NMC Dynaplas Toronto
NMC Dynaplas Shanghai
NMC Medical Products
National Molding Miami

Supply Quality Assessment

CONFIDENTIAL

C-F105-01 Revised: 02/23/18

Supplier General Information

Supplier Name:		Audit Date:
Address of audit location:		City: State: Country: Zip Code:
List other locations operated by supplier:		
Is there a signed supplier confidentiality agreement in place? (Please check one)	Yes / No	Dated:

Key Supplier Contacts

(President, General Manager, Quality Manager, Manufacturing Manager, Sales / Account Manager, Purchasing Manager, Materials Manager, etc.)

Name	Title	Phone / Cell Number	Open	Close	Email

Facilities & Company Data (Attach detailed data as necessary)

Total plant square footage:	Number of buildings:
Sales $ previous year:	Privately held or public?
Number of exempt employees:	Number of non-exempt employees:
Exempt employee turnover rate:	Non-exempt employee turnover rate:
Union or non-union:non	Represented by:
Strike History:N/A	Contract Expires:
Languages Spoken:	Primary Language:
EDI Capabilities:	ISO / IATF Cert Status:
List any scheduled shutdowns or holidays:	

Core Competencies

Describe the supplier's self-defined core competencies.	

Development & Value Improvement Projects

Describe the supplier's ability to contribute to new product, design, and prototype opportunities.	

Active Continuous Improvement Program

Describe the supplier's continuous improvement culture, including how improvements are fostered and maintained.	

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Supplier Name: 0	Audit Date:

Element Subsystem Ratings: 0 = No System 1 = Significant Deficiencies 2 = Minor Deficiencies 3 = Satisfactory 4 = Commendable with Continuous Improvement	Supplier Self-Assess Points	Natmo Audit Points
SECTION 1: MANAGEMENT RESPONSIBILITY		
1 Roles and Responsibilities for the Organizational Management structure are documented.		
2 Quality Objectives are clearly stated, widely communicated, measured and understood throughout the company. Metrics are in place for all key areas to track progress.		
3 Regularly scheduled management reviews occur to verify the effectiveness of the quality system, and the General Manager is clearly involved in driving a Total Quality focus. Corrective action/continuous improvement plans result from management reviews.		
4 Management has a "defect prevention" culture to achieve continuous quality improvement.		
5 Management empowers line-level employees with the authority to stop the production line when safety or quality issues arise.		
6 Management clearly understands the concept of process variation, and takes necessary steps to reduce and control process variation.		
7 Management has invested in appropriate resources to drive and maintain critical support activities: [x] Pre-production quality planning [x] Corrective action [x] Employee training [x] Continuous improvement [x] Lean manufacturing [x] Process capability [x] Preventative maintenance [x] Gages and fixturing [x] Legal / Regulatory Compliance [x] Environmental, Health, and Safety Awareness (EHS)		
SECTION 2: OPERATIONAL FOCUS - DELIVERING THE BASICS		
1 There is a documented Safety Plan and it is communicated throughout the facility.		
2 There is a housekeeping / facility management system in place, such as 5-S deployment.		
3 Systems and metrics are in place to drive and maintain quality improvements. Internal scrap, external failure costs (customer charge backs), and customer concerns/complaints are tracked – with documentation to demonstrate activities to drive required improvements.		
4 Tools, resources and management support necessary to drive continuous (year-over-year) productivity improvements are in place and being utilized.		
5 Metrics are in place to monitor schedule completion/attainment and utilization (ex. OEE) of critical equipment and work cells.		
6 Acceptable lead times are maintained, or if necessary, a solid plan is in place to reduce the lead-time required to produce customer product.		
7 Metrics are in place to measure on time delivery. A process is in place to communicate to the customer, in advance, when the possibility of missing a delivery exists.		
8 Adequate capacity planning and verification processes are in place to effectively manage customer demand requirements.		
9 Effectively manages material flows and has adequate visual manufacturing / part identification methods in place for processing, staging, and packaging.		
SECTION 3: QUALITY SYSTEM		
1 A clearly documented Quality System is in place, which follows an element-based (ISO9001) or process-based (IATF16949) methodology. An internal audit program is in place.		
2 Pre-production quality planning (APQP) system is deployed which ensures compatibility of design, process, inspection, and test procedures along with applicable documentation.		
3 There is a system in place for new product sample submissions that complies with FBHS company-specific qualification requirements (i.e. lab test, PPAP, FAIR, Trial, etc).		
4 Process Flow Diagrams, PFMEAs, Control Plans, Gauge R&R, and Capability Studies are documented and deployed for critical areas.		
5 Employees are adequately trained and actively involved in pre-production quality planning, corrective actions, and continuous improvement teams.		

Supplier Name:	0	Audit Date:	01/00/00

	Element	Supplier Self-Assess Points	Natmo Audit Points
Subsystem Ratings:			
0 = No System	1 = Significant Deficiencies	2 = Minor Deficiencies	
3 = Satisfactory	4 = Commendable with Continuous Improvement		
SECTION 3: QUALITY SYSTEM - continued			
6	A formal system exists to manage change in the business, including notifying the customer of process, tooling, equipment, location, and material changes. Customer approval is required before change is implemented.		
7	Quality records are controlled and adequate to verify conformance to specification, conformance to operating (SOS / SOP) procedures, and provide problem-solving evidence.		
8	Necessary tools, infrastructure, and working conditions exist to properly promote an environment that is conducive to quality improvement.		
SECTION 4: PURCHASING			
1	A formal supplier rating / evaluation program is used when making sourcing decisions.		
2	All purchased materials / items have adequately specified requirements, with appropriate revision level details; and there is clear evidence that they are being enforced.		
3	An effective supplier 'certification' program is used that includes quality, price, delivery, and service measurables.		
4	An effective material quality improvement program is deployed that includes sub-suppliers.		
5	A system is in place to ensure that the company is notified before supplier process, tooling, equipment, material, or location changes occur. Sourcing, Supplier Quality, and Engineering approval is required prior to the change being implemented.		
6	Purchased material is labeled, controlled, and adequate traceability exists.		
7	Adequate product auditing at the sub-supplier (tier 2) is implemented and documented or receiving inspection process is deployed for key characteristics.		
SECTION 5: PROCESS CONTROLS AND INSPECTION			
1	Detailed Control Plans exist with clearly identified process control steps, reaction plans, and critical parameters (or limits) are identified.		
2	Control Plans are complete for all critical processes, current, easily accessible, and followed.		
3	Product critical to quality (CTQ) characteristics and in-process inspection & testing requirements have been clearly identified and documented.		
4	A method exists at the supplier for identifying and controlling key process steps or elements that affect critical to quality (CTQ) product characteristics.		
5	SOPs, SOSs, or work instructions are complete for all critical production operations, visible, and accessible to employees within the appropriate working areas. These documents are followed.		
6	SOPs, SOSs, or work instructions are complete (as required) detailing correct procedures for machine startup and shutdown, as well as proper adjustments of tooling. Procedures are followed.		
7	Setup and operating parameters (or limits) are documented and monitored during production runs. For example, setup piece checks are completed and periodic sample audits are conducted for critical dimensional requirements. Signoffs are required.		
8	Critical tooling (dies, molds, fixtures, etc.) are verified prior to use and maintained appropriately. A documented tooling PM program is deployed.		
9	Critical / special characteristics are measured throughout the process using appropriate, calibrated measuring equipment that is maintained in a documented metrology system. Records of these measurements are also retained.		
10	All employees have the authority and are expected to initiate line stoppage and/or take appropriate containment action when suspect defective material is identified.		
11	Adequate lighting conditions exist for all critical work areas, inspection areas, auditing stations, and aesthetic review areas (for example, color-review rooms) as required.		
12	Statistical Process Control (SPC) methods are employed on appropriate manufacturing processes to minimize the variability of critical product (CTQ) characteristics.		

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SECTION 6: CONTROL OF MEASURING AND TEST EQUIPMENT			
1	A documented and effective metrology system is deployed including; identification & location, calibration intervals, traceability, calibration method/equipment, visual confirmation, and adequately trained personnel.		
2	Gages, measurement tools, and test equipment are statistically evaluated (using gage repeatability & reproducibility studies) to determine stability, acceptability, and capability.		
3	Quality measurement and control equipment, including tools and fixtures used for inspection, are sufficient to assure conformance to requirements.		
4	A process is in place, with a clearly defined course of action, in the event that measuring and/or monitoring equipment is found to be suspect or out of calibration. Steps for proper consideration of process, equipment, and product affected is included in this process.		
SECTION 7: CONTROL OF NONCONFORMING PRODUCT			
1	Suspected non-conforming product is adequately identified to prevent further use and moved out of the normal process flow. Product identification of non-conforming material is adequate to ensure that it does not reach customer facilities.		
2	Suspected non-conforming product is reviewed by qualified associate(s) and validated for conformance to quality standards prior to re-introduction into the value stream.		
3	Formal customer (deviation) approval is required for any product that meets form, fit, and function requirements, but does not meet all documented specification requirements.		
4	Steps for dealing with non-conforming materials are established in documented procedures with examples of tags, forms, and reports.		
5	Adequate steps are taken to prevent recurrence of non-conformity.		
SECTION 8: CORRECTIVE AND PREVENTATIVE ACTION			
1	A formal corrective action system is deployed to ensure effective closure and follow-up of both customer and internal problems and complaints.		
2	An effective containment process is in place to protect the customer until root cause is determined and corrective/preventative action is implemented.		
3	The corrective action process includes evidence that closed-loop activities are taking place to validate the effectiveness of corrective action(s) in addressing the root cause(s) of a problem.		
4	Corrective actions are completed in a timely manner.		
5	When corrective and preventive measures are implemented, controls are verified and monitored as required to ensure that the desired results are achieved on a sustained basis.		
6	Permanent changes that result from corrective action(s) are recorded in work instructions, SOSs, SOPs, manufacturing and test processes, control plans, specifications, training documents, etc.		
7	The corrective and preventative action process is system based, not 'people' focused.		
SECTION 9: QUALITY MANUALS AND DOCUMENT CONTROL			
1	The supplier has a Quality Manual that is easily accessible to all employees.		
2	The supplier maintains a master list to avoid the use of invalid or obsolete documents.		
3	There is a system or process in place to train employees to follow SOPs, SOSs, or work instructions.		
4	The Quality Manual, SOPs, SOSs, work instructions, inspection & testing documents, specifications, etc. are maintained in a formal document control system that manages updating of documents and ensures that only the current revision of a controlled document is available to users.		
5	Document change procedures ensure that key users are informed of changes and their feedback is considered before changes are made.		
6	Process audits (i.e. LPAs) are deployed to verify compliance to SOPs, SOSs, or work instructions.		
SECTION 10: HANDLING, STORAGE, PACKAGING, & DELIVERY			
1	Work In Progress (WIP) is adequately identified, labeled, and stored.		
2	Packaging is adequate to withstand environmental extremes and prevent damage.		
3	Final finished packaging is labeled to ensure accurate selection and identification by warehouse employees and receiving personnel at the customer location.		
4	Product with limited shelf life has been indentified, documented, and is effectively managed.		
5	FIFO inventory management practices are used throughout the supplier's facility.		

	0	01/00/00
Audit Section	**Objective Evidence / Comments:** Complete for Scored Items in Sections 1-10	**Corrective Action Required?**

0	01/00/00
Other Documented Observations or Concerns:	**Corrective Action Required?**

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Audit Summary

Assessment Section	Supplier Self-Assessment Total Points		Natmo Audit Total Points		Total Available Points
1. Management Responsibility	0	0%	0	0%	28
2. Operational Focus - Delivering the Basics	0	0%	0	0%	36
3. Quality System	0	0%	0	0%	32
4. Purchasing	0	0%	0	0%	28
5. Process Controls and Inspection	0	0%	0	0%	48
6. Control of Measuring and Test Equipment	0	0%	0	0%	16
7. Control of Nonconforming Product	0	0%	0	0%	20
8. Corrective and Preventative Action	0	0%	0	0%	28
9. Quality Manuals and Document Control	0	0%	0	0%	24
10. Handling, Storage, Packaging, & Delivery	0	0%	0	0%	20
TOTAL SCORE	0	0%	0	0%	280

Audit Participants

Supplier Management Team

Department	Name	Position	Date
Quality (required)			
Operations (required)			

FBHS Management Team

Department	Name	Position	Date
Supply Quality (required)			

FBHS Final Approval of Supplier Assessment

Lead Assessor / Supplier Quality Engineer (required)

V.P / Director of Supply Quality (required)

- ☐ **Level 5: System Excellence (252 - 280)**
- ☐ **Level 4: System Maturity (196 - 251)**
- ☐ **Level 3: System Development (126 - 195)**
- ☐ **Level 2: System Awareness (70 - 125)**
- ☐ **Level 1: System Unfamiliarity (0 - 69)**

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