## 1.0 PURPOSE

1.1 The purpose of this Validation Master Plan (VMP) is to identify the validation and testing requirements necessary to qualify the products manufactured by Value Plastics dba Nordson MEDICAL after relocation from 3325 South Timberline Road, Ft. Collins, CO 80525 to 805 West 71st Street, Loveland, CO 80538.

1.2 There will be no changes to the Quality System, materials, ERP system, tools, equipment, manufacturing processes and quality inspections as a result of this facility move. In addition the people who have been doing the work in the current plant will be the same people doing the work in the new plant.

## 2.0 POLICY COMPLIANCE

This Plan complies with corporate policy requirements for validation as stated in the Validation Master Plan IFS document VMP7.1 and ISO 9001 and ISO 13485 requirements

## 3.0 REVIEWERS, APPROVERS AND EXECUTERS

Reviewers, approvers and executers of this plan are captured in the approval routing tab of this document in IFS.

## 4.0 SCOPE OF VALIDATION

**NOTE: All products manufactured by Value Plastics are proprietary to Value Plastics; the majority of the machines, molds and equipment are owned by the company. There is not a 1:1 correlation with mold and machine for building individual parts (i.e, parts can be built on any number of machines using a number of different molds). With over 4200 molded parts that can be run in multiple different machines and molds, it would require over 180,000 individual validations to verify every possible combination of part and mold to machine. This would result in approximately 1.42M validation hours. It is not feasible to validate each part in each configuration. Therefore we will approach this facility move validation in a staged manner. We will validate every piece of critical manufacturing equipment using a representative mold and part and will allow our standard quality inspection processes to verify that parts produced post-facility move continue to meet specification. (Note that we <u>will</u> conduct a validation for any dedicated molds/machines.)**

This Master Validation Plan addresses all activities related to equipment, utilities, processes, and systems that may impact product quality post facility move. Specific systems, equipment, infrastructure and procedures to be qualified and processes to be validated were determined based on our standard Validation Master Plan (VMP7.1) and associated work instructions.

4.1 In-Scope

4.1.1 Injection Molding Machines moved to new facility

4.1.2 Injection Molding Machine monitoring software

4.1.3 Injection Mold Tooling moved to new facility

4.1.4 Testing equipment moved to new facility
4.1.5 Measuring equipment moved to new facility
4.1.6 Packaging equipment moved to new facility
4.1.7 Assembly Equipment, Welders and joining equipment, Automated Assembly Machines, etc.
4.1.8 Tool room machining equipment
4.1.9 New equipment installed in the new facility

4.2 Out of Scope

4.2.1 ERP software - This VMP will not cover software validation for the ERP system (IFS) because software validation is a separate validation activity (reference IFS document 1031072)

4.2.2 Technical Specifications – Tests conducted to confirm tensile and burst strength, and material properties (i.e, biocompatibility, USP Class VI, etc) will not be repeated because there will be no change to the material, equipment or processes with the move to the new facility.

4.2.3 Facility systems (i.e., HVAC, Plumbing, Electrical) because these facility systems are part of a separate commissioning plan.

## 5.0 DEFINITIONS

CMM – contact measuring machine
CNC – computer numeric control
EDM – electric discharge machining
IMM – injection molding machine
IQ – installation qualification
OQ – operational qualification
PPP – product preparation and packaging
PQ – process qualification

## 6.0 ACCEPTANCE CRITERIA

6.1 Product – The first run of parts produced in an IMM post facility move must pass all quality checks per our standard processes. Additionally, a detailed comparison of the part measurements will be made between the part run post facility move, as compared to the measurements for the last time the part was run in the old facility. Once the run of this part has passed, the machine is considered validated to run any part in that machine.

Start up verification is conducted as part of our standard process for every part. Quality inspections are also conducted per our standard process using production control plans for every part. This process will not change post facility move and provides an additional verification that the parts will continue to meet specification.

6.2 All applicable equipment will be verified for proper functioning in the new facility through IQ and if applicable, OQ and PA.

## 7.0 EQUIPMENT/SYSTEM DESCRIPTION

This VMP will focus on the following equipment and processes. Specific validation requirements will be supplied in the reference documents listed on table 10.2

7.1 Primary Equipment

This class of equipment has a direct affect on the quality of the product or verifies (by measurement or testing) the quality of the product being produced. It comprises equipment that may require IQ, OQ, and PQ validations. This equipment could be classified as, but is not limited to, equipment that contacts the raw material or product at some point in its manufacture. The transfer of this equipment has applicable risk if damaged or misplaced. To mitigate the risk, we have redundancies and duplicity in processes with all of our primary production equipment.

Primary equipment will be classified as such in the Validation Matrix (example in Appendix 2)

- Injection Molding Machines
- Assembly machinery – Leak testers, Welders and joining equipment
- PPP – Baggers, Part cleaning equipment
- Quality machines- Micro-Vu CMM, Part Measurement Scopes

7.2 Support Equipment

This class of equipment assists the people and primary machinery in support of the manufacture and development of existing and new product. It comprises equipment that may not require IQ, OQ, and PQ validations. This equipment may be regularly calibrated or its condition and/or output is not easily affected or changed. This equipment is not essential to keep our existing product line running if damaged or misplaced in the facility transfer.

This equipment could include, but is not limited to:

- R&D lab equipment- Instron force tester, life cycle testers, 3D printer
- Tool and die machinery - CNC's, Lathes, EDM's
- Supplemental measuring devices- scopes, indicators, calipers

7.3 Non-Critical

This class of equipment assists the day to day function of our facility. It comprises equipment which in most cases will not require IQ, OQ, or PQ validations. This equipment may be regularly calibrated or its condition and/or output is not easily affected or changed. This equipment is readily available, we own multiples, and there is low risk if damaged or misplaced in the facility transfer. This equipment is not essential to keep our existing product line running. Examples of

non-critical equipment includes, but is not limited to:

- Hoists, dollies, cranes
- Conveyors, bins, carts
- Hand Tools
- Byproduct Grinders

7.4 Facilities/Utilities

New equipment/systems include:

- Raw Material handling system – Nordson MEDICAL will utilize state of the art automated material handling equipment to properly condition and deliver the proper material to production machinery. This system is also being configured with bar code verification proofing to ensure proper lot/batch tracking for all production runs.
- Process Water chilling system –To ensure tight processing parameters on production equipment and molds, we are installing a state of the art process water chill system to provide tightly temperature-controlled chilled water.
- Compressed air
- Clean Room

7.5 Prepping equipment and moving into new facility

Equipment will be protected during the move. Prior to introducing equipment into the cleanroom at the new facility, the equipment will be properly cleaned per our documented procedure (#1019143) for moving equipment and fixtures into the controlled area.

7.6 Laboratory Equipment

No special laboratory equipment will be used for this VMP. Measurement equipment will be utilized and documented as specified in individual equipment qualifications.

## 8.0 VALIDATION PROTOCOL

8.1 Validation strategy

All equipment was reviewed and assessed for validation requirements. A list of equipment requiring some level of validation was created and for those that did not require validation, a rationale as to why. A snapshot of this validation matrix is included as Appendix 2.

All applicable equipment will be verified for proper function in the new facility through IQs. Any equipment requiring calibration will be calibrated as part of its IQ. Any equipment validated previously that requires calibration will have the calibration status verified as current. All equipment, asset ID's and preventative maintenance procedures will be updated as part of the IQ process.

Process qualifications (PQ) will be performed after the equipment is successfully installed. The

PQ's will consist of confirming proper process outputs, as well as our standard start up acceptance and quality inspections.

8.2 Planning Definition

8.2.1 Equipment/System Requirements

The manufacturing equipment covered by this VMP is existing equipment used at our existing facility. New equipment being introduced to the new facility is listed in section 7.4. A building commissioning plan outlines the validation plan for the new equipment.

8.2.2 Purchase Specifications

Drawings and/or purchase specifications will be confirmed to be in place and in line with any new equipment used per standard VP Purchasing procedures.

8.2.3 Equipment/System Design Review

A thorough review of the proposed line layout will be held by Manufacturing Engineering and Production to ensure ergonomic and flow issues are addressed.

8.3 Risk Management

Current PFMEA's will undergo a review by Quality as part of this VMP. Any updates will be documented in the VMP Summary report.

Product Performance is not considered a risk because machine, molds, processes, personnel and quality systems used to manufacture parts are not changed. Potential risks to this VMP include:

| Risk | Cause | Mitigation |
|---|---|---|
| Inability to produce parts after equipment moved to new facility. | IMM damaged during move, failed IQ | Equipment move will occur in phases over several months so parts will be able to be produced at the old facility in the event validation fails. |
| New equipment does not pass validation. | Failed IQ; inadequate/-incorrect system | Equipment will not move from existing facility until new equipment passes validation. Redundancy at both facilities will be maintained until all machines are moved. |

8.4 Qualification

8.4.1 IQ

Installation Qualification records will be attached to the Validation Plan for the piece of equipment and documented in the validation matrix. (Appendix 2)

8.4.2 OQ

Operational Qualification records will be attached to the Validation Plan for the piece of equipment and documented in the validation matrix.

8.4.3 PQ

A Process Qualification will be created and executed to satisfy the validation matrix requirements.

## 9.0 VALIDATION DELIVERABLES

9.1 Validation matrix

For each Qualification required by the Validation matrix, an executive summary will be added to the Validation Plan document and submitted for approval to complete the affiliated protocol.

9.2 Procedures

No new procedures will be created as part of this VMP; however some SOPs may require updating to satisfy the validation requirements and/or to reflect the use of new equipment in the new facility.

| Document # | Title | New/Revise |
|---|---|---|
| MP6.3 | Infrastructure and work environment | Revise |
| *TBD* | | |

9.3 Methods

No new methods will be developed as a result of this VMP.

9.4 Training

Training will occur if any documents executed under this VMP require it. Also, personnel will be trained to any SOP's that are updated under this VMP. Documentation of training to any qualification protocols will occur within the summary report to the qualification protocol. Training to any revised SOP's will be documented after the facility transfer and prior to the employee executing the task per our standard training procedure (AP6.2.2).

9.5 VMP Summary Report

Once all individual Qualifications are summarized and approved via our documented process, a summary report to this VMP will be created to list and document all necessary qualifications and actions required by this VMP were successfully executed and implemented. Once the VMP summary report has been reviewed and approved, it will be posted on www.nordsonmedical.com

9.6 Individual Part validation

As noted above, individual parts will be validated during their first production run as they are today in every production run. Data from the first of this first production run will be made available as needed when the part is run based on normal planning and scheduling.

## 10.0 REFERENCES

10.1 Project Schedule

A project schedule has been completed for the facility move:

- Release VMP — February 2015 **(Complete)**
- Validation Plans created/ IQ/OQ/PQ checklists finalized — April 2015 **(Complete)**
- Validation Plans approved (Primary Equipment) — July 2015 **(Complete)**
- Facility/commissioning plan complete — July 2015 **(Complete)**
- Begin Moving Injection Molding Machines — July 2015 **(In process)**
- Last set of IMMs moved — September 2015 (Planned)
  - Validation tags attached
  - Execute IQ/OQ/PQ
  - Complete Validation report
- Release VMP Summary report — October 2015 (Planned)
- Obtain ISO 13485 certification — October 2015 (Planned)

10.2 Applicable Reference Documents, Regulations, and Procedures

All SOPs required have been listed in prior sections of this VMP. All summary report document numbers corresponding to documents required as per this VMP will be included in the VMP summary report. These document numbers have not been created at this time.

See below for list of references from this document:

| Document Number | Title |
|---|---|
| AP 6.2.2 | Training Competence and Awareness |
| VMP7.1, Sheet 4 | Validation Matrix |

## Appendix 1: Process Flow: Injection Molding – NO CHANGE