SYKEHUSAPOTEKENE I MIDT-NORGE

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 Advanced Unit Dose Packaging and Dispensing Solution

SSA-K Appendix 1 Customer requirements specification

Case number: 2022/512

Contents

Appendix 1: Customer requirements specification

1 Introduction

This appendix is the Customer requirement specification in respect of the deliverables. The Contractor's proposed solution for delivery of the Advanced 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 Customisations 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.

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 "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.

8 Instructions for answering the requirement specification

8.1 Instructions for answering requirement

8.1.1 Importance of requirements

Information ("I") is just a request for information. This will not be evaluated and is not an obligatory requirement.

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
I	Information	N/A
O	Obligatory. All obligatory requirements must be satisfied	Pass/Fail
H	High importance	15
M	Medium importance	5
L	Low importance	2

8.1.2 Description of requirements

The Contractor shall provide an in-depth description of how the Offered Solution responds to the requirement in the "The Contractor's description/confirmation" column or refer to a description in a separate document.

8.1.3 Confirmation of requirements

Contractor shall insert "confirm" or "does not confirm" in the "The Contractor's description/confirmation" column.

8.1.4 Tender evaluation

Quality criteria will be assessed according to the degree of added value that the offered solution provides, in accordance with the intended workflow in "K Appendix 3". Example of added value can be efficiency, ease of use, security, capacity, flexibility, methodology and technical quality.

9 Requirements regarding the delivery of the Offered Solution

No.	Requirement	Type	Award criteria	The Contractor's description/confirmation
1 General requirements				
1.	The Contractor shall, in K Appendix 2, confirm that the offered solution is suitable for installation and operation in classified rooms (Class D) in accordance with EU GMP (Chapter 3 (equipment) and Annex 1, 4), with controlled ventilation.	O		*Confirm*
2.	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.	O		*Confirm*
3.	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		*Confirm*
4.	The Contractor shall, in K Appendix 2, confirm that the offered solution meets formal requirements for validation according to GAMP5.	O		*Confirm*
5.	The Contractor shall, in K Appendix 2, confirm 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.	O		*Confirm*
6.	The Contractor shall, in K Appendix 2, confirm that the offered solution can operate within the assigned work area, described in K Appendix 3.	O		*Confirm*

	This area includes the area needed for the operator and maintenance operations. See figure 3 in K Appendix 3 for a drawing of the work area.			
7.	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		*Confirm*
1.1 Contractor's understanding of the scope of the mission				
8.	The Contractor should, 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 the Contracting Authority 's planned production and tentative workflow can be found in K Appendix 3.	H	Quality - Technical solution - General	*Describe*
9.	The Contractor should, 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. High level of automation is strongly preferred. The overview should describe how the offered solution functionally and technically supports the tentative workflow in K Appendix 3 when implemented.	H	Quality - Technical solution – Deliverables	*Describe*
10.	The Contractor should, in K Appendix 2, describe its future commitment to the development of the offered solution, both hardware and software, and their vision of development in the next five years. If applicable, the Contractor should, in K Appendix 2, provide an overview of the current	I		

	development plans for the solution for the next five years.			
1.2 Specification of the offered solution (hardware and software)				
1.2.1 The offered solution in general				
11.	The Contracting Authority requires a complete delivery of all equipment and software needed for the offered solution. The Contractor shall, in K Appendix 2, present an overview of the solution offered. This overview must include a list of all relevant components, equipment, spare parts and software, including version numbers.	O	D	*Confirm and describe*
12.	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.	O		*Confirm*
13.	The Contractor should, in K Appendix 2 give an overview of the technical specifications e.g., regarding dimensions, total height with integrations (PTS) and weight of the offered solution, the offered solution's need for power connections, electric supply, pneumatic air supply, vacuum and ventilation etc. Any required room conditions such as lighting, humidity, temperature etc. should be specified. If the offered solution has a pre-installation guide (or similar) this should be provided as part of the description (or as an attachment). The Contractor should provide an example (illustration) of installation (layout) for the offered	H	Quality - Installation, test and validation	*Describe*

	solution within the assigned production area for the centralized production plant. The Contracting Authority prefers solutions that requires few modifications of the planned production area. (See K Appendix 3 for technical description and drawing of the production area).			
14.	The Contractor shall, in K Appendix 2, confirm that the offered solution can be transported to the assigned work area through the described transportation path given in K Appendix 3. Any deviation needs to be described by the Contractor in K Appendix 2, with a suggestion for alternative transportation.	O	D	*Confirm and describe*
1.2.2 Lifetime and capacity				
15.	The Contractor shall, in K Appendix 2, confirm that the expected lifetime when producing and dispensing unit doses at max capacity, 5200 hours/per year (approximately 14 hours a day, 7 days a week and 52 weeks a year) is at least 10 years. Preconditions for service and maintenance should be described.	O		*Confirm*
16.	The Contractor should, in K Appendix 2, describe the capacity of the offered solution. This description should include the dispensing and production rate (unit dose per hour) for the different medication forms, and the number of hours the offered solution can operate per day. All operations that could affect capacity should be described, e.g., inventory, return to stock etc.	H	Quality - Technical solution - Functionality	*Describe*

1.2.3 Delivery time				
17.	The Contractor should, in K Appendix 2, describe the delivery time for the offered solution from date of ordering until the solution is installed at site and an expected validation time schedule including the SAT – IQ/OQ is preformed and accepted. The Contracting Authority's tentative time schedule for delivery is described in K Appendix 4.	H	Quality - Installation, test and validation	*Describe*
1.2.4 Barcodes				
18.	The Contractor shall, in K Appendix 2, confirm that the offered solution is delivered with the necessary devices to retrieve information from the barcode of the drug package (1D- and 2D-barcodes).	O		*Confirm*
19.	The Contractor shall, in K Appendix 2, confirm that offered solution's barcode system is complying with relevant international standard (such as ISO 15434). Reference ISO/IEC 15434 Barcode Specifications, which is mandatory for the EU falsified medicines directive (2011/62/EU).	O		*Confirm*
20.	The Contractor should, in K Appendix 2, describe the different encoding/decoding methods supported (such as GS1, Code 128, Code 39, EAN-13/UPC-A etc.). The description should include how the decoded information is used and stored in the offered solution.	M	Quality - Technical solution - Functionality	*Describe*

21.	The Contractor shall, in K Appendix 2, confirm that the barcodes generated by the offered solution, e.g., barcode printed on the unit dose, is compatible throughout the complete solution.	O		*Confirm*
1.3 General security requirements				
22.	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).	O		*Confirm*
23.	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 of software and hardware.	O	D	*Confirm and describe*
1.3.1 Operator safety				
24.	The Contractor shall, in K Appendix 2, describe the safety features of the offered solution regarding work safety for the operator, e.g., that the production/operation stops when the doors (or similar) are opened during automated movement.	O	D	*Confirm and describe*

	The offered solution must have safety features to prevent the operator from getting cuts or compression injuries, electric shock etc.			
25.	The Contractor shall, in K Appendix 2, confirm that the offered solution is designed in accordance with the applicable laws, standards and regulations, including: • Maskindirektivet (Regulations on machines/Forskrift om maskiner FOR-2009-05-20-544) • Act relating to working environment, working hours and employment protection, etc. (Working Environment Act) (Working Environment Act) The Contractor is obliged to inform about necessary training and use of personal protective equipment.	O	D	*Confirm and describe*
26.	The Contractor shall, in K Appendix 2, confirm that the average noise level for the noisiest hour during operation, does not exceed 70 dB (A). The noise level should be measured 1 m distance from the noisiest elements and measured from the operator's position at head height, in normal operative conditions.	O		*Confirm*
27.	The Contractor should, in K Appendix 2, describe the noise level generated by the offered solution. The measured noise level during operation and in idle state, and method of measuring should be part of this description. If there are any noise absorbing materials included in the offered solution, these should be described. Low noise level is preferred.	H	Quality - Technical solution - General	*Describe*

1.3.1.1 Alarms and labels				
28.	The Contractor shall, in K Appendix 2, confirm that messages and alarms will contain audio and/or be easily visible, visual alarm with flashing lights or similar.	O		*Confirm*
29.	The Contractor should, in K Appendix 2, describe the different alarms and messages in the solution, including a description of which alarms (and messages) will interrupt/stop the process. The offered solution should display how to resolve the different issues causing the alarms.	H	Quality - Technical solution - General	*Describe*
30.	The Contractor shall, in K Appendix 2, confirm that all labels regarding HMI (human machine interface), e.g., pushbuttons, switches and so on, will be in Norwegian or English language.	O		*Confirm*
1.3.2 Drug safety				
31.	The Contractor should, in K Appendix 2, describe how the offered solution maintains traceability and hygiene during all drug-handling processes. The description should include detailed information of all security measures implemented in the solution to prevent cross contamination during the preparation and prevent mix-up of drugs.	H	Quality - Technical solution - Patient safety	*Describe*
32.	The drugs loaded into the offered solution should not be exposed to temperatures below 8 °C or exceeding 25 °C throughout the whole solution. The Contractor should, in K Appendix 2, describe the offered solution's heat dissipation, and the	H	Quality - Technical solution - Patient safety	*Describe*

	temperatures the drugs are exposed to during preparation, production, storage and dispensing. The offered solution should be rigged/prepared for temperature monitoring in critical/relevant areas. A stable heat dissipation is preferred.			
1.4 Training				
33.	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 enabling the pharmacy staff to operate the offered solution and instruct them how to prevent any form of injuries or working hazards. All training must be performed in English or Norwegian language.	O		*Confirm*
34.	The Contractor should, in K Appendix 2, give an overview of the training that will be part of the implementation of the offered solution. If there are different levels (training courses) of training given to the pharmacy staff, this should be specified. The description should also include training of local technicians. If the Contractor has requirements regarding the qualifications of the technical staff to be trained, this should be described. Technical training should be performed at the Contractor's location/equipment and completed before the offered solution is fully delivered to the Contracting Authority.	H	Quality - Installation, test and validation	*Describe*
1.5 Documentation				
35.	The Contractor shall, in K Appendix 2, confirm that any form of documentation and training course	O		*Confirm*

	material from the Contractor, shall be made available in an electronic format and paper version for the Contracting Authority in accordance with GMP. All documentation and training course material must be written in English language.			
36.	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. All documents must be electronic format and fully searchable.	O		*Confirm*
37.	The Contractor shall, in K Appendix 2, confirm that all hardware changes and upgrades will be documented, and all technical documentation updated accordingly and made available for the Contracting Authority. All documents must be electronic format and fully searchable.	O		*Confirm*
1.6 Test and acceptance				
1.6.1 Definitions				
38.	The Contractor shall, in K Appendix 2, accept that the Contracting Authority will not approve the FAT and SAT until the following number (or less) of errors (ref. definition of errors in SSA-K) is achieved:	O		*Confirm*

	A. Critical errors: None (0) B. Serious errors: None (0) C. Less serious errors: 10			
39.	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-K) must not exceed: A. Critical errors: None (0) B. Serious errors: None (0) C. Less serious errors: 5	O		*Confirm*
1.6.2 General testing and validation				
40.	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 and SAT. The Contracting Authority shall approve the protocols before they are used. For an overview of the validation and testing activities, see K Appendix 5.	O		*Confirm*
41.	The Contractor shall, in Appendix 2, confirm that all relevant validation and testing shall be performed as stated in K Appendix 5.	O		*Confirm*
42.	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.	O		*Confirm*
43.	The Contractor should, in K Appendix 2, describe their Methodology and standards used for testing of the offered solution. The Contractor should	H	Quality - Installation, test and validation	*Describe*

	provide one example of a protocol for validation activities.			
44.	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.	O		*Confirm*
1.7 Administrative requirements				
45.	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 of the offered solution.	O	D	*Confirm and describe*
46.	The Contractor shall, in K Appendix 2, guarantee that they will give the Contracting Authority access to qualified personnel throughout the project. The Contractor shall, in K Appendix 2, confirm this and state the names of dedicated key personnel and their qualifications.	O		*Confirm*
2 Drug preparation				

The Contracting Authority will evaluate on the complete drug preparation process. Drug safety, ease of use, overall traceability and stock control will be emphasized as parameters for evaluation.				
47.	The Contractor should, in K Appendix 2, describe all processing needed for the different medication forms in order to make them ready for unit dose production in the offered solution, e.g., removal of packaging, removal from blister, blister cutting, handling of ampules and vials etc. If the solution uses specific containers/boxes/trays etc. for the drugs, all containers/boxes/trays etc. should be described. The Contracting Authority prefers a solution that provides the possibility for storing prepared drugs as a buffer for production.	H	Quality - Technical solution - Functionality	*Describe*
48.	The Contractor should, in K Appendix 2, describe the method used to load the drugs into the solution and how the prepared drugs are identified, both by printed identification and electronically (e.g., RFID chip or barcode, label etc.) throughout the solution. The description should also include what information is available for the prepared drugs, e.g., batch number, expiration date and quantity.	H	Quality - Technical solution - Patient safety	*Describe*
49.	The Contracting Authority is required to reduce the expiration date for drugs when removing their primary packaging. The Contractor shall, in K Appendix 2, confirm that the offered solution has functionality for reducing shelf life for the drugs indented for unit doses, compared to the expiration date given by the manufacturer, at the	O	D	*Confirm and describe*

	time of primary packaging removal. This functionality should be described.			
50.	The Contractor should, in K Appendix 2, describe what information about the drug is obtained by scanning the 2D barcode on each medication package during drug preparation. This functionality should not allow for different batches or different drugs to part of the same production, or the same 2D barcode to be used multiple times. The scanning of all packages included in each production should be mandatory. The solution should offer a manual option for entering the information needed, e.g., pack code, batch number, expiration date and quantity. This option should require verification by a different user. If linear barcodes could be used in the manual process, this should be described.	H	Quality - Technical solution - Functionality	*Describe*
51.	The Contractor shall, in K Appendix 2, confirm that the offered solution provides a system for documentation and quality control of the preparation process of the drug. All operations performed must be electronically logged, and the offered solution must have functionality for Pharmacist control of the prepared drugs for unit dose production.	O	D	*Confirm and describe*
52.	The Contractor should, in K Appendix 2, describe the offered solutions safety measures to ensure that the prepared drugs cannot be tampered with within the solution. The solution should offer the possibility for opening of containers after preparation but opening of containers within the	H	Quality - Technical solution - Patient safety	*Describe*

	solution should be limited by user group, documented, and traceability maintained.			
53.	The Contractor shall, in K Appendix 2, confirm that the offered solution has functionality for calculating and reporting which drugs need to be prepared for unit dose production, based on all existing stock levels of the drug. This functionality must be described.	O	D	*Confirm and describe*
54.	The Contractor should, in K Appendix 2, describe if the offered solution has a storage system for drugs prepared for unit dose production, or which storage solutions is recommended by The Contractor.	L	Quality - Technical solution - Deliverables	*Describe*
55.	The Contractor should, in K Appendix 2, describe how equipment used in the preparation process and for storing drugs (containers/boxes/trays etc.) should be cleaned. If specific cleaning equipment is required, this should be specified and provided by the Contractor.	M	Quality - Technical solution - Ease of use	*Describe*
56.	The Contractor should, in K Appendix 2, describe the offered solution's functionality for performing inventory of drugs prepared for production.	M	Quality - Technical solution - Functionality	*Describe*
3 Unit dose production				
3.1 Medication forms				
57.	The Contractor shall, in K Appendix 2, confirm that the offered solution can produce unit doses of different medication forms. The solution must be able to produce the following medication forms:	O	D	*Confirm and describe*

	• Oral solids (bulk and blisters) • Ampules • Vials • Suppositories			
58.	The Contractor should, in K Appendix 2, describe any limitations of drug size and/or shape, material or other factors inflicting compatibility with the offered solution.	H	Quality - Technical solution - Functionality	*Describe*
59.	The Contractor should, in K Appendix 2, describe the offered solutions ability to produce unit doses of other medication forms than mentioned in requirement 57, and describe how the offered solution is adaptable to handle new medication forms if necessary. Any limitations in drug size and/or shape, and any other limitations should be described.	M	Quality - Technical solution - Functionality	*Describe*
60.	The Contractor should, in K Appendix 2, describe how the offered solution handles the different medication forms. This description should include details of the technology involved, if any manual involvement will be necessary, and the production capacity for the different medication forms (unit doses per hour).	H	Quality - Technical solution - Functionality	*Describe*
61.	The Contractor should, in K Appendix 2, describe their blister cutter functionality, focusing on limitations in blister layout, size, shape and materials. The offered solution should be able to handle blisters cut both automatically and manually.	H	Quality - Technical solution - Functionality	*Describe*
62.	The Contractor should, in K Appendix 2, describe the offered solutions capability to produce unit doses from drugs that require storage between 2 °C - 8°C. It should be possible to complete the	L	Quality - Technical solution - Functionality	*Describe*

	production of these unit doses within 30 minutes in room temperature.			
3.2 Drug quality				
63.	The Contractor should, in K Appendix 2, describe the offered solutions functionality for avoiding cross contamination between the different drugs that are handled by the solution. This should include if the system has ways of detecting possible contamination, which parts of the system may transmit contamination between drugs, and what measures needs to be taken by the operator in case of drug spillage in the packaging unit.	H	Quality - Technical solution - Patient safety	*Describe*
64.	The Contractor should, in K Appendix 2, describe how the offered solution protects the drugs against external influence during the production process, i.e., protection from light, humidity etc. Solutions that offer possibilities for controlled air quality will be preferred.	H	Quality - Technical solution - Patient safety	*Describe*
65.	The Contractor should, in K Appendix 2, describe if the solution offered has a system for quality control of unit dose production, i.e., vision system or similar. The description should include method of detection, where in the process the detection is done, what response the system gives when deviations are detected and if the production is stopped due to consecutive errors defined by given parameters. If there is any possibility for, by given parameters, to automatically dispense unit doses for manual inspection without discontinuing the production process, this should be described.	H	Quality - Technical solution - Patient safety	*Describe*

3.3 Unit dose design				
66.	The Contractor shall, in K Appendix 2, confirm that the information given on each unit dose as a minimum include the following: • dispensing pharmacy • medicinal product name, strength and form • administration and dosing instructions (as defined by pharmacy) • warnings and storage instructions as applicable (as defined by pharmacy) • expiry date • batch number (from producer) • Serial number to ensure full traceability • active substance • GS1 2D matrix barcode. What information should be included in the 2D matrix needs to be decided together with the Contracting Authority during the design phase. Additional information possible should be described.	O	D	*Confirm and describe*
67.	The Contractor should, in K Appendix 2, describe the possibilities for unit dose print design and configuration of layout, and barcode options. The Contractor should enclose an illustrated example of a possible design in K Appendix 2.	H	Quality - Technical solution - General	*Describe*
68.	The Contractor shall upon submission of the offer, deliver product samples. The samples shall contain as a minimum 5 produced unit doses with placebo of • Oral solid in bulk	O		*Confirm*

	• Oral solid in blister • Ampule • Vial • Suppository with all related information printed on the packaging material, ref. requirement 66. The product samples will not be returned to the Contractor.			
69.	If the Contractor offers different packaging materials, a sample for each material should be delivered. Each product sample should be marked clearly, so that the Contracting Authority can identify which sample is which. Prices should be listed in K Appendix 7. If applicable, the Contracting Authority would also like to see how unit doses are linked together, e.g., strip, ribbon, ring etc. The product samples will not be returned to the Contractor.	M	Quality - Technical solution - Deliverables	*Describe*
70.	The Contractor should, in K Appendix 2, describe the readability of the print on the unit doses after 36 months, when properly stored. The Contracting Authority expects the durability to be at least 36 months but prefers prolonged readability.	H	Quality - Technical solution - Patient safety	*Describe*
3.4 Production process				
71.	The Contractor should, in K Appendix 2, describe the information (input) necessary to start a production. The description should include what information must be entered manually, and what information is retrieved from preapproved master data.	H	Quality - Technical solution - Ease of use	*Describe*

72.	The Contractor should, in K Appendix 2, describe the offered solution's functionality for initiating and planning the packaging of unit doses. The offered solution should automatically produce a prioritized overview/list of what needs to be produced, generated from the needed stock of unit doses. Needed stock should be based on both existing stock and pending orders with the possibility to sort by, e.g., missing drugs for fulfilling pending orders. The automatic list should be possible to override manually in order to produce other drugs as defined by the operator.	H	Quality - Technical solution - Functionality	*Describe*
73.	The Contractor should, in K Appendix 2, describe the offered solutions functionality for preloading drugs in the packaging unit and how this is handled by the packaging unit. It should be possible for the operator to prioritize the drugs as needed. Preloaded drugs should be automatically produced in the packaging unit without the need for manual intervention.	H	Quality - Technical solution - Functionality	*Describe*
74.	The Contractor should, in K Appendix 2, describe how the offered solution accomplishes clearance of the production area between different productions. Validated automatic solutions will be preferred.	H	Quality - Technical solution - Ease of use	*Describe*
75.	The Contractor should, in K Appendix 2, give a short description of changeover workflow in the production unit.	H	Quality - Technical solution - Ease of use	*Describe*
76.	The Contractor should, in K Appendix 2, describe if there are any limitations to the quantity of unit doses in each production.	H	Quality - Technical solution - Ease of use	*Describe*

77.	The Contractor should, in K Appendix 2, describe the average time to start up, carry out and finish a production of a defined number of unit doses from different medication forms. The description should include time used to e.g., insert production data, loading drugs, loading packaging material, loading unit doses to stock, handling waste etc.	H	Quality - Technical solution - Ease of use	*Describe*
78.	The Contractor should, in K Appendix 2, document known errors that can occur in the offered solution while used as intended by the Contracting Authority, with corresponding frequency (%). This description should also include the consequences and necessary actions related to fix the error.	I		*Describe*

3.5 Consumables and maintenance

3.5.1 Consumables

79.	The Contractor should, in K Appendix 2, describe what consumable material the operator has to supply the solution with, and if there are any special preparations to be done with the material in order to start the production (e.g., packaging material, ink/toner/ribbon etc.). If there is a need to change between different consumable materials (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 consumable materials as possible.	H	Quality - Technical solution - Ease of use	*Describe*

3.5.2 Packaging material				
80.	The Contractor shall, in K Appendix 2, confirm that the packaging material for unit doses from bulk of oral solids is in accordance with requirements in the European Pharmacopoeia for plastic packaging materials. The packaging material must be able to withstand transportation via pneumatic tube system.	O		*Confirm*
81.	The Contractor should, in K Appendix 2, describe the available packaging materials for the unit doses. If there are different types of materials and sizes available, this should be specified. Packaging material should allow easy visual inspection of the unit doses. Unit doses should be completely sealed but easy to open without the need of any equipment. The Contractor should also describe if the packaging materials are made of environmentally friendly material, or if environmentally friendly alternatives are available.	H	Quality - Technical solution - Deliverables	*Describe*
82.	The Contractor should, in K Appendix 2, describe the integrity of the unit doses over time. This description should include recommended storage conditions (temperature, humidity and light exposure) for the packaging material. If there are any stability studies done, this should be described, and studies included.	H	Quality - Technical solution - Patient safety	*Describe*
3.5.3 Maintenance				
83.	The Contractor should, in K Appendix 2, describe if the offered solutions outer and inner panels and	H	Quality - Technical	*Describe*

	surfaces are smooth and easy to clean. All surfaces should be compatible with cleaning agents used in D classified rooms, e.g., rectified ethanol 75%. The Contractor should also describe the cleaning and maintenance process/procedure that needs to be carried out by the pharmacy staff (daily, weekly, monthly, yearly etc.).		solution - Ease of use	
84	The Contractor should, in K Appendix 2, describe the start-up/closing time (including daily maintenance and cleaning time) for the offered solution. The description should include start-up/closing procedures.	M	Quality - Technical solution - Ease of use	*Describe*
4 Unit dose storage				
85.	The Contractor shall, in K Appendix 2, confirm that the offered solution provides an automated storage solution for the produced unit doses.	O		*Confirm*
86.	The Contractor should, in K Appendix 2, give a detailed description of the offered storage solution, e.g., how the unit doses are stored and handled. This should include a detailed description of time consumed and labour involved, for transferring the unit doses from production until registered in the automated storage solution for a batch of: • 200 unit doses of ampules • 200 unit doses of blister • 200 unit doses of bulk	H	Quality - Automation	*Describe*

87.	The Contractor should, in K Appendix 2, describe the overall capacity of the drug storage unit and which factors affects storage capacity, e.g., drug size and bag size. A flexible and compact storage solution is preferred. The Contracting Authority's needs for storage of unit doses is described in K Appendix 3, chapter 3.	H	Quality – Technical solution – Deliverables	*Describe*
88.	The Contractor shall, in K Appendix 2, confirm that the offered solution has the functionality for monitoring drug expiration date and an implemented automatic function to handle expired drugs. The functionality for handling expired drugs must be described.	O	D	*Confirm and describe*
89.	The Contractor shall, in K Appendix 2, confirm that the offered solution has functionality to perform automatic inventory of the unit dose storage for all drugs, and the possibility for counting only narcotics. This functionality must be described. Inventory reports must be available for the Contracting Authority.	O	D	*Confirm and describe*
90.	The Contractor shall, in K Appendix 2, confirm that the offered solution prioritizes which unit doses to dispense for fulfilling orders according to expiration date.	O		*Confirm*
91.	The Contractor shall, in K Appendix 2, confirm that the offered solutions unit dose storage can be locked and secured.	O		*Confirm*
92.	The Contractor shall, in K Appendix 2, confirm that the offered solution has the functionality to dispense a defined batch from the unit dose storage. It should be possible to block dispensing of specific batches for customer use.	O		*Confirm*

93.	The Contractor shall, in K Appendix 2, confirm the possibility to dispense unit doses by given parameters, e.g., all units produced in a specific time period, in case of production issues affecting unit dose quality.	O		*Confirm*
94.	The Contractor should, in K Appendix 2, describe how the offered storage solution prevents the drugs from exposure to light and temperature fluctuations. To ensure sufficient air exchange to maintain correct storage temperature in the surrounding area, the energy consumption of the offered solution should be described as a basis to calculate heat dissipation.	H	Quality - Technical solution - Patient safety	*Describe*
95.	The Contractor shall, in K Appendix 2, confirm that the offered solution handles return of unit doses to the storage unit and describe this functionality. The description must include if and how the return functionality affects other functions like dispensing and/or loading of unit doses.	O	D	*Confirm and describe*
5 Unit dose dispensing				
96.	The Contractor should, in K Appendix 2, describe how the unit doses are dispensed by the offered solution and any limitations of dispensing quantity, e.g., how the solution separates dispensing for different recipients. The description should include if and how the dispensing process affects or is affected by other functions, like loading and return of unit doses.	H	Quality - Technical solution - Functionality	*Describe*
97.	The Contractor should, in K Appendix 2, describe if the offered solution has any functionality for sorting dispensed unit doses by recipient.	H	Quality - Technical	*Describe*

	The Contracting Authority would like a solution that offers automatic sorting of unit doses for each recipient into dedicated transport boxes, and automatic labelling, sorting and dispensing of the transport boxes. The offered solution should keep track of the content of each box and be able to convey this information to the Contracting Authority's ERP-system.		solution - Deliverables	
98.	The Contractor should, in K Appendix 2, describe the offered solutions functionality for labelling dispensed unit doses. This description should include how the unit doses are joined together when dispensed. All dispensed unit doses should be given additional labelling with the following necessary information: • Recipient (Ward or regional hospital pharmacy) • Dispensed drugs: quantity and name • Date and time of dispensing • ID number for unit doses joined together (e.g., ring number or similar) • Barcode with information as defined by Contracting Authority If one dispensing has to be separated due to limitations in quantity, the label should include a number series for this dispensing, e.g., 1/3, next dispensing 2/3 and so on. Quantity limitations when dispensing should be described.	H	Quality - Technical solution - Functionality	*Describe*

99.	The Contractor shall, in K Appendix 2, confirm that the offered solution is capable of dispensing patient specific orders. The patient specific orders should be labelled with the following information: • patient's name and date of birth/ national ID-number • dispensing pharmacy • ward name or ward ID • medicinal product name, strength and form • quantity of medicinal products • date and time of medication use (multiple administration times) • ID number for unit doses joined together (e.g., ring number or similar) • Barcode with information as defined by Contracting Authority Additional labelling possibilities should be described.	O	D	*Confirm and describe*
100.	The Contractor should, in K Appendix 2, describe how the offered dispensing solution will sort approved and rejected dispensed units. All security measures to ensure the quality of the dispensed units should be described. Dispensing error rate (%) and calculation method should be documented.	M	Quality - Technical solution - General	*Describe*
101.	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	O	D	*Confirm and describe*

	- which patients using a certain drug			
5.1 PTS Integration				
102.	The Contractor should, in K Appendix 2, describe how the offered solution will be integrated with the hospitals pneumatic tube system for automatic deliveries of unit doses (as described in Appendix 3). The Contractor should deliver the physical/mechanical integration and during development cooperate with PTS-manufacturer to ensure working ICT integration.	H	Quality - Automation	*Describe*
6 Regional pharmacies - OPTION				
The Contractor should provide possible solution(s) for automated handling of unit doses in the regional pharmacies and the cost(s) of these solutions. Due to differences in need for unit doses and in available storage areas between the regional pharmacies, the Contracting Authority requires flexibility regarding size and capacity. Each location will be an individual option and should be priced individually in K Appendix 7. Available area is uncertain, and the storage needs are unknown for the regional pharmacies. The Contracting Authority is open for suggestions regarding size of the individual automated storage units, based on the numbers from Table 4 K Appendix 3.				
103.	The Contractor shall, in K Appendix 2, confirm that the offered solution for regional pharmacies fulfils these general requirements: 4, 5, 12, 18, 21, 22, 23, 24, 25, 26, 28, 30, 33, 35, 36, 37, 38, 39, 40, 41, 44, 45, 46, 101.	O		*Confirm*
104.	The Contractor should, in K Appendix 2, describe how the offered solution handles deliveries to the regional pharmacies. In addition, a return delivery process should be described for returning unit doses from regional pharmacies to the centralized production plant.	H	Quality - Technical solution – Regional pharmacies	*Describe*

	The description should include both the physical solution for sorting and sending unit doses, and how the information regarding unit doses will be registered and transferred during shipping.			
105.	The Contractor should, in K Appendix 2, describe if the offered solution includes transport boxes. If applicable, this description should include sizes, shapes, closing and sealing methods, and if any tracking system is available. Prices should be listed in K Appendix 7.	L	Quality - Technical solution – Regional pharmacies	*Describe*
106.	The Contractor shall, in K Appendix 2, confirm that the offered solution includes an automated storage solution for unit doses at the regional pharmacies. The proposed storage units for the regional pharmacies should be described and must be suitable to maintain the tentative workflow described in K Appendix 3. The storage units should maintain all the obligatory requirements stated in Chapter 4 “Unit dose storage” and 94.	O	D	*Confirm and describe*
107.	The Contractor should, in K Appendix 2, describe the possibility to deliver different size storage units to fit the different regional pharmacies. The Contracting Authority will need automated storage units of different physical sizes and different storage capacities. Pricing of these units should be specified in K Appendix 7.	H	Quality - Technical solution – Regional pharmacies	*Describe*
108.	The Contractor should, in K Appendix 2, describe how goods receipt and loading of unit doses into the automated storage unit is performed at the regional pharmacies. This description should include what must be done manually and which	H	Quality - Technical solution – Regional pharmacies	*Describe*

	processes are automated. For details regarding ICT information flow for this process, see K Appendix 3, section 5.2.3.			
109.	The Contractor should, in K Appendix 2, describe how the unit doses will be dispensed from the regional storage units. The description should include labelling and grouping of unit doses when dispensing, and if and how the dispensing process affects or is affected by other functions. The dispensing process for regional pharmacies should also fulfill all requirements mentioned in 98 and 99.	H	Quality - Technical solution – Regional pharmacies	*Describe*

7 ICT requirements

All the ICT requirements for the offered solution are presented in a separate document, K Appendix 1a – ICT requirements. The Contractor must deliver a complete answer to all requirements in both Appendix 1 and Appendix 1a.

110.	The Contractor shall, in K Appendix 2, confirm that they have considered and answered all requirements in K Appendix 1a - ICT requirements.	O		*Confirm*

8 References

Maskindirektivet (Forskrift om maskiner) (only in Norwegian)
https://lovdata.no/dokument/SF/forskrift/2009-05-20-544

Act relating to working environment, working hours and employment protection, etc. (Working Environment Act)
https://lovdata.no/dokument/NLE/lov/2005-06-17-62