The Hospital Pharmacy
The Capital Region of Denmark

Selection process for the procurement of an automated robotic solution for cytotoxic compounds

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BACKGROUND

The Capital Region Hospital Pharmacy in Copenhagen (Denmark) compound: in total more than 100.000 bags of cytotoxic treatments a year at three different hospitals. In 2012 it was decided to invest in a robot to reconstitute approximately 1/3 of all the cytotoxic compounds in the Region.

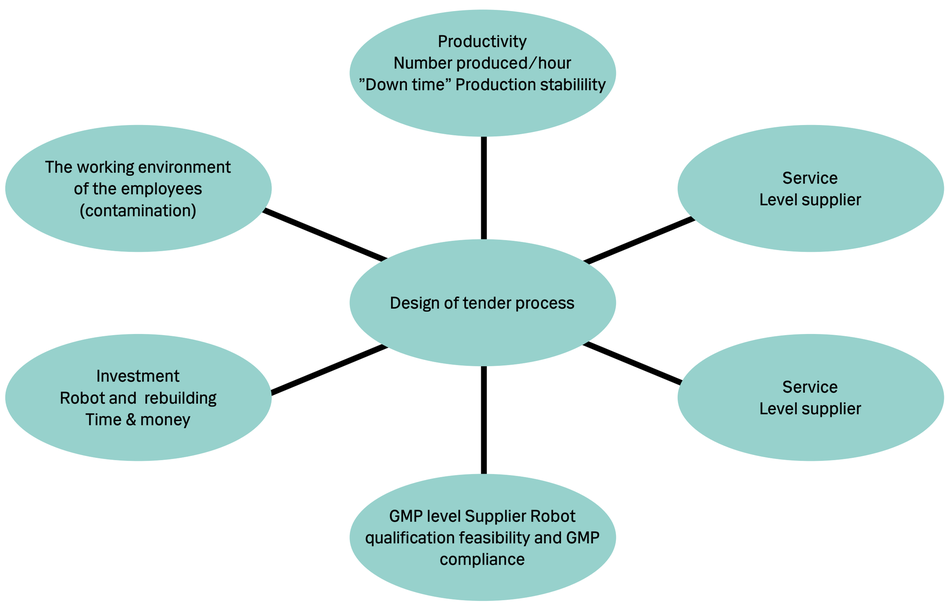
A business case where made, which made the framework for the estimated cost reduction due to efficiency effect and it also outlined the milestones for the different steps in the project.

The reconstitution production areas including robot compounding are inspected by the Danish Medicine Agency and comply fully with the EU GMP requirements.

OBJECTIVES

The procurement process was designed to ensure, that the chosen supplier delivered a robot which fulfilled our needs on the following aspects:

All the aspects where elaborated in critical selection criterias in a User Requirement Specification (URS), which where part of the tender material (see methods).

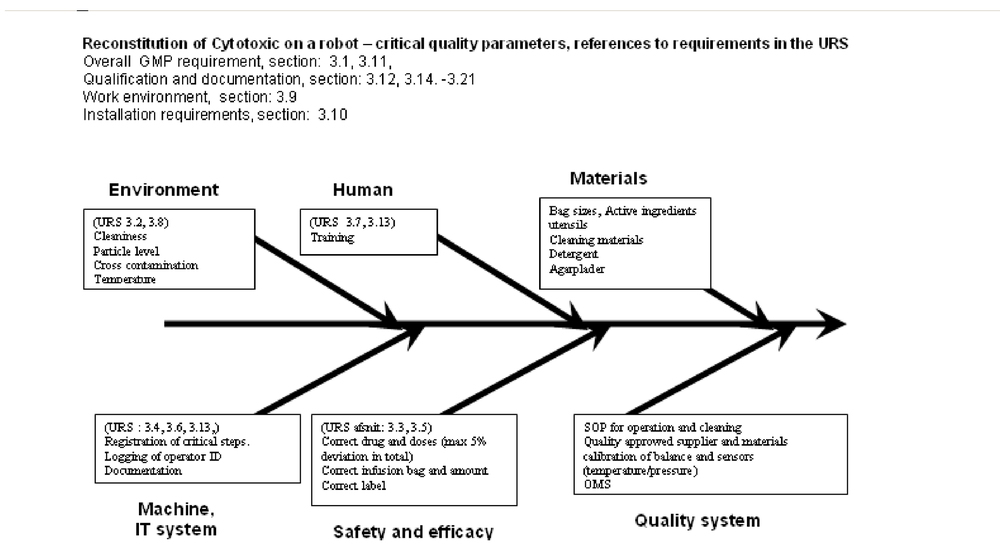


METHODS

A User Requirements Specification, URS, containing 234 requirements for the robot was prepared. Emphasis was placed on the above mentioned critical selection criteria's.

Enabling an overview of all the critical selection criteria in the URS:

As a pre study to specify the GMP requirements (GMP level Supplier, Robot qualification feasibility and GMP compliance. See model above) the following fishbone analysis was made to identify the different GMP areas to be covered in the URS.



How to evaluate submitted supplies systematically:

The suppliers` answers on the requirements given in the requirement specification were collected in one document. The requirements in the URS were categorized into A- and B-requirements. A-requirements had to be met by the supplier. Fulfilment of the B-requirements was desirable but not a demand. The answers to all of the 234 requirements were scored in a summary table and weighted in relation to the A and B requirements: Completely fulfilled (Green), partly fulfilled (yellow) and not fulfilled (Red).

In a situation where there is an A-requirement, which is not fulfilled, the respective supplier is not relevant to move on with. The suppliers, who meet the A-requirement or partly fulfilled the A-requirement (the answer was not clear initially), were exposed to quality audit and a reference site visit.

Finally this evaluation was supplied with conclusions from reports from the quality audit and the reference sites.

Requirements specification for an automatic (robotic) solution for the aspetic preparation of intravenous chemotherapeutic compounds for patientspecific and batch admixtures for The Capital Region Pharmacy (RAP)

		Supplier X		Supplier Y	
	A-requirements	Fulfillment of A requirement	Coments	Fulfillment of A requirement	Coments
2.12	If the doors to the production zone has to be opened during the production of an batch - this batch has to be rejected automatically.	OK	-	OK	-
2.13	The robot must be able to control that the temperature in the chamber containing the active substances remains within specified limits. It must be possible to set the temperature limits between 15 to 25 degrees Celcius inclusive measurement uncertainties.	(OK)	Answer is not clear. Has to be evaluated at an audit at the supplier.	not OK	Produce to much heat
2.14	There must be thermocouples/sensors to monitor temperature in the chambers for the storage of active drug substance. The temperature must be within 15 to 25 degrees inclusive measurement uncertainties.	(OK)	Answer is not clear. Has to be evaluated at an audit at the supplier.	OK	-

RESULTS

Due to the highly specialised nature of the project only two quotations were received. The number of fulfilled requirements where 228 for vendor X, one B-requirement where not fulfilled and five A- requirement partly fulfilled. For vendor Y, 203 requirements where fulfilled, nine A –requirements where not fulfilled, seven A-requirements where partly fulfilled and 15 B requirements where partly or not fulfilled. A quality audit showed that vendor X had an acceptable level of GMP. Two reference sites where also visited with a positive outcome.

After reviewing the tenders and execution of audits, our choice fell on the APOTECAchemo robot.

DISCUSSION

This extensive work prior to the purchase of a new robot has been time consuming. It is estimated, however, that the overall project during qualification and production scale-up of the robot have been more cost and time effective.

CONCLUSION

Due to the detailed URS and comprehensive tender process the project had a successful outcome. With the detailed preparation the robot was delivered and made operational according to plan and budget.

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No conflict of interest