documentation will be written in English or in a Scandinavian language.	H	
G 18	The Contractor shall, in K Appendix 2, confirm that the documentation provided by The Contractor shall be approved by the Contracting Authority, if the Contracting Authority requires this. Disapproved documents should be revised by the Contractor.	H	

10.6 Procedure for ordering

No.	Requirement	Importance (O/H/M/L)	Describe
G 19	The Contractor shall, in K Appendix 2, confirm that they will notify the Contracting Authority by e-mail when the order is received. There must be issued at order confirmation and an invoice in accordence with matching rates specified in Appendix 7.	M	

10.7 Test and Acceptance

10.7.1 Definitions

No.	Requirement	Importance (O/H/M/L)	Describe
G 20	The Contractor shall, in K Appendix 2, confirm that the Contracting Authority for the FAT and SAT will not be approved until the following number of errors (ref. definition of errors in SSA-V) A. Critical errors: None (0) B. Serious errors: None (0) C. Less serious errors: 10	H	G 20
G 21	The Contractor shall in K Appendix 2, confirm that in order to get the Customer Acceptance Test (CAT) accepted the following number of errors (ref. definition of errors in SSA-V) must not exceed: A. Critical errors: None (0)	H	G 21

	B. Serious errors: None (0) C. Less serious errors: 5		

10.7.2 General testing and validation requirements

No.	Requirement	Importance (O/H/M/L)	Describe
G 22	The Contractor shall, in K Appendix 2, confirm that they are in terms of activities responsible for preparing protocols and test plans for all activities through DQ, FAT-IQ and SAT-IQ/OQ, IQ and OQ. The Contracting Authority shall approve the protocols before they are used. For an overview of the validation and testing activities, see K appendix 5	H	
G 23	The Contractor shall, in Appendix 2, confirm that all relevant validation and testing shall be performed as stated in K Appendix 5. Any deviations needs to be described by the Contractor in K Appendix 2.	H	D
G 24	The Contractor shall, in K Appendix 2, confirm that documentation from testing will be handed over to the Contracting Authority. The documentation shall as a minimum contain information stated in K appendix 5.	H	
G 25	The Contractor shall, in K Appendix 2, describe their Methodology and standards used for testing of the offered solution.	H	D
G 26	The Contractor shall, in K Appendix 2, provide one example of a protocol for validation activities.	H	D
G 27	The Contractor shall, in K Appendix 2, confirm that a Test Manager will be appointed. The Test Manager will be responsible towards the Contracting Authority, and: • Ensure that the Contractor's deliveries are in accordance with this document. • Have overall responsibility for all tests to be performed and documented by the Contractor in accordance with this document. • Assess reported errors in collaboration with developer, testers, and test managers. • Ensure that the reported errors are corrected and delivered as soon as possible. • Maintain regular dialogue with the Contracting Authority's test manager in relation to the follow-up of issue-reporting.	H	

10.8 Administrative requirements

No.	Requirement	Importance (O/H/M/L)	Describe
G 28	The Contractor shall, in K Appendix 2, deliver a complete list of both Contractor's and Contracting Authority's responsibilities in all phases of the implementation and validation of the offered solution.	H	D
G 29	The Contracting Authority requires that the Contractor shall guarantee qualified personnel to the Contracting Authority throughout the project. The Contractor shall in K Appendix 2 confirm this.	H	

11 Functional requirements of the Offered Solution.

11.1 Process requirement

No.	Requirement	Importance (O/H/M/L)	Describe
F 1	The Contractor shall, in K Appendix 2, give an overview of the offered solution (software and hardware) , and describe the production workflow for unit doses from start to finish. What is done automatically and what is done manually, needs to be specified. The overview should describe how the offered solution functionally and technically supports the tentative workflow in K Appendix 3 when implemented.	H	D
F 2	The Contractor shall, in K Appendix 2, confirm that the offered solution is able to scan and retrieve information regarding the drug, when scanning the barcode of the drug (both linear and 2D-barcodes).	H	
F 3	The Contractor shall, in K Appendix 2 confirm that offered solution's barcode system is able to read two-dimensional barcode (2D) which includes multiple data e.g.. GS1 Data matrix or ISO/IEC 15434 Barcode Specifications, which is mandatory for the EU falsified medicines directive (2011/62/EU).	H	
F 4	The Contractor shall, in K Appendix 2 describe which standards of barcode that will be interpreted, and which information from the barcode that may be used to automatically fill information fields in the production.	H	D
F 5	The Contractor shall in K Appendix 2, describe which information (input) is required in order to start the production that must be entered manually and which master data the solution can have stored (or imported).	H	D
F 6	The Contractor shall in K Appendix 2, describe what disposable material the operator supplies the solution with, and if there are any special preparations to be done with the material, in order to start the	H	D

No.	Requirement	Importance (O/H/M/L)	Describe
	production (e.g. packaging material, ink/toner etc.). If there is a need to change between different disposable material (e.g. size or material) between productions this should be specified in the description. The Contracting Authority would prefer as few changes between different types of disposable material as possible.		

11.2 Safety and efficacy of the product

No.	Requirement	Importance (O/H/M/L)	Describe
F 7	The Contractor shall, in K Appendix 2, describe the offered solution's system for ensuring that the correct drug is loaded /used in the system.	H	D
F 8	The Contractor shall, in K Appendix 2, confirm that the offered solution includes a bar code reading system to identify drugs loaded into the system.	H	
F 9	One of the most important safety features in the production is to confirm the correct drug by scanning. The Contractor shall, in K Appendix 2, confirm that all packages that will be part of one or unique production could be scanned individually.	H	
F 10	The Contractor shall, in K Appendix 2 confirm that The offered solution is able to read one-dimensional barcodes (1D) e.g. EAN-13. The Contractor shall describe which standards that can be read.	H	D
F 11	The Contractor shall, in K Appendix 2 describe how the system handles production requests while producing. It should be possible to send new production requests to the system while the system is producing unit doses, without discontinuing the production.	H	D
F 12	The Contractor shall, in K Appendix 2 describe how many different drugs that can be stored in the dispensing unit simultaneously. If there are different models that can handle different number of drugs, the Contractor shall give a short overview of the different models.	H	D
F 13	The Contractor shall, in K Appendix 2 describe how the solution will indicate which cassettes/ boxes /trays (or similar) will be needed for the next batch to be packed. The Contractor shall also give a short description of changeover workflow between batches (for unit doses and patient specific unit doses, respectively).	H	D
F 14	All drug cassettes/ boxes /trays or similar shall have a validated method of identification. The Contractor shall, in K Appendix 2 describe how all different boxes/cassettes/trays or similar used to load the drugs are identified (e.g. an RFID chip or barcode).	H	D
F 15	The Contractor shall, in K Appendix 2, confirm that all cassettes/boxes/trays (or similar) should be exchangeable between identical dispensing unit models.	H	
F 16	The Contractor shall, in K Appendix 2, confirm that the number of calibrated and validated cassettes / boxes /trays (or similar) should not be limited to the number of available locations in the dispensing	H	D

No.	Requirement	Importance (O/H/M/L)	Describe
	unit. Each unit should be able to hold an unlimited number of cassettes/boxes/trays or similar. Any deviation should be described.		
F 17	The Contractor shall in K Appendix 2, describe how a Master cassette/tray/box or similar may be grouped to a Slave cassette/tray/box or similar, enabling continous production.	M	D
F 18	The Contractor shall, in K Appendix 2, describe the process of validating cassettes / boxes /trays (or similar). Any involvement from the Contractor in the validation process shall be described.	M	D
F 19	The Contractor shall , in K Appendix 2 describe if there are any safety mechanisms based on a visual system (E.g. Picture-, video-recognition etc.) for quality control of the production. The Contractor shall describe this system (if applicable), including security and method of detection, where in the process the detection is done, and response if any deviations is detected.	H	D
F 20	The Contractor shall , in K Appendix 2 describe the dispensing error rate. Dispensing error rate (%) and calculation method should be documented. Dispensing error rate should be described separately for patient specific multiple doses and unit doses.	H	D
F 21	The Contractor shall, in K Appendix 2, document known errors that can occur during production, with corresponding frequency (%). This description shall also include the consequences and necessary actions related to fix the error.	H	D
F 22	The Contractor shall in K Appendix 2 describe the offered solutions response to input of illegal values, illegal combinations of values, or lack of values/input.	H	D
F 23	The Contractor shall in K Appendix 2 describe what type of master data that may be stored in the software, and which control steps to be performed when storing new master data. The audit trail for the master data should also be described.	H	D
F 24	The Contractor shall in K appendix 2 describe the storage capacity for medical products and associated master data, logs, reports and any other applicable data in the offered solution.	H	D
F 25	The Contractor shall in K appendix 2 confirm that the process of entering new drugs to the database (e.g. new drugs, manufactures change the design etc.) can be done by the pharmacy staff, without the involvement of the Contractor.	H	
F 26	The Contractor shall in K Appendix 2 describe, the process of entering new drugs to the database (e.g. new drugs, manufactures change the design etc.). This description should give an example of the time it takes to enter a new drug in the offered solution.	H	D
F 27	The Contractor shall in K Appendix 2 describe if the offered solution has a system (or mechanism) to recognize if there is a single tablet packed, or multiple tablets in each single unit. This description should include the response of the offered solution and how the pharmacy staff is alerted if there is a deviation.	H	D

11.3 Application and suitability of the Offered Solution

No.	Requirement	Importance (O/H/M/L)	Describe
F 28	The Contractor shall in K Appendix 2, describe the offered solution's limitations regarding drugs on the European market, e.g. size, coating or other factors that makes the drug not compatible with the offered solution.	H	D
F 29	The Contractor shall, in K Appendix 2 describe how the offered solution handles divided tablets (e.g. 1/2 tablets) or other drugs that are not possible to pack from a drug cassette or similar. This description should include how a picking list is generated, and how the dispensing is documented.	H	D
F 30	The Contractor shall, in K Appendix 2, confirm that the offered solutions outer panels and surfaces are smooth and easy to clean.	H	
F 31	The Contractor shall in K Appendix 2, confirm that the GUI (graphical user interface), including field-labels, button-texts, menu-items and other texts is presented in Norwegian or English language. Any deviations should be described in K Appendix 2.	H	D

11.4 General functional requirement

11.4.1 Batch documentation and labels

No.	Requirement	Importance (O/H/M/L)	Describe
F 32	The Contractor shall, in K Appendix 2 describe what information is stored in the production log, such as date and name of all process-related events and alarms. The description should also include how long this log is stored in the system, the audit-trail, and how logs can be exported and made available for the customer.	H	D
F 33	The Contractor shall, in K Appendix 2 confirm that the production log in the system shall not be possible to manipulate or delete (except after an agreed storage period).	H	
F 34	The Contractor shall, in K Appendix 2 describe if there are any limitations to batch sizes.	H	D
F 35	The Tender shall in K Appendix 2, describe how lot/batch number will be assigned and documented.	H	D
F 36	In some cases the pharmacy would want to set a shorter expiration date. The Contractor shall, in K Appendix 2 describe the possibility to override the expiration date if given by the drugs barcode or imported via possible future integrations.	M	D
F 37	The Contractor shall, in K Appendix 2 describe the possibilities for unit dose label design and configuration of layout, and barcode options. The description should also describe the possibilities for symbols and colours. The Contractor should enclose an illustrated example of a possible label design in K Appendix 2.	M	D
F 38	The Contractor shall in K Appendix 2, confirm if it is possible to make sequential numbers on each unit dose. This is used in internal control, and should not be printed in the same size and/or area as the	H	D

No.	Requirement	Importance (O/H/M/L)	Describe
	information intended for the customers. Any deviation must be described in K appendix 2		
F 39	The Contractor shall in K Appendix 2, describe if the solution prevents data from being lost due to an emergency or power shortage. The Contractor shall describe the offered solution's response in case of an emergency power shortage, including potential damage and data loss.	H	D
F 40	The Contractor shall, in K Appendix 2 describe the possibilities for accessing or generating reports about i.e. the number of approved and rejected preparations, utilization rate, and time periods when the offered solution is running . The description should include how the Contracting Authority can access or generate these reports.	H	D
F 41	The Contractor shall, in K Appendix 2 describe the package materials for the unit doses. If there are different types of materials and sizes available this should be specified in the description. The contracting Authority prefers if the package is in a material that allows easy visual inspection of the content, but would also like to know if other types of package materials are recommended or available. The Contractor shall also describe if the package materials are made of a environmental friendly material, or if environmental friendly material is available.	H	D
F 42	The Contractor shall upon submission of the offer deliver minimum 2 product samples of each packaging material (disposal material). The samples shall contain a packed tablet/capsule representable for a produced unit dose, with related information printed on the packaging material. If there are different sizes of the packaging material available, a sample for each size should be delivered. Each product sample should be marked clearly, so that the Contracting Authority can identify which sample is which to the reference in K appendix 2 (F 41) and prices in V appendix 7 during the evaluation. If applicable the contracting Authority would like to see how different unit doses are linked together, e.g. strip, ribbon, ring etc. The product samples will not be returned to the Contractor.	H	D
F 43	The Contractor shall, in K appendix 2 describe the readability of the print on the unit dose bags after 36 months. The Contracting Authority expects the durability to be at least 36 months but prefer as long as possible.	H	D
F 44	The Contractor shall, in K appendix 2 describe the integrity of the unit dose bags over time. If there are any stability studies done, this should be described.	H	D
F 45	The Contractor shall, in K Appendix 2 describe the different options/solutions for separating a defined number of unit doses in a strip/ribbon or ring.	M	D

11.4.2 Alarms, alerts, messages

No.	Requirement	Importance (O/H/M/L)	Describe
F 46	The Contractor shall, in K Appendix 2 confirm that messages and alarms will contain audio and/or be easily visible, for example by blinking or change of color.	H	
F 47	The Contractor shall in K Appendix 2, confirm that Notification / Alarm/ Alerts /messages should appear in full text on the screen with a reference number for that individual alarm/alert.	H	
F 48	The Contractor shall in K Appendix 2, describe the different alarms and messages on the solution, including a description of which alarms (and messages) that will interrupt/stop the process.	H	D
F 49	The Contractor shall in K Appendix 2, confirm that the software logs all errors in an alarm list, which clearly indicates the nature of the error, date and time, and action.	H	

11.4.3 User access

No.	Requirement	Importance (O/H/M/L)	Describe
F 50	The offered solution should have different access controls, ensuring that access can be defined by e.g.; department affiliation, functionality and other rights to be individually assigned to the individual. The Contractor shall in K Appendix 2, describe the process of creating a user for the system, and the possibility to create different access levels for different users.	H	D
F 51	The Contractor shall in K Appendix 2, confirm that each user requires a username and personal password.	H	
F 52	The Contractor shall in K Appendix 2, describe the possibilities for electronic signatures in the system.	H	D

11.4.4 Patient specific and multi dose packages

No.	Requirement	Importance (O/H/M/L)	Describe
F 53	The Contractor shall, in K Appendix 2 confirm that the offered solution is able to dispense and pack unit doses and patient specific unit dose without any technical alterations and or interventions.	H	
F 54	The Contractor shall, in K Appendix 2 confirm that the offered solution can pack combi dose.	L	
F 55	The Contractor shall, in K Appendix 2 confirm that the offered solution can pack unit doses in patient specific multi dose packages.	M	

No.	Requirement	Importance (O/H/M/L)	Describe
F 56	The Contractor shall, in K Appendix 2 confirm that the offered solution can print the following information on patient specific unit dose packages: • active substance • drug manufacturer • warnings and storage instructions as applicable;	H	
F 57	The Contractor shall, in K Appendix 2 confirm that the offered solution shall be able to function with different types of national identification number. In Norway this different formats are; • F-number: Standard number. Consists of 11 digits, where the first six indicates date of birth. • D-number: For people born outside of Norway. Consists of 11 digits, where the numbers indicating the day of birth is modified by adding a 4 to the first number. (e.g. 310101 becomes 710101) • H-number: Help number for people with unknown F or D number. Consists of 11 digits, where the numbers indicating the day of birth is modified by adding a 4 to the third number. (e.g. 310101 becomes 314101) • FH-number: Used when communication is not possible. Consists of 11 digits, the first number is always 8 or 9, then eight randomly selected numbers and two control numbers. This is the only number that does not indicate date of birth or gender. Any deviations need to be described by the Contractor.	H	D
F 58	The Contractor shall, in K Appendix 2 confirm that the offered solution shall allow: - ordering, dispensing and entering of half tablets - a minimum of eight drug administration times per day - defining administration times per patient and per ward - drug dispensing in descending and ascending dosages - periodic drug doses on certain day(s) of the week Any derivations should be described.	H	D
F 59	The Contractor shall, in K Appendix 2 confirm that the offered solution enables viewing and reporting of patient medication data in the following way: - drugs dispensed to patients and/or ward - which patients using a certain drug	H	

11.5 Health and Work safety

No.	Requirement	Importance (O/H/M/L)	Describe
F 60	The Contractor shall, in K Appendix 2, describe the safety features of the offered solution when it comes to work safety for the operator (the safety features that prevent the operators from getting cuts or compression injuries etc.). E.g. that the production/operation stops when the doors (or similar) are opened during automated movement.	H	D
F 61	The Contractor must confirm in K Appendix 2 that the maximum noise exposure, and that the average noise level during operation does not exceed 70 dB (A). The noise level should be measured 1 m height from the noisiest elements and measured from the operator's position at head height, in normal cleanroom conditions. The measured noise level of the offered solution shall be described by the Tender in K Appendix 2.	H	D

11.6 Technical requirements

No.	Requirement	Importance (O/H/M/L)	Describe
F 62	The Contractor shall, in K Appendix 2 describe the capacity of the offered solution. This description should include the average production rate (unit/hour) and the number of hours the offered solution can operate per day.	H	D
F 63	The Contractor shall, in K Appendix 2, describe the average time to start up and finish a production. The description should include time used to e.g.: insert production data, loading drugs, loading packaging material, unloading unit doses, handling waste etc. The Contractor should use the following 2 examples: 1) 2000 unit doses of Drug X 2) 1000 unit doses of Drug X and 1000 unit doses of Drug Z There should be only one tablet per packed unit dose.	H	D
F 64	The Contractor shall, in K Appendix 2, describe the start-up / closing time (including daily maintenance and cleaning time) for the offered solution.	M	D
F 65	The Contractor must, in K Appendix 2, describe the cleaning and maintenance process/procedure that needs to be carried out by the pharmacy staff (daily, weekly, monthly, yearly etc.).	H	D

11.7 Technical Process requirement - Air quality and temperature

No.	Requirement	Importance (O/H/M/L)	Describe
F 66	The Contractor shall in K Appendix 2 describe the offered solutions air treatment system and requirement for air supply that must be provided by the contracting authority. The description should also include an overview of filters included in the offered solution (if applicable).	H	D
F 67	The Contractor shall, in K Appendix 2, confirm that the offered solution will not generate particles or microbiological contamination in the production room, at a rate that exceeds the requirements for Class D (EU GMP) in and out of operation.	H	
F 68	The drugs loaded into the offered solution should not be exposed to temperatures below 15 degrees Celsius or exceeding 25 degrees Celsius during the process of cutting and packing unit doses. The Contractor shall, in K Appendix 2, describe how the temperature in the offered solution is monitored or ensured in the offered solution. The description should also state whether the temperature measurements are saved and included in the system log (if applicable).	H	D

11.8 General technical software requirements

No.	Requirement	Importance (O/H/M/L)	Describe
F 69	The Contractor shall, in K Appendix 2, confirm that the system offered includes the most recently updated software. Further, the Contractor shall confirm that following information will be provided upon software updates: current software version, history, date/reason for revisions, change log,	H	
F 70	The Contractor shall, in K Appendix 2, confirm that the Software updates will be announced to the Contracting Authority for approval at least one month before the upgrade is commenced. The announcement to the Contracting Authority should include an evaluation if there is any need to revalidate any part of the production process after the update, and a "rollback-plan" if the update fails or have significant errors.	H	
F 71	The Contractor shall, in K Appendix 2, confirm that the system can be remotely controlled through a VPN service or similar, and that all remote access connections would have to be approved by the Contracting Authority before initiated. The Contractor shall describe their solution for remote access in K Appendix 2	H	D

11.9 Design / Installation Requirements – Mechanical

No.	Requirement	Importance (O/H/M/L)	Describe
F 72	The Contractor shall, in K Appendix 2 give an overview of the technical specifications e.g. regarding dimensions and weight of the offered solution, the offered solution's need for power connections and electric supply etc. If the offered solution has a pre-installation guide (or similar) this should be provided as part of the description (or as an attachment).	H	D
F 73	The Contractor shall confirm in K Appendix 2 that the CE marking and declaration of conformity demonstrate that the offered solution has been designed, constructed and conformity assessed in accordance with applicable legislation in the EU.	H	
F 74	The Contractor should provide an example (illustration) of installation (layout) for the offered solution within the assigned work area. (See figure 1 in K Appendix 3 for a drawing of the work area) in K Appendix 2	H	D
F 75	The Contractor shall in K Appendix 2, confirm that the offered solution can be transported to the assigned work area through the described transportation way, given in K Appendix 3. Any deviation needs to be described by the Contractor in K appendix 2, with a suggestion for alternative transportation.	H	D

11.10 Requirements for the IT-Architecture

No.	Requirement	Importance (O/H/M/L)	Describe
F 76	The Contractor shall in K Appendix 2, describe the IT-architecture of the solution.	H	D
F 77	The Contractor shall, in K Appendix 2, describe how data may be exported from the offered solution's database to an external IT solution(s).	H	D

11.11 Integrations

No.	Requirement	Importance (O/H/M/L)	Describe
F 78	The Contractor shall, in K Appendix 2, describe the possible standard(s) for information exchange (e.g. HL7) . This description shall include which versions are supported and list available services/messages.	H	D

No.	Requirement	Importance (O/H/M/L)	Describe
F 79	The Contractor shall, in K Appendix 2, describe the software integrations accessible in the offered solution and which standards are supported. The Contractor should state references to previous similar integrations if applicable.	H	D
F 80	Describe, in K Appendix 2, which integration possibilities that the offered solution may support: Integration for production (receive information needed to start a production), production documentation (integration: return of production steps information to an external production documentation program), ERP integration (integration: stock reduction of drugs prepared for a production, stock increase of packed unit doses)	H	D

11.12 Technical Infrastructure

No.	Requirement	Importance (O/H/M/L)	Describe
F 81	Please indicate, in K Appendix 2, the requirements for the IT-infrastructure for the offered solution, include supported operating systems and databases. The Contractor shall, in K Appendix 2, document proposed technical solution and mechanisms for high availability.	H	D
F 82	The Contractor shall, in K Appendix 2, describe the normal response time for the most common user questions or if Questions & Answers is available	H	D
F 83	The Contractor shall in K Appendix 2, confirm that application- and database software will be able to manage special characters like ® , © etc.	H	
F 84	The Contractor shall, in K Appendix 2, confirm that the software application and database is able to manage Norwegian date and time (dd.mm.yyyy and 24 hour-clock)	H	
F 85	Any network requirements shall be described in K Appendix 2. The Contractor shall also describe what this network connection will be used for in the offered solution.	H	D
F 86	If there are any hardware and/or software requirements that needs to be provided by the Contracting authority (that is not part of the offered solution), this shall be described in K Appendix 2.	H	D
F 87	All ports and protocols the offered solution uses should be described in K Appendix 2.	M	D
F 88	The Contractor shall in K Appendix 2, describe the solution for the license control and related management practices. Any links to physical hardware, or other hardware locks (dongles) must be specified.	H	D
F 89	The Contractor shall, in K Appendix 2, describe the recommended software back-up of the offered solution, and the procedure for software-backup/restore, including which party is responsible for the elements in the procedure.	H	D

No.	Requirement	Importance (O/H/M/L)	Describe
F 90	The tender shall, in K Appendix 2 describe the offered software solution's limitations in the size/length of text fields, E.g. on the GUI screen, master data and printing on unit dose bags.	H	D
F 91	The Contractor shall, in K Appendix 2, describe if the use of Active Directory (AD) can be integrated with the offered solutions software for user identification.	M	D