PharmaState

USER REQUIREMENTS SPECIFICATION (URS)

FOR

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Revision No	:
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APPROVAL

Document	Designation	Name	Signature and Date
Prepared			
Verified by			
Approved by			

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1.0 OBJECTIVE:

To define the functional specification and minimum design attributes for _____

2.0 PURPOSE:

The purpose of this User Requirement Specification is to establish and document

- Salient features of the equipment from process, cGMP and safety point of view.
- Other specific features regarding the equipment efficient use.
- Other equipment details that support to fix price prior to placing an order.

3.0 RESPONSIBILITIES:

4.0 INTRODUCTION:

(Describe the equipment general specification)

5.0 PROCESS OVERVIEW:

(Describe the process)

6.0 SYSTEM OBJECTIVE:

Describe the specific features requirement and its specification.

7.0 MODES OF OPERATION & OPERATIONAL REQUIREMENTS

(Write the desired operation features, if applicable such as:

- Modes of Operation:
  Specify the detail of all modes of operation required for the system such as Automatic / Manual, Start-up/Shutdown etc.
- Functional Operation:
  Describe the functions of the systems such as Sequences and Routines cross-referenced to the modes of operation, Alarms, Display, Data Archiving and Retrieval.
- Operator Interfaces:
  Detail the requirements for the system interface to the operator. Where computer systems are utilized, describe how the operator is to interact with the system, touch screen, keyboard mouse etc. Detail the requirements for the requirements for audible / visual warning devices if required, as appropriate.

- Report Outputs:

  Detail hard copy printed reports required from the system if required.

- Data Archiving:

  Where records are required to be held within a computer system detail the requirements for holding data, how the data is to be recalled)

8.0 SAFETY FEATURES*:*

(Describe safety features required)

9.0 ENVIRONMENTAL CONDITIONS:

(Detail the environment in which the system operates, i.e. temperature, dust and humidity of the area where the equipment is to be situated. Also, detail the constraints of the system with respect to the operating environment).

10.0 SERVICE CAPABILITIES:

(Detail the available services relevant to the system. This allows the supplier to make an informed discussion as to the service requirements. For example, an additional compressor may be required due to the load requirements of the system on the compressed air).

11.0 OTHER ATTRIBUTES:

Include following as applicable:

Availability - required running time of the machine/plant.

Maintenance - include any support requirements

Training - requirements for operator and technical training

Documentation - detailed documents to be delivered under the scope of the project (FDS, Operator Manuals, etc.)

Validation services such as Qualification documentations

12.0 DOCUMENTATION

(Describe the documentation support requirent)

13.0 TESTING

(Specify the levels of testing required such as Factory Acceptance Tests (FAT) and on-site validation and also the test details)

14.0 STATUTORY OBLIGATION

(List the statutory obligation compliance including Health and Safety)

15.0 TIME SCALE/DELIVERY

(Add the required time scale for the execution)

16.0 GLOSSARY

(List the terminologies and abbreviations used.)