MesaLabs

QS-513 Validation Summary
Apex Product Line

Executive Summary

The Apex manufacturing process is validated according to QS-501 *Validation Master Plan for the Mesa Labs, Inc., Bozeman Manufacturing Facility 625 Zoot Way*.

The Apex manufacturing process, under anticipated conditions, will consistently produce product that meets pre-determined specification requirements.

Process Performance Qualification

Process Performance Qualification (PPQ) conducted under Protocol #180508P *Performance Qualification for the Manufacture of Apex Biological Indicators*. This PPQ qualifies manufacturing of the Apex product line at 625 Zoot Way, Bozeman MT 59718.

Validation Lots

SBC-327 GST log6 ribbons 100ct/bag, Lot AS-001
HMV-091 GST log6 discs 100ct/bag, Lot AH-001
KCD-404 GST log4 discs 100ct/bag, Lot AK-001

Rationale for selection of products

Apex manufacturing is a multi-phase process: inoculation of stainless-steel carrier, packaging in Tyvek/Tyvek envelopes, qualification testing and final labeling/packaging. The inoculation phase consists of distributing a known quantity of bacteria onto the stainless-steel carrier per AX-101 or AX-103. The inoculated carriers are either packaged by hand or on automated equipment (DON-101) and subjected to qualification testing consisting of population and VPHP resistance testing (ISO-101). The results are used to generate the label claim for each lot of Apex biological indicators. Satisfactory completion of the qualification testing results in release Apex biological indicators for distribution.

- The components used to manufacture these lots are representative of the components used to manufacture all variants of Apex biological indicators.
- The 3 runs were considered sufficient to simulate conditions that will be encountered during routine manufacturing, such as start-up, shut-downs, breaks, and manufacturing over multiple days.

As compared to the manufacturing process prior to transfer to the new facility, there were no changes to specifications, and no changes to components or component suppliers. In conjunction with the relocation, Mesa installed and qualified equipment to automate the packaging of all Apex products except for SBC-327 & LOG-456. Procedures were renumbered to align with the quality system, and a number of minor changes occurred to allow for slightly different workflow in the new facility; they otherwise remained unchanged.

Acceptance criteria and results

Three consecutively manufactured lots meeting the criteria provided below were required to confirm that the Apex manufacturing process, under anticipated conditions, will consistently produce product that meets pre-determined specification requirements.

For the QA final inspection per QSWI-103, the Acceptable Quality Level (AQL) for acceptability of a particular lot's inclusion in this qualification was based on criticality and frequency of the defect. If the lot in question fell within these established limits it was deemed acceptable for use as a validation lot. The defects were divided into two tiers. Defects considered *Critical to Performance* were assigned an AQL of 99%. Defects considered as having *No Impact to Performance* were assigned an AQL of 95%. Results are reported below for each validation lot.

SBC-327, Lot AS-001		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed carrier must be the targeted population log: Log6	2.2×10^6	PASS
VPHP resistance must 0.2-2.5minutes.	2.0 minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS

HMV-091, Lot AH-001		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed carrier must be the targeted population log: Log6	2.3×10^6	PASS
VPHP resistance must 0.3-2.4minutes.	2.1 minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS

KCD-404, Lot AK-001		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed carrier must be the targeted population log: Log4	3.1×10^4	PASS
VPHP resistance must 0.1-1.5minutes.	1.1 minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS

Deviations to protocol

There were no deviations encountered during the execution of protocol 180508P.

Method Verification

The following Compendial Method Verifications were completed as part of this protocol:

- Population assay testing of stainless-steel carriers per ISO 11138-1 and Mesa procedure AX-203
- VHP resistance testing on stainless-steel carriers packaged in Tyvek pouches per Mesa procedure AX-202.

Equipment Qualification

The following equipment qualifications were completed in order to execute this protocol:

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
ROB-101	Disc Robot	ROB101-IOQ-001	None	The disc robot has been installed successfully. The installation and operation qualification criteria have been met.
DRY-201	Drying Oven	DRY201-IOQ-001	None	The drying oven has been installed successfully. The installation and operation qualification criteria have been met.

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
DRY-202	Drying Oven	DRY202-IOQ-001	None	The drying oven has been installed successfully. The installation and operation qualification criteria have been met.
DON-101	Apex Automated Packaging System	DON101-IOQ-001	None	The Apex automated packaging system has been installed successfully. The installation and operation qualification criteria have been met.
ISO-101	VPHP Isolator	ISO101-IOQ-001	None	The VPHP isolator has been installed successfully. The installation and operation qualification criteria have been met.
HEP-115	Biosafety Cabinet	HEP115-IOQ-001	None	The biosafety cabinet has been installed successfully. The installation and operation qualification criteria have been met.
INC-105	55-60°C Incubator	INC105-IOQ-001	None	The 55-60°C incubator has been installed successfully. The installation and operation qualification criteria have been met.

Utility Qualification

The following utility qualifications were completed in order to execute this protocol:

System Number	Utility	Qualification document(s)	Protocol Deviations	Conclusion
AIR-101	Compressed Air System	AIR101-IOQ-001	None	The Compressed Air System has been installed successfully. The installation and operation qualification criteria have been met.

Standard Operating Procedures

The protocol was executed under the following standard operating procedures:

Document Number	Revision	Title
AX-101	1	Manufacture of Apex Discs
AX-102	1	Inoculation Process for Apex Biological Indicators - Confidential
AX-103	1	Manufacture of Apex Ribbons
AX-104	1	Printing of Labels for Apex Products
AX-202	1	Resistance Testing of Apex Biological Indicators
AX-203	1	Population Assay of Apex Biological Indicators
AX-303	1	Apex Automation Packaging
AX-304	1	Operation of the Vapor Phase Hydrogen Peroxide Isolator
QSWI-103	5	QA Release of Finished Product Inventory

Training

The operators in the table below completed qualification training on the SOPs identified above during the PPQ.

Operator	Procedure(s)	Status of read-and-understand training on SOPs	Status of qualification training on SOPs*
ES	AX-102, AX-103, AX-104, AX-202, AX-203	Complete	Complete
JH	AX-102, AX-202, AX-203	Complete	Complete
CB	AX-101, AX-102, AX-103, AX-104, AX-202, AX-203, AX-304	Complete	Complete
CC	AX-101, AX-303	Complete	Complete
LL	AX-101, AX-103, AX-104	Complete	Complete
RL	AX-101, AX-103, AX-104, AX-303	Complete	Complete

*AX-104 and AX-202 do not require qualification training.

Attachments:

List of Catalog Numbers Validated Under Protocol 180508P

Approvals:

Validation: _____ Date: 07 Aug 2018
Kurt McCauley - Director of Manufacturing

Production: _____ Date: 06 Aug 2018
Robert Bradley - Director of Manufacturing

QA: Janis E Smoke Date: 08 Aug 2018
Janis Smoke – Director QA/RA

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List of Catalog Numbers Validated Under Protocol #180508P

HMV-091
HMV-091E3
SBC-327
KCD-404
NAS-152
NAS-152E3
NAS-152E4
LOG-456
GRS-090
GRS-090E3
GRS-090E5
PLN-060
BMWK-750