RSSL User Requirement Specification
(Refer to QSOP-42)

URS Title:	Purchase of a new glasswasher for Knights Building
Change Control reference:	CC-1535 and CC-1537

Please note this document shall be used for complex type B and type C pieces of equipment or software. For balances please use WKS-1155

Part 1: **USER REQUIREMENTS / DQ** (Part 1 must be completed before Part 2):

1. Scope and Purpose (URS Level 1)

This URS details the requirements for the piece of equipment/software detailed below. The further qualification activities for the equipment/software will be documented in the IQ/OQ/PQ protocols and reports. The completed URS and IQ/OQ/PQ protocols and reports should be attached to the relevant change control on Q-Pulse. The URS is designed to meet the requirements of Eudralex Volume EU Guidelines for GMP - 4 Annex 15

Type of equipment/software required:	Glasswasher
Intended purpose of equipment/software: *(include a brief description of why the equipment/software is to be purchased and the intended main function(s) of the equipment/software)*	This is being purchased as a required piece of equipment for the Pharmaceutical Chemistry laboratory relocations to Knight's building (see CC-1375). The intended use for this glasswasher is to wash used laboratory glassware items that are able to be re-used.

RSSL User Requirement Specification
(Refer to QSOP-42)

2. Requirements (URS Level 2) / DQ Level 2

The following sections detail the requirements for the equipment/software. Any requirements listed should be measurable to identify if the chosen equipment/software satisfies the requirements. If the requirement is not compulsory but merely desirable, this should be specified in the list. For a proposed asset which is software only please note Section b. is not required.

a. Operational Requirements

The equipment/ software must meet the operational requirements *(operational requirements include system functions, interfaces and data);*

Requirements
e.g. measurement range, measurement accuracy, display requirements, ability to interface with printers/ other equipment, throughput etc.
Must be capable of working at parameters currently defined and being used by other glasswashers in RSSL for Pharmaceutical Chemistry purposes (Cycle D - 75°C)
N/A
N/A
N/A

b. Practical/Facilities requirements

The equipment/software must meet the practical requirements (practical requirements include sufficient space, utilities available and any environmental requirements);

Requirements
e.g. size of space available, utilities available, any temperature or humidity requirements etc.
Maximum size (in mm) 900(H) x 650(W) x 650 (D) – [*1300 (D) with door open*]
Able to work with the planned installation of mains water and Milli-Q water in Knights
Appropriately sized baskets to sit within for a variety of glassware types (i.e. pronged baskets to appropriately house volumetrics)
N/A

RSSL User Requirement Specification
(Refer to QSOP-42)

c. IT/Data integrity Requirements

The equipment/software must meet the specific regulatory requirements. (Consider data backup requirements, individual login requirements and audit trail functionality)

Requirements
e.g. GMP compliance, data back up requirements, user levels, Audit trail functionality, operating system compatibility, individual log ins.
N/A
N/A
N/A
N/A

d. Documentation Requirements

The specified documentation requirements must be met;

Requirements
e.g. Manufacturer's manual, declaration of conformity, calibration certificates, QA approved supplier (i.e. Supplier listed as approved in Q-Pulse), technical specifications, list of spare parts etc.
Manufacturer's manuals / technical folder
N/A
N/A
N/A

e. Support Requirements

The manufacturer/ vendor of the equipment/ software must be able to meet the specified requirements;

Requirements
e.g. Service/ maintenance provision, provision of spare parts/ repairs, warranty, training, emergency call out, equipment qualification , review of contracts and payment term and conditions.
Manufacturer capable of servicing the unit (either adhoc or with service contract)
Manufacturer capable of providing IQ / OQ / PQ service
N/A
N/A

RSSL User Requirement Specification
(Refer to QSOP-42)
Part 2: URS VERIFICATION CHECK LIST:
Use this checklist to verify that all the identified requirements from Part 1 will be fulfilled by the chosen equipment.

Supplier:	**Miele**
Model chosen:	**PG8583 x 2**

	Operational and Practical Requirements	**Yes/No/NA***
1.	Will the equipment meet the required measurement capabilities?	Yes
2.	Will the equipment fit into the space available?	Yes
3.	Will the equipment meet the RSSL IT requirements and capabilities?	N/A
4.	Are there sufficient utilities available (i.e. gas lines, electricity, waste removal) for the equipment at RSSL?	Yes
5.	Will the equipment meet the RSSL EHS requirements?	Yes
6.	Will all other operational requirements be met?	Yes
	IT/ Data Integrity Requirements	**Yes/No/NA***
7.	Is the software compatible with Windows 10 and future operating system updates?	N/A
8.	Does the software have user levels with defined permissions? e.g. Standard user; Super User & Administrator	N/A
9.	Does the software have individual user logins?	N/A
10.	Is an audit trail present and can this be accessed by a basic user profile?	N/A
11.	Can the raw data produced be backed up?	N/A
12.	Is it possible to delete data within the standalone software or asset?	N/A
13.	Will the software interact with other assets/equipment? If yes provide details below	N/A
N/A		
14.	Will a GMP Gap Assessment (WKS-701) be required?	N/A
14.1	If required has the GMP Gap Assessment action been added to the change control?	N/A

RSSL User Requirement Specification

(Refer to QSOP-42)

	Documentation Requirements	**Yes/No/NA***
15.	Is the vendor a QA approved supplier (i.e. listed as approved in Q-Pulse)?	Yes
16.	Does the vendor provide all the required documentation i.e. certificates, manuals, technical specifications?	Yes
17.	Is the equipment classed as a financial asset? (If yes this must be documented against the asset record on Q-Pulse)	No
	Support Requirements	**Yes/No/NA***
18.	Is the instrument qualification (IQ/OQ) provided by the vendor? If not how will this be addressed, complete below:	Yes
	Provided by manufacturer	
19.	Does the vendor supply training? (if yes this must be documented internally) If not detail below how training will be provided if required:	N/A
	Machine from current manufacturer of our existing glasswashers, and operation (based on manuals) will be very similar to that of current glasswashers. No specific training required	
20.	Does the vendor provide ongoing support i.e. annual maintenance, requalification, servicing and repairs? If not who will provide this, detail below:	Yes
	Provided by manufacturer	
21.	Does the vendor provide any other required support services? Add detail in the Comments section.	Yes

Comments: *Provide details of any other pertinent information. If the equipment does not satisfy any of the criteria listed on the previous page, provide a justification for acceptance:*
-Spare parts -Service contracts if required -URS being raised retrospectively as equipment has already been purchased (see DEV-4173) -Note; 2 of the same model have been purchased, so this one URS is applicable to both change controls

RSSL User Requirement Specification
(Refer to QSOP-42)

	Name	Signature	Date
Completed By:	REG FERNANDES		14SEP22
Approved By (Lab Manager):	REG FERNANDES		14SEP22

RSSL User Requirement Specification
(Refer to QSOP-42)

QAU Cross Check			
URS complete?	**Supplier Approved?**	**Audit trail facility?**	**IQ/OQ required?**
Yes / No **If "No" cannot be signed**	Yes / No **If "No" cannot be signed**	Yes / No **If "No" justify why acceptable**	Yes / No
DI Assessment Required?	**Backup possible?**	**Utilities in place?**	**EHS requirements met?**
Yes / No	Yes / No **If "No" justify why acceptable**	on 15/09/2022 Yes / No **If "No" justify why acceptable**	Yes / No **If "No" justify why acceptable**
Comments Justifications	-No audit trail as not possible, asset not computerised. -No data to back up as none generated. - Utilities currently not in place however this URS is for pre-purchase of assets prior to CC completion. CC contains actions to ensure utilities in place.		
Approved By (QA):	**Name** Jedd Marston	**Signature**	**Date** 15/09/2022

Following QA approval, the user is approved to purchase the specified equipment/ software and the design qualification stage is complete.

The Change Control is used to capture the IQ/OQ and approval, completion of a DI gap Assessment with any reparative actions (if required), training requirements being fulfilled and population of the Asset module in Q-Pulse.