Document Cover Page

Document Title:	22_System Release Compliance Report for IGMP
Classification:	CSVP
Type:	System Release Compliance Report
Document Number:	CSVP-SSR-001
Version #:	26
Document ID:	CSVP-SSR-IGMP-3.016.103
File Name:	csvp-srr-igmp-3.016.103.pdf
Status:	Approved
Effective Date:	02/01/21
Review Date:	/ /
Reason for Change:	New Functionalities •An Automated Report was added that allows any number of recipients to receive a Current Inventory report by email on a selected day of the month. •A new report Inv on hand on a date allows users to search for the Quantity of Hand of all inventory items for a selected day. Improvements •When creating a Current Inventory report the depleted inventory can be removed for the report. •When inventory items are used in the manufacturing instructions of a Batch Production Record a checkbox allows the user to see depleted receipts. This can be used to return material to stock for a depleted receipt.

Reviewers:

Richard Soltero (rs01) 01/30/21 12:47 PM EST

Angelo Nardone (ANardone01) 01/30/21 04:03 PM EST

Jeremy Hall (JH02) 02/01/21 09:12 AM EST

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1. Definitions and Acronyms

Term	Definition
GXTest	Automated Validation Software used for Operation Qualification testing
SOP	Standard Operating Procedures
SRR	System Release/Commissioning Report
MVP	Master Validation Plan

2. Purpose

The purpose of this System Release/Commissioning Report is to document the release of the InstantGMP system for use.

1. Scope

The scope of this System Release/Commissioning Report is the release and commissioning of the InstantGMP system.

3. System Description

3.1. Software and Hardware

The software operates as a cloud application with the following minimum basic parameters for the software and hardware configuration.

- Software
  Windows Server 2012 R2 64-bit (Application server, Web server roles required)
  Microsoft SQL Server 2012 R2
  Application and database are stored on separate servers

- Hardware
  Shared application and database server - 8GB RAM // Standalone servers - 4GB RAM
  Application and database servers - Quad core 2GHz CPU // Standalone servers - Dual core 2GHz CPU
  Servers are virtualized and dedicated to InstantGMP

4. References

The purpose of this section is to serve as an index of all documents referenced for production of this document.

Document Identification	Document Title
CSVP-POL-IGMP	Computer System Validation Policy
CSVP-MVP-IGMP	Master Validation Plan
CSVP-IQ-IGMP	Installation Qualification
CSVP-GXTEST-OQT-IGMP	CSVP-OQT-Test Script-IGMP
CSVP-GXTEST-OQE-IGMP	CSVP-OQE-Test Script-IGMP
CSVP-VSR-IGMP	CSVP-Validation Summary report

5. Roles and Responsibilities

The roles and responsibilities for the IQ/OQ protocols are defined below.

Functional Group	Assigned Employee / Company
System Owner	Richard Soltero, Ph.D., InstantGMP
Information Technology	Angelo Nardone, InstantGMP
Quality Unit	Jeremy Hall, InstantGMP

5.1. System Owner

The ultimate responsibility for the controlled development, implementation, maintenance, and validation of the computer or automated system resides with the identified system owner. Responsibilities include:

- Define the business area needs and the intended use of the system.
- Ensure that system development, implementation, and use conform to the principles of the System Development Life Cycle (SDLC) process and the IQ/OQ.
- Ensure that the use and maintenance of the system complies with documented procedures that maintain the system in a validated state.
- Ensure the accuracy and integrity of the data entered into and resident on the system.

5.2. Information Technology

The person performing or overseeing the development and technical aspects of the system is responsible for the following items:

- Create a system technical design that satisfies the specified business area and regulatory requirements.
- Ensure that the technical design, construction, testing and delivery of the system conform to principles of the SDLC process and the IQ/OQ protocols.
- Ensure that maintenance and changes to the system are performed according to documented procedures that maintain the validated status of the system.
- Ensure that the products or services supplied by external vendors and/or suppliers adhere to the principles of the SDLC process.

5.3. Quality Assurance

The Quality Assurance Unit is that organization or person designated by InstantGMP to be an independent reviewer for all completed and/or executed validation documentation. The Quality Assurance Unit is responsible for the following items:

- Maintain independence and objectivity relative to the system development, implementation, use and validation processes.

2. Compliance Statement

This InstantGMP system has been validated to comply with the standards outlined in the following references:

Document Identification	Document Title
N/A	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
21 CFR Part 11	Electronic Records; Electronic Signatures
21 CFR Part 820	MEDICAL DEVICES - QUALITY SYSTEM REGULATION
21 CFR Part 111	CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS
21 CFR Part 211	CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS
Annex 11	EudraLex Volume 4, Annex 11: Computerized Systems
ISO 9001	Quality Management System
ISO 13485	Medical Devices - Quality Management System
GAMP 5	General Automated Manufacturing Practices

3. System Release Statement

This System Release Statement is written to indicate that the InstantGMP system is accepted by the system owner and is deemed suitable for release. The Business Owner and IT base this release upon the successful completion, review and approval of the Validation deliverables and the other activities required by the Master Validation Plan for the InstantGMP system.