Document Cover Page

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Review Date:	/ /
Reason for Change:	New Functionalities Provide a Responsive Design of the entire software. Allow the creation and editing of master manufacturing instructions to be done on the MPR summary screen. Add QR Codes to bar code labels. Improvements Remove timer button in BPR closed steps. When a Project is hidden, hide the MPRs, BPRs and MTOs on the summary screens. Add Status to MPR and BPR Cover Pages. When InstantGMP Dashboard Setting “Specs Off” is selected, allow both FG/oWIP and RM/iWIP/O materials to be added to a Project. Add software version number to the menu of the responsive design. Update GeneXus from v17 u10 to v17 u11 and update PXTools to latest version Fixes Equipment Task spelling error. The cover page of some word documents in the DMS don't show the Reviewer's date/time stamp. Inventory Label Design copy function can only be seen by DBADM. CLOSE button missing on executed BPR steps. “Results” and “Comments” on the BPRs are single-line text fields instead of memo fields.

Reviewers:

Richard Soltero (rs01) 07/14/24 05:08 PM

Angelo Nardone (ANardone01) 07/15/24 10:27 AM

Approvals:

Richard Soltero (rs01) Approved 07/15/24 10:39 AM

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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.

3. Scope

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

4. System Description

4.1. Software and Hardware

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

- Application Server
  - Windows Server 2019
  - IIS 10.0 version 1809
    - URL Rewrite 2.0.
    - WebSockets enabled
  - .NET Framework 3.5 and 4.7 – All features enabled

- Database Server
  - Windows Server 2019
  - SQL Server 2019 Standard or Enterprise

- Servers are virtualized and dedicated to InstantGMP, Inc.

5. 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-4.004.301	Computer System Validation Policy
CSVP-MVP-IGMP	Master Validation Plan
CSVP-IQ-PRS-IGMP-4.001.001	IQ Protocol Summary Report for IGMP
CSVP-GXTEST-OQT-IGMP	CSVP-OQT-Test Script-IGMP
CSVP-OQE-GXtest-IGMP-4.004.301	CSVP-OQE-Test Script-IGMP
CSVP-VSR-IGMP-4.004.301	CSVP-Validation Summary Report for IGMP

6. 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	Brandy Irons, InstantGMP

6.1. 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.

6.2. 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.

6.3. 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.

7. 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
HIPAA	Health Insurance Portability and Accountability Act Privacy Rule
GDPR	General Data Protection Regulation

8. 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.