LEIDS UNIVERSITAIR MEDISCH CENTRUM

USER REQUIREMENT SPECIFICATIONS COMPOUNDING ROBOT

COMPOUNDING ROBOT FOR READY TO ADMINISTER IV ADMIXTURES

Afdeling Klinische Farmacie & Toxicologie/Dept Clinical Pharmacy & Toxicology	
Verantwoordelijke sectie:	*Bereidingen/Production*
Versie	*1*
Laatste wijziging d.d.	*30-04-2015*
Lokatie:	*I:\prod\algemeen\robot*

Autorisatie Plan van Eisen/Authorisation URS			
Rol	Naam	Functie	Handtekening en datum
Author	M.Y.E.C. van der Stoep	AIOS Ziekenhuisfarmacie	
Evaluation	K.J.M. Schimmel	Zapo Bereidingen	
Evaluation	J. Zwaveling	Zapo doelmatigheid en inkoop	
Approval			
Approval			

Inhoud

1 Introduction

This is the User Requirement Specification (URS) for a compounding robot. This robot needs to prepare IV admixtures that are ready to administer to the patient. With this compounding robot cytostatic and non-cytostatic IV admixtures will be prepared.

2 Aim

The aim of this specification is to describe the specific requirements for the compounding robot.

3 User Requirement Specifications

3.1 General:

- Compliant with the current GMP directives.
- Compliant with the current CE certificating directives.
- Input supply voltage/frequency: 230 V / 50 Hz
- Designed for pharmaceutical processes.
- Rebuilding of the existing manufacturing facility is not necessary in order to place the robot.
- Is able to fit within a Laminar Downflow Unit. Preferable in Clean Air EF/SB4 (interior dimensions lxdxh (mm): 1180x550/470x744).
- Is already been put into operation in other hospitals for patient care.

3.2 Material

- In- and outside surfaces have to be smooth and easily cleaned/disinfected.
- Product quality: material made of stainless steel AISI 316L, silicon, Teflon or EPDM suitable for pharmaceutical use

3.3 Technical specifications

- IV bags and syringes of different dimensions are compatible.
    - IV bags: 50, 100, 250, 500, 1000 ml
    - Syringes: 1,0-50 ml
- A minimum of 10 bags or syringes can be produced per batch.
- Can handle pre-attached lines
- RFID controlled to ensure correct drug and container
- Gravimetric controlled dispensing
- Weight accuracy: deviations should not exceed >5% of declared
- Low heat generating (should not be more than the heat emission of a laminar downflow unit in work mode).
- Carry over vial management is possible in order to reduce spillage.
- Capable of removing fluid from bag to achieve specific volumes.
- It is possible to determine the order in which preparations are compounded.
- It is possible to compound multiple (up to four) ingredients in one bag (e.g. ifosfamide and mesna).
- The balances that are used for pre- and postprocessing the batch can be calibrated.

3.4 Datamanagement/software

- Compliant with GAMP5 guidelines
- Can be interfaced with current pharmacy computer systems (CMS/CS-EZIS)

- User defined security levels

3.5 Safety (ARBO)

- Minimal vial and bag contact to reduce contamination risk
- Does not require working in a stressful posture

3.6 Documentation

- Clear instructions/manual in English or Dutch
- Functional (FS) and design specifications (DS) are provided
- IQ/OQ Installation and Functional Qualification documents are sent for approval to the customer before FAT.
- Required basic records:
  - Lay-out (drawing/as built drawing)
  - Specification
  - Documentation
  - P&ID
  - Wiring diagram
  - Material certificates
  - Calibration certificates
  - Machine safety

3.7 Maintenance

- Prevention maintenance is included in service agreement
- Available (by telephone or internet) for troubleshooting during office hours
- Time to repair not more than 2 working days
- Regular software updates to keep the robot up to date

This User Requirement Specification should be approved and signed by the supplier before purchase and is part of the purchase-order.