MesaLabs

QS-502 Validation Summary Rev. 3
Process Challenge Devices (PCD) Product Line

Executive Summary

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

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

Process Performance Qualification

Process Performance Qualification (PPQ) conducted under Protocol #170603P Rev. C *Process Qualification for PCD Manufacturing*. This PPQ qualifies manufacturing of all Mesa PCD catalog numbers at 625 Zoot Way, Bozeman MT 59718.

Validation Lots

PCD 2.3 2000 Units Lot B170004
PCD 4.13 5100 Units Lot B170005
PCD 6.5 500 Units Lot B170006

Rationale for selection of products

PCDs consist of either a naked paper carrier, a spore strip in glassine, or a self-contained biological indicator sealed into any of seven pouch types, assembled against a backer card with a unit label. The PCD manufacturing process consists of insertion of the finished biological indicator into a pre-formed pouch sealed on three sides, sealing of the fourth side under conditions of controlled temperature and pressure, placement of the sealed pouch against a backer card, and application of the unit label.

A matrix approach was followed for validation of the PCD manufacturing process.

- The three products are representative of the three BI types used in PCDs: naked paper carriers (PCD 2.3), spore strips in glassine (PCD 6.5), and self-contained biological indicators (PCD 4.13).
- The pouches represent a range of different pouch types. Type 2 was chosen as a pouch which represents the greatest challenge to pouching and in-process inspections. Of the seven pouch types, it is most easily deformed by inadvertent stretching, and thus poses the greatest challenge to the operators to produce a seal which meets pre-determined specifications. Types 4 and 6 were chosen as representing the greatest challenge to sealing operations, as these are the pouch types composed of the thickest plastic film.
- The lot sizes of 500 and 2000 units represent 97.7% of existing order sizes; the lot size of 5100 was chosen as representative of a greater challenge to the process.
- Three 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 the manufacturing process, no changes to specifications, and no changes to components or component suppliers. 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 PCD 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 Peformance* were assigned an AQL of 99%. Defects considered as having *No Impact to Peformance* were assigned an AQL of 95%. Results are reported below for each validation lot.

PCD 2.3 Lot B170004			
Critical to Performance	**Defect rate**	**No impact to Performance**	**Defect rate**
Defective seals	0% (0 defects) PASS	Debris or human hair in pouch	0% (0 defects) PASS
Damaged pouches	0% (0 defects) PASS	Print placement	0% (0 defects) PASS
Labeling, specific to product traceability PCD type, lot number and expiration date)	0% (0 defects) PASS	Label/pouch orientation	0% (0 defects) PASS
		Damaged or missing BIs	0% (0 defects) PASS
		Labeling, specific to supplemental descriptive information	0% (0 defects) PASS

PCD 4.13 Lot B170005			
Critical to Performance	**Defect rate**	**No impact to Performance**	**Defect rate**
Defective seals	0% (0 defects) PASS	Debris or human hair in pouch	0% (0 defects) PASS
Damaged pouches	0% (0 defects) PASS	Print placement	0% (0 defects) PASS
Labeling, specific to product traceability PCD type, lot number and expiration date)	0% (0 defects) PASS	Label/pouch orientation	0% (0 defects) PASS
		Damaged or missing BIs	0% (0 defects) PASS
		Labeling, specific to supplemental descriptive information	0% (0 defects) PASS

PCD 6.5 Lot B170006			
Critical to Performance	**Defect rate**	**No impact to Performance**	**Defect rate**
Defective seals	0% (0 defects) PASS	Debris or human hair in pouch	0% (0 defects) PASS
Damaged pouches	0% (0 defects) PASS	Print placement	0% (0 defects) PASS
Labeling, specific to product traceability PCD type, lot number and expiration date)	0% (0 defects) PASS	Label/pouch orientation	0% (0 defects) PASS
		Damaged or missing BIs	0% (0 defects) PASS
		Labeling, specific to supplemental descriptive information	0% (0 defects) PASS

Deviations to protocol

There was one deviation to Protocol #170603P.

Deviation Number	Summary	Impact
170603-D-01	Lots B170001 and B170003 did not meet process performance qualification acceptance criteria. Nonconforming material documented as ZT-NMR-1706 and ZT-NMR-1707 and investigated under ZT-IR-1701. ZT-CAPA-1702, ZT-CAPA-1703, ZT-CAPA-1704, and ZT-CAPA-1705 were assigned to address causes identified in the investigation.	No protocol impact. As part of ZT-CAPA-1705, Protocol 170603P was revised to require running three new validation lots: PCD 2.3, PCD 4.13, and PCD 6.5. The new validation lots represent a range of different pouches and biological indicators, as required per the protocol.

Method Verification

No compendial methods are used in manufacture of PCD products.

Equipment Qualification

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
BST-101	BT-1000 Package Tester	BST101-IOQ-101	None	The BT-1000 package Tester has been installed successfully. The installation and operation qualification criteria have been met.
LBR-101	Sidco Universal Labeling System Label Applicator with Sato Printer	LBR101-IOQ-001	None	The PCD (Sidco) Universal Labeling System label Applicator with Sato Printer has been installed successfully. The installation, operation, and performance criteria have been met.
		LBR101-PQ-001	None	
LBR-102	Sidco Universal Labeling System Label Applicator	LBR102-IOQ-001	None	The PCD (Sidco) Universal Labeling System label Applicator

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
	with Sato Printer	LBR102-PQ-001	None	with Sato Printer has been installed successfully. The installation, operation, and performance criteria have been met.
LBR-103	Sidco Universal Labeling System Label Applicator with Sato Printer	LBR103-IOQ-001	None	The PCD (Sidco) Universal Labeling System label Applicator with Sato Printer has been installed successfully. The installation, operation, and performance criteria have been met.
		LBR103-PQ-001	None	
LBR-104	Sidco Universal Labeling System Label Applicator with Sato Printer	LBR104-IOQ-001	None	The PCD (Sidco) Universal Labeling System label Applicator with Sato Printer has been installed successfully. The installation, operation, and performance criteria have been met.
		LBR104-PQ-001	None	
LBR-105	Sidco Universal Labeling System Label Applicator with Sato Printer	LBR105-IOQ-001	None	The PCD (Sidco) Universal Labeling System label Applicator with Sato Printer has been installed successfully. The installation, operation, and performance criteria have been met.
		LBR105-PQ-001	None	
SLR-101	Doboy B550M Medical Sealer Band Sealer	SLR101-IOQ-001	None	Sealing of Pouch Types 1, 2, 3, 4, 5, 6 and 7 were qualified. The Doboy B550M Medical Sealer has been installed successfully. The installation, operation, and performance criteria have been met.
		SLR101-PQ-001	None	
SLR-102	Doboy B500M Medical Sealer Band Sealer	SLR102-IOQ-001	None	Sealing of Pouch Types 1, 2, 3, 4, 5, 6 and 7 were qualified. The Doboy B500M Medical Sealer has been installed successfully. The installation, operation, and performance criteria have been met.
		SLR102-PQ-001	None	

Utility Qualification

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

Standard Operating Procedures

Document Number	Revision	Title
SP-301	2	PCD Control Plan
AP-401	1	PCD Label Printing
AP-402	2	PCD Assembly Procedure
AP-403	1	Burst Tester (BT-1000-V5) Operation
AP-404	2	Operation of Doboy Medical Heat Sealer
AP-406	1	PCD Manufacturing Area Cleaning Requirements
LP-502	1	Gowning Requirements for Controlled Environments
QS-205	1	Line clearance
QSWI-103	1	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	Status of read-and-understand training on SOPs	Status of qualification training on SOPs
CK	Complete	Complete
JK	Complete	Not required
LL	Complete	Complete as required
OR	Complete	Complete as required
TB	Complete	Complete as required

Approvals:

Process Lead: _____ Date: 07Dec2017
Apex Laboratory Manager

Process Owner: _____ Date: 06Dec2017
Director of Production

Metrology: _____ Date: 07DEC2017
Director of R&D / Support Services

QA: Janis E Smoke Date: 07Dec2017
Director of Quality and Regulatory Affairs

Document Change History

Revision	Changes	Reason for change
1	Original document	**Note:** no revision number appears on Rev 1
2	Added statement to *Rationale for selection of products* section regarding changes to process and components. Removed reference to ZT-CAPA-1701 from *Deviations to protocol* section. Revised footers to pages 2-5 to add page numbering.	Statement regarding changes added to provide more information that is useful to customers Reference to ZT-CAPA-1701 was inadvertently included in previous version Page numbering added to increase document useability
3	Added multiple clarifications to *Rationale for selection of products:* • Added brief descriptions of product and manufacturing process. • Clarified that a matrix approach was followed for the process validation. • Identified the type of biological indicator included in each PCD part number chosen to include in the validation matrix. • Provided additional justification for choice of pouch types included in the process validation. The Equipment Qualification section was revised for SLR-101 and SLR-102 to add the pouch types included in the sealer qualifications.	All edits made to provide more information that is useful to customers.