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 3 Customer technical platform

Case number: 2022/511

Contents

1. Introduction

In the Southeast region, there is an ongoing project on establishing regional standard for closed loop medication. Whether the regional standard in the future includes patient specific unit doses is yet to be decided. The Southeast region already have sites, dispending and packing unit doses, for the most part naked tablets. However, the need to cut and repack blisters is increasing, thus the Southeast region anticipating the need of an additional solution for blisterpacking, but the site is still not decided.

The following section, therefore, describes a generic unit dose dispensing and packaging processes in Sykehusapotekene HF.

2. Process for repackaging medication into unit dose

A process on repackaging medication into electronically identifiable unit doses contains several steps. Each step is conducted in different systems. Even though there are only simple integrations, or no integrations at all, ensuring coordination, each system ensures traceability and quality for our products. Our products will be available in three different package sizes, each with different quantity of unit doses in the container; 5 unit doses, 20 unit doses or 50 unit doses. Each repacked product is assigned with a locally defined article number and GTIN (Global Trade Item Number).

Anticipated workflow for unit dose repackaging

The ERP[1]-system generates a production proposal. An operator provides a unique lot number for each production, from a production journal. Operators generate paper worksheets and correct amount of labels prior to production. In the worksheet, the operator types e.g. the production's lot number, expiry date of the medicine used, quantity (e.g. 10 x 20 unit doses).

The correct amount of labels are printed after visual control of the first dosage bag (or printed automatically from the packaging unit). The labels contain a barcode together with the necessary information for the tablet/capsule. Operators apply labels onto the cardboard boxes. Both the unit doses and the secondary packages contain bar codes with a predefined article number. The article number of the drug connects master data in all software to ensure printing of correct labelling during dispensing.

Post-production, operators conduct a visual examination on every dose bag. The machine cuts strips so they do not have to be counted and tore off manually. Thereafter the strips are rolled and placed into the pre-labelled secondary package.

The product is available for sale after approval by both a production pharmacist and a control pharmacist.

In the future it may be desired that the offered solution is able to communicate indirectly or directly (an integration) with e.g. ERP or a future production program[2], if possible.

3. Specific requirements

Production volume and number of users

The total production volume for the offered solution is expected to be 2 000 000 unit doses per year. Operating hours are estimated to be 10 work hours daily, 5 days a week, 52 weeks a year.

[1] Enterprise Resource Planning. The current ERP system, FarmaPro, will be replaced with Oracle E-business Suite in 2023.

[2] A digital program not yet decided, that may generate worksheet and labels from Master data in the future. The same data will be transferred to the packaging machine, where production will be launched in accordance with the data.

The number of users is yet to be decided.

Location and delivery address

Yet to be decided.

Ventilation system and Air supply

There is currently no dedicated ventilation system for in/exhaust/cooling, and currently no access to air supply for e.g compressed air. All need for this or other adaptations of the designated operation room must be explicitly specified.