# Bozeman Manufacturing Facility Product Relocation Information – Validation Activities

Dear Valued Client,

As detailed in a previous correspondence Mesa will be transferring manufacturing lines for many products currently manufactured at 10 Evergreen Drive, Bozeman MT 59715 to a newly constructed facility located at 625 Zoot Way, Bozeman MT 59718. The target for completion of transfer of each line will be posted in separate communications, as it becomes available.

This communication provides information on the validation activities that will be completed to support transfer of manufacturing lines to the new facility.

## Master Validation Plan

Qualification and validation activities will be conducted under approved QS-501 *Validation Master Plan for the Mesa Labs, Inc Bozeman Manufacturing Facility 625 Zoot Way*. The Validation Master Plan includes the following activities:

### *Equipment Classification*

A risk-based approach has been used to classify each piece of equipment used in manufacture of Mesa Biological Indicators, with resulting classifications used to establish the qualifications to be performed pre-and post-transfer.

### *Equipment and Utility Qualification*

Depending on potential to impact product integrity and quality, and complexity of the process or equipment, IQ/OQ and in some cases PQ protocols will be executed for each piece of equipment prior to release for use in commercial production. All protocols will include pre-determined acceptance criteria. A qualification report documenting disposition of the equipment or utility for intended use will be prepared and approved for each piece of equipment or utility.

### *Process Performance Qualification*

Process Performance Qualification (PPQ) protocols will be executed for each product line to provide documented evidence that manufacturing processes as defined in SOPs, specifications and control plans perform as expected. The IQ/OQ reports for equipment to be used for the PPQ will be complete prior to the start of the qualification. All protocols will include pre-determined acceptance criteria. A qualification report documenting QA release of the product line from the new facility will be prepared and approved for each product line.

### *Compendial Method Verification*

Compendial Method Verifications (CMVs) will be performed to establish documented evidence that the compendial methods used by Mesa for in-process, release, and stability testing can be reliably and reproducibly performed for all products and process intermediates. CMVs will be performed under approved protocols which will include pre-determined acceptance criteria, and may be performed concurrently with PPQ. Summary reports will be prepared documenting results of the verification, including whether acceptance criteria were met.

## Customer review of Validation documents

Summary documents for each product line intended to help our customers maintain supplier qualification will be posted to our website as they become available: http://biologicalindicators.mesalabs.com/BIrelocation/. Validation documents and associated data supporting conclusions may be reviewed during an on-site audit.

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We acknowledge that some customers may need to perform a validation on the product once manufacturing is initiated at the new facility. If you anticipate you will need product to validate this change, please contact our Customer Service group to be put on our list for validation shipments.

| **Ordering Information** | |
|---|---|
| Telephone | 303-987-8000 Ext. 10040 |
| Fax | 406-585-9219 |
| Email | bicustomerservice@mesalabs.com |

If you have any questions related to planned validation activities, please don't hesitate to contact us. Contact information for questions is provided below:

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| Robert Bradley<br>Director of Production<br>(303) 987-8000 x10217<br>rbradley@MesaLabs.com | Janis Smoke<br>Director of Quality and Regulatory Affairs<br>303-987-8000 x 10352<br>jsmoke@MesaLabs.com |

Thank you for being a valued client and we look forward to continuing to serve you.