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 1 Customer requirements specification

Case number: 2022/511

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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 Blister 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 and intended workflow, 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 production of unit doses 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 a 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	Will not be evaluated
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 production and 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
General requirements regarding the delivery of the solution				
1.	Offered solution Sykehusapotekene HF (South East Region) • The offered solution must have sufficient capacity to produce 1.6 million unit doses per year. Expected production time is 50 hours per week (10 hours per day, 5 days a week). • Fill in all details and pricing in Appendix 7a - Price sheet	O		
2.	The Contractor shall, in K Appendix 2, confirm that the offered solution is able to dispense and pack unit doses of drugs from blister packs.	O		
3.	The Contractor shall, in K Appendix 2, confirm that the offers solution is suitable for installation in classified rooms (Class D) in accordance with EU GMP (Chapter 3 (equipment) and Annex 1, 4), with controlled ventilation.	O		*Confirm*
4.	The Contractor shall in K Appendix 2, confirm that the offered solution meets formal requirements for validation according to EU GMP (Annex 1, 4), EU GMP Annex 11: "Computerized Systems", EU GMP Annex 15 "Qualification and Validation" and established industry standards including GAMP.	O		*Confirm*
5.	The Contractor shall, in K Appendix 2, confirm if the offered solution is compliant with GDPR (The EU General Data Protection Regulation) and describe how the solution will meet GDPR requirements.	O		*Confirm*
6.	The Contractor should, in K Appendix 2, describe the minimum required area needed for installation of the offered solution as well as minimum ceiling height and weight.	H	Quality - Technical	*Describe*

			solution - General	
7.	The Contractor shall, in K Appendix 2, confirm that the offered solution can operate within the assigned work area (including ceiling height), as 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 the work area drawing.	O		*Confirm*
8.	The Contractor shall, in K Appendix 2, confirm that the software application and database must be able to manage special letters, such as Ü, Æ, Ø, Å.	O		*Confirm*
9.	The Contractor shall, in K Appendix 2, confirm that the unit dose label, on each individual bag 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 • batch identification number to ensure full traceability; • active substance • drug manufacturer • barcode (GS1-standard)	O		*Confirm*
10.	The Contractor should, in K Appendix 2, describe any special adaptations or additional functions that are included in the offered solution.	H	Quality - Technical solution - General	*Describe*
11.	The Contractor should, 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 an overview of the	I		*Describe*

	current development plans for the solution for the next five (5) years.			
12.	The Contractor shall, in K Appendix 2, confirm that the offered solution has a 10-year minimum life expectancy based on the following: producing unit doses at max capacity, 3640 hours/per year (10 hour a day, 7 days a week and 52 weeks a year). Preconditions for service and maintenance must be described.	O		*Confirm and describe*
13.	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*
14.	The Contractor should, in K Appendix 2, elaborate all relevant requirements for required components (OS, client applications, server software, etc.) that are not supplied as a part of the offered solution, or that deviate from the Contracting Authority's standards. For example: Browser, web server, databases, Java, Flash, Silverlight, MS Office, .NET Framework, C++ Redistributable, MDAC etc. and any specific versions of these.	H	Quality - ICT - General	*Describe*
15.	The Contractor should, in K Appendix 2, describe the delivery time for the offered solution installed at site and SAT - IQ/OQ/PQ is performed and accepted.	M	Quality – Installation, test and validation	*Describe*
General security requirements				
16.	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*
17.	The Contractor shall, in K Appendix 2, confirm that they in cooperation with the Contracting Authority will implement	O		*Confirm*

	changes with respect to the relevant laws, regulations and regulatory requirements that 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.			
18.	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). 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	O		*Confirm and describe*
19.	The Contractor shall, in K Appendix 2, confirm that training of the pharmacy staff and technical personnel is a part of the implementation of the offered solution.	O		*Confirm*
20.	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.	M	Quality - Installation, test and validation	*Describe*
Documentation				
21.	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 and paper version for the Contracting Authority in accordance with GMP, and must be editable if the Contracting Authority requires it.	O		*Confirm*

	All documentation and training course material must be written in English language.			
22.	The Contractor shall, in K Appendix 2, confirm that the documentation linked to service, maintenance, software updates and the Contracting Authority shall approve training course material provided by The Contractor, if the Contracting Authority requires this. Disapproved documents must be revised by the Contractor. All electronic documents provided must be searchable.	O		*Confirm*
Test and acceptance				
23.	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: A. Critical errors: None (0) B. Serious errors: None (0) C. Less serious errors: 10	O		*Confirm*
24.	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*
25.	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 FAT, SAT, IQ and OQ. The Contracting Authority shall approve the protocols before they are	O		*Confirm*

	used. For an overview of the validation and testing activities, see K Appendix 5.			
26.	The Contractor shall, in Appendix 2, confirm that all relevant validation and testing shall be performed as stated in K Appendix 5.	O		*Confirm*
27.	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*
28.	The Contractor should, in K Appendix 2, describe their methodology and standards used for testing of the offered solution. The Contractor should, in K Appendix 2, provide one example of a protocol for validation activities.	L	Quality - Installation, test and validation	*Describe*
29.	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*
30.	The Contractor should, 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.	M	Quality - Installation, test and validation	*Describe*
31.	The Contracting Authority requires that the Contractor shall guarantee qualified personnel to the Contracting Authority	O		*Confirm*

	throughout the project. The Contractor shall, in K Appendix 2, confirm this.			
Functional requirements of the Offered Solution **Process requirement**				
32.	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 performed automatically and what is performed 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 - General	*Describe*
33.	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 (linear and 2D-barcodes).	O		*Confirm*
34.	The Contractor should, 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	Quality - Technical solution - General	*Describe*
35.	The Contractor should, 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. Import is strongly preferred.	H	Quality - ICT - Integration	*Describe*
36.	The Contractor should, in K Appendix 2, describe what consumables the operator supplies 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 etc.). If there is, a need to change between different consumables (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 consumables as possible.	H	Quality - Technical solution - Ease of use	*Describe*

Functional requirements of the Offered Solution **Safety and efficacy**				
37.	The Contractor should, in K Appendix 2, describe the offered solution's system for ensuring that the correct drug is loaded /used in the system.	H	Quality - Technical solution- Patient safety	*Describe*
38.	The Contractor shall, in K Appendix 2, confirm that the offered solution includes a bar code reading system to identify all drug packages loaded into the system.	O		*Confirm*
39.	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.	O		*Confirm*
40.	The Contractor should, 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.	L	Quality - ICT - Functional	*Describe*
41.	The Contractor should, in K Appendix 2, describe the offered solutions possibility for storing, prior to production, different drugs simultaneously. The description should describe if there are any manually involvement between the production of the different drugs, how many different drugs that can be loaded into the offered solution simultaneously, and if there are any limitations in the amount of drug cassettes/boxes/trays or similar that can be used with the offered solution.	H	Quality - Technical solution - Ease of use	*Describe*
42.	The Contractor should, in K Appendix 2 give a short description of changeover workflow between batches.	H	Quality - Technical solution - Ease of use	*Describe*
43.	The Contractor should, in K Appendix 2 describe how all different boxes/cassettes/trays or similar used to load the drugs are	O		*Confirm and describe*

	identified (e.g. An RFID chip or barcode). All drug cassettes/ boxes /trays or similar should have a validated method of identification. The Contractor should, in K Appendix 2, confirm that all cassettes/boxes/trays (or similar) should be exchangeable between identical dispensing unit models. This requirement only applies to solutions that use drug cassettes/ boxes /trays (or similar).			
44.	The Contractor should, in K Appendix 2, describe if the solution can handle continuous production with a low level of manual interference in the process.	H	Quality - Technical solution - Ease of use	*Describe*
45.	The Contractor should, in K Appendix 2, describe the dispensing error rate. Dispensing error rate (%) and calculation method should be documented. (E.g unreadable text, incorrect welding, incorrect number of drugs).	H	Quality - Technical solution - General	*Describe*
46.	The Contractor should, in K Appendix 2, document known errors that can occur during production, with corresponding frequency (%). This description should also include the consequences and necessary actions related to fix the error.	I		*Describe*
47.	The Contractor should, in K Appendix 2 describe the offered solutions response to input of illegal values, illegal combinations of values, or lack of values/input. Example: letters instead of digits or vice versa.	H	Quality - ICT - Functional	*Describe*
48.	The Contractor should, 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	Quality - ICT - Functional	*Describe*
49.	The Contractor should, in K appendix 2, describe the data storage capacity for medical products and associated master data, logs, reports and any other applicable data in the offered solution.	M	Quality - ICT - Functional	*Describe*

50.	The Contractor should, in K Appendix 2, describe the process of entering new drugs. • Registration into the database (e.g. new drugs, manufactures change the design etc.), whether registration can be done by the pharmacy staff, without the involvement of the Contractor this should be described. • Validation of cassettes / boxes /trays (or similar). Any involvement from the Contractor in the validation process should be described (if applicable). • Validation of cutting • Example of the time it takes to enter a new drug in the offered solution (both registrations in database and validation).	H	Quality - Technical solution - Ease of use	*Describe*
51.	The Contractor should, in K Appendix 2, describe if the offered solution has a system (or mechanism) to recognize if there is a single tablet packed, multiple tablets in each single unit, empty unit bags as well as identify if tablets has been injured during the packing process. This description should include the response of the offered solution and how the pharmacy staff is alerted if there is a deviation.	H	Quality - Technical solution - Patient safety	*Describe*
52.	The Contractor should, in K Appendix 2 describe if the offered solution got any functionality for automatic visual control of the finished production of a unit dose batch. (E.g. Picture-, video-recognition).	H	Quality - Technical solution - Patient safety	*Describe*

53.	The Contractor should, in K Appendix 2 describe if the offered solution got any automatic functionality for preparing unit dose batches for further distribution (E.g.-. automatic counting/rolling/cutting predefined numbers of unit doses).	H	Quality - Technical solution - Ease of use	*Describe*
Functional requirements of the Offered Solution **Application and suitability**				
54.	The Contractor should, in K Appendix 2, describe how the offered solution cuts the blister packed drugs.	H	Quality - Technical solution - General	*Describe*
55.	The Contractor should in K Appendix 2, describe the offered solution's limitations regarding drugs on the European market, e.g. size, material or other factors that makes the drug not compatible with the offered solution. The Contractor must describe if there are any of the blister packs listed in K Appendix 1a - List of Blister pack that the offered solution are not able to cut and repack.	H	Quality - Technical solution - General	*Describe*
56.	The Contractor should, in K Appendix 2, describe if the offered solutions outer panels and 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 must describe the cleaning and maintenance process/procedure that needs to be carried out by the pharmacy staff (daily, weekly, yearly etc.)	H	Quality - Technical solution - General	*Describe*
57.	The Contractor shall, in K Appendix 2, confirm that the GUI (graphical user interface) used by operator, including field-labels, button-texts, menu-items and other texts is presented in Norwegian or English language.	O		*Confirm*

58.	The Contractor shall in K Appendix 2, confirm that all labels in regards to Human Machine Interface (HMI), e.g. pushbuttons, switches etc. must be labelled in Norwegian or English language.	O		*Confirm*
Functional requirements of the Offered Solution **General functional requirement**				
59.	The Contractor should, 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.	L	Quality - ICT - Functional	*Describe*
60.	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).	O		*Confirm*
61.	The Contractor should, in K Appendix 2 describe if there are any limitations to batch sizes for the end product.	H	Quality - Technical solution - Ease of use	*Describe*
62.	The Contractor should in K Appendix 2, describe how lot/batch number will be assigned and documented, if possible. This description should also include if the lot/batch number can be assigned by the pharmacy.	L	Quality - Technical solution - General	*Describe*
63.	The Contractor should, 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	Quality - Technical solution - General	*Describe*
64.	The Contractor should, in K Appendix 2, describe if it is possible to create a barcode print to label, e.g. boxes used for further distribution of unit doses.	H	Quality - Technical solution - General	*Confirm*
65.	The Contractor must provide a continuous back-up solution.	O		*Describe*

	The Contractor shall describe the offered solution's response in case of an emergency power shortage, including potential damage and data loss.			
66.	The Contractor should, 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	Quality - ICT - Functional	*Describe*
67.	The Contractor should, in K Appendix 2, describe the packaging 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 packaging materials are recommended or available.	H	Quality - Technical solution - Patient safety	*Describe*
68.	The Contractor should also describe if the disposable materials are made of an environmental friendly material, or if environmental friendly material is available.	H	Quality - Environmental	
69.	The Contractor shall, in K Appendix 2, confirm that the package materials for the unit doses is in accordance with the requirements of the Ph. eur. 3.1 and 3.2.	O		*Confirm*
70.	The Contracting Authority will evaluate the quality of the packaging material, quality of print and the ease of use for the end user of the product. The Contractor should upon submission of the offer deliver minimum 10 product samples of each packaging material. The samples should contain a packed tablet/capsule (placebo) representable for a produced unit dose, with all required information printed, as described in requirement number 9. If there are different sizes of the packaging material available, a sample for each size should be delivered.	H	Quality - Technical solution - Patient safety	*Describe*

	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. <u>Address of delivery:</u> Sykehusinnkjøp HF / Att: Deborah Suarez Richard Johnsens gt. 2, 4021 Stavanger Norway			
71.	The Contractor shall, in K appendix 2 confirm that the print on the unit dose bags are readable for a minimum of 24 months.	O		*Confirm*
72.	The Contractor shall, in K appendix 2 confirm that the unit dose packaging material is suitable for a shelf life of minimum 24 months after the packaging material is delivered to the Contracting Authority and stored correctly. If any stability studies has been performed, this should be described and included.	O		*Describe*
73.	The Contractor should, in K Appendix 2 describe the different options/solutions for separating a defined number of unit doses in a strip/ribbon/ring or similar.	H	Quality - Technical solution - Ease of use	*Describe*
74.	The Contractor should in K Appendix 2, describe how the offered solution responds to incidents of drug contamination due to malfunction in the system. This description should include how the solution detects and responds to malfunctions that may cause drug contamination, and describe the necessary cleaning procedure following an incident of drug contamination.	M	Quality - Technical solution - Patient safety	*Describe*
75.	The Contractor should in K Appendix 2, describe if the offered solution is capable of automatically pack unit doses in boxes/ containers/cassettes of predefined numbers of unit doses (E.g. 5,	H	Quality - Technical	*Describe*

	20 and 50). The packages will further be distributed and stored for further distribution and storage in automated storage and dispensing systems.		solution - Ease of use	
Functional requirements of the Offered Solution Alarms, alerts, messages				
76.	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 colour.	O		*Confirm*
77.	The Contractor shall in K Appendix 2, confirm that Notification / Alarm/ Alerts /messages will appear in full text on the screen with a reference number for that individual alarm/alert.	O		*Confirm*
78.	The Contractor should 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. The offered solution should display how to resolve the different issues causing the alarms.	H	Quality - ICT - Functional	*Describe*
79.	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.	O		*Confirm*
Functional requirements of the Offered Solution User access				
80.	The Contractor shall in K Appendix 2, confirm that the offered solution 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. The content in the different access levels must be described.	O		*Confirm and describe*
81.	The Contractor should in K Appendix 2, describe the possibilities for electronic signatures in the system. It is preferred that it is possible to co-sign selected process steps.	L	Quality - ICT - Functional	*Describe*

Functional requirements of the Offered Solution Health and Work safety				
82.	All equipment that is a part of the solution must be designed and have the necessary protective devices so that the operator and/or service personnel is protected against injuries. The equipment must be in accordance with relevant standards, laws and regulations, including: • FOR-2009-05-20-544 Forskrift om maskiner (Directive 2006/42/EC) • Lov om arbeidsmiljø, arbeidstid og stillingsvern mv. (arbeidsmiljøloven)	O		*Confirm*
83.	The Contractor should, 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	Quality - Technical solution - General	*Describe*
84.	The Contractor shall, in K Appendix 2, confirm that the maximum noise exposure, and the 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 operative conditions.	O		*Confirm*
85.	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*
Functional requirements of the Offered Solution Capacity and efficiency				

86.	The Contractor should, 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 3 examples: 1) 2000 unit doses of Divisun 800iE (15 tablets per blister pack) 2) 2000 unit doses of Dexamethason 4 mg (10 tablets per blister pack) 3) 1000 unit doses of Divisun 800iE and 1000 unit doses of Dexamethason 4 mg (subsequent production) There should be only one tablet per packed unit dose. See picture of the blister packs in the end of this document.	H	Quality - Technical solution - Ease of use	*Describe*
87.	The Contractor should, in K Appendix 2, describe the start-up / closing time (including daily maintenance and cleaning time) for the offered solution.	M	Quality - Technical solution - General	*Describe*
88.	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.). A cleaning plan should be provided.	H	Quality - Technical solution - General	*Describe*
Technical Process requirement Air quality and temperature				
89.	The Contractor should, 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	Quality - Technical solution - General	*Describe*
90.	The Contractor shall, in K Appendix 2, confirm that the offered solution will not generate particles or microbiological	O		*Confirm*

	contamination in the production room, at a rate that exceeds the requirements for Class D (EU GMP) in and out of operation.			
91.	The drugs loaded into the offered solution should not be exposed to temperatures below 8 degrees Celsius or exceeding 25 degrees Celsius during the packaging process. The Contractor should, in K Appendix 2, describe what measures must be implemented to meet these requirements.	H	Quality - Technical solution - General	*Describe*
General technical software requirements				
92.	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,	O		*Confirm*
93.	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, unless otherwise agreed. The announcement to the Contracting Authority must 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.	O		*Confirm*
Design / Installation Requirements – Mechanical				
94.	The Contractor should, 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).	I		*Describe*
95.	The Contractor shall, in K Appendix 2, confirm that the offered solution will be compatible with the following local electrical conditions: - Supply voltages are 3 x 230V 50 Hz	O		*Confirm*

	- Normal voltage tolerances are +/- 10% for all installation sites. Transients and rapid voltage variations can occur. - If there is a need for voltage stabilization equipment w / filter and possibly a transformer, this must be included in the total pricing.			
96.	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.	O		*Confirm*
97.	The Contractor should provide an example (illustration) of installation (layout) for the offered solution. The Contractor should also describe what is required to create an optimal workflow.	H	Quality - Technical solution - General	*Describe*
98.	The Contractor should, in K Appendix 2, describe dimensions of the largest modules that need to be transported in to the production area (height width, length and weight).	H	Quality - Installation, test and validation	*Confirm*
Requirements for the IT-Architecture				
99.	The Contractor, should in K Appendix 2, describe the IT-architecture of the solution.	I		*Describe*
100.	The Contractor should, in K Appendix 2, describe how data may be exported from the offered solution's database to an external IT solution(s).	H	Quality - ICT - Functional	*Describe*
101.	The Contractor should, in K Appendix 2, describe the possible standard(s) for information exchange (e.g. HL7 FHIR). This description should include which versions are supported and list available services/messages.	H	Quality - ICT - General	*Describe*

102.	The Contractor should, in K Appendix 2, describe if the offered solution use APIs in a secure manner for integration and information exchange. Elaborate which security mechanisms the offered solution can support using APIs. Any exchange of information should be established using international standards. Note: Examples of such standards are HL7 and DICOM.	H	Quality - ICT - General	*Describe*
103.	The Contractor should, in K Appendix 2, describe 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	Quality - ICT - Integration	*Describe*
Technical Infrastructure				
104.	The Contractor should, in K Appendix 2, describe the requirements for the IT-infrastructure for the offered solution, include supported operating systems and databases and their versions. The Contractor should, in K Appendix 2, document proposed technical solution and mechanisms for high availability.	H	Quality - ICT - General	*Describe*
105.	The Contractor shall, in K Appendix 2, confirm that application- and database software will be able to manage special characters like ® , © etc.	O		*Confirm*
106.	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)	O		*Confirm*
107.	Any network requirements should be described in K Appendix 2. The Contractor should also describe what this network connection will be used for in the offered solution.	L	Quality - ICT - General	*Describe*
108.	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 should be described in K Appendix 2.	L	Quality - ICT - General	*Describe*

109.	All ports and protocols the offered solution uses should be described in K Appendix 2.	I		*Describe*
110.	The Contractor should in K Appendix 2, describe the solution for the license control and related management practices.	H	Quality - ICT - General	*Describe*
111.	The Contractor should, 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	Quality - ICT - General	*Describe*
112.	The Contractor should, in K Appendix 2, describe the offered software solution's limitations in the size/length of text fields, E.g. on the GUI screen (scalability), master data and printing on unit dose bags.	H	Quality - ICT - Functional	*Describe*
113.	The Contractor should in K Appendix 2, describe how user access can be configured and maintained, either manually, or preferably, by integration with IAM systems (Active Directory or other), and if the possibility of integration exists, if this is done by offering a interface to maintain user membership, or directly by mapping of groups where group memberships need not be transferred from the IAM systems to the Contractor's system. The Contractor should in K Appendix 2, describe the process of creating a user for the system, either manually, or preferably, by integration with IAM systems (Active Directory or other). If any integration is involved, the contractor should notify if passwords must be transferred to the system, or preferably, if authentication can be done externally with a challenge/response against a IAM system (through LDAPS, SAML, OpenID connect or other protocols) and the response returned to the contractor's system.	H	Quality - ICT - General	*Describe*
114.	The contractor should also describe solutions for single sign-on.	H	Quality - ICT - Functional	*Describe*


Vnr 11 45 25
Divisun® 800 IE
kolekalsiferol/cholecalciferol
(vitamin D3)
90 tabletter
MEDA


100x1 tabletter/tabletit/töflur
Vnr 57 90 43
Dexametason Abcur 4 mg
ABCUR