Functional Specifications

Preparing the Buffer

Name / Project Role

Author

Approver

Signature

Date

(dd/mmm/yyyy)

1. Introduction

1.1 Glossary

2. Block identity card

3. Block Input Variables

4. Block Detailed specification

4.1 Design description

The goal of this document is to describe the IS teams interpretation of the requirements, and

describes the proposed functionality to be delivered.

1.1. Glossary

This section defines specific project/system term and acronym that could be used on this

document.

Term or Acronym

N/A

Definition

N/A

2. BLOCK IDENTITY CARD

Name

XAWT

Version

V1

Description

Preparing the Buffer

Variable Name

Equipment identification

Equipment Allocation

Status of equipment (GMP)

Instruction

GMP Status of complaint

equipment

GMP Date of compliant

equipment

File review completed

Input Variable

Data Type

Equipment identification

Equipment Allocation

Text

Text

List

Date

List

Description

Equipment identification

Equipment Allocation

Status of equipment (GMP)

Instruction

GMP Status of complaint

equipment

GMP Date of compliant

equipment

File review completed

4.1 Design description

ID

CBF001

Detailed description

1. System displays the equipment

identification.

"FRM0001" description is "Before

manufacturing begins, perform the following

checks on the equipment used (EQP001,

EQP002, EQP003 and EQP004)". Formula

type activity with formula: [Equipment

identification "variable" EQPCHK]

2. System displays the status of equipment

(GMP).

"FRM0002" description is "Before

manufacturing begins, ensure that items

related to the manufacturing of the previous

batch (absence of raw

materials/consumables, absence of

documents, absence of labels, absence of

samples, absence of small dirty equipment)

have been removed from the work area for

manufacturing". Formula type activity with

formula: [Text "variable" GMPSTS]

3. System displays the qualification/calibration

status check of equipment.

"FRM0003" description is "Qualified/calibrated

equipment". Formula type activity with

formula: [List "variable" QLFCAL]

4. System displays the GMP status of

compliant equipment.

"FRM0004" description is "Status of

equipment authorized for GMP use". Formula

type activity with formula: [Date "variable"

GMPDAT]

5. System displays the file review completed.

"FRM0005" description is "File review

completed AND buffer accepted". Formula

type activity with formula: [List "variable"

FILREV]