SUPPLIER MANUAL

CONTENTS

1.0 MYOTEK QUALITY EXPECTATIONS

Myotek is committed to producing products that satisfy and/or exceed Customer quality, delivery and cost requirements.

It is essential that Myotek has agreement and commitment from each Myotek Supplier for these expectations to be met. Only by adhering to these goals and striving together for continuous improvement can a positive, cost-effective relationship be maintained between Myotek and its Suppliers.

As a part of doing business with Myotek, Suppliers are required to:

Comply with specific requirements detailed in the Myotek Supplier Manual and the Myotek General Agreement.

Follow Myotek's requirements for reporting of restricted or reportable substances according to the End-of-Life (ELV) Directive.

Myotek and its Customers reserve the right to conduct on-site audits at the Supplier's and sub-supplier's premises to verify compliance with Myotek requirements. This allowance is described in the Myotek's Terms and Conditions of Purchase.

2.0 MANUAL REVISION/AMENDMENTS

DATE	SECTION	DETAIL OF REVISION	PAGE(S)
22/02/2017	All	First Release (Not distributed)	All
7/17/2018	All	Incorporate IATF/ First Article inspection / PPAP/ MAQMSR	All

3.0 QUALITY

3.1 Quality System and Document Retention Requirements

The Supplier bears the responsibility to develop and maintain a quality assurance system. The quality system will ensure that products are manufactured and shipped according to Myotek's quality, delivery and cost requirements.

Myotek Suppliers are required to be 3rd party registered to ISO 9001:2015 at a minimum and, if not already registered to IATF 16949, to continually work towards compliance and obtain registration no later than six (6) months after Supplier receives its first purchase order from Myotek.

For sub-tier supplier, at a minimum, the Supplier will require their sub-tier supplier to demonstrate compliance to the Minimum Automotive Quality Management System Requirements for sub-tier Suppliers (MAQMSR available through AIAG).

Document Retention: Unless stated otherwise, the following are Myotek's minimum requirements for document retention.

1. Production part approvals, tooling records (customer owned tooling) and APQP records shall be maintained until 1 year after production & service part supply ends.

2. Lot control records for materials, sub-components, manufacturing conditions, inspection results, change points, shipping records, etc. shall be maintained for a minimum of 15 years.

3.2 Product Quality

All product delivered to Myotek must be of 100% acceptable quality according to Myotek requirements. The Supplier is required to produce products which comply with appearance, form, fit, function and/or regulatory requirements as indicated on the Myotek part drawing(s) and Inspection Standard.

The Supplier is required to incorporate product requirements/tolerances and critical or special control characteristics into the manufacturing processes and reference them on the relevant PFMEA, control plan and operator instructions.

Any deviations to current product, process or quality requirements must be approved <u>prior</u> to the shipment of product, in accordance with Section 17.0 and Appendix I of this manual.

3.3 Product Liability/Reimbursement

(Refer also to the Myotek Terms & Conditions of Purchase)

The Supplier is responsible for all Supplier product rejects related to Supplier non-compliance with quality, packaging, labeling and delivery requirements. These include the following types of rejects:

a. Myotek Customer rejects
b. Warranty/field claim rejects
c. Myotek receiving inspection, in-process and/or assembly rejects

The Supplier is also responsible for reimbursement of "additional costs" incurred by Myotek related to Supplier product and/or delivery non-compliance. These "additional costs" include, but are not limited to, the following:

a. Additional testing/validation costs
b. Customer-specific charges
c. Disposal/replacement costs (Myotek assemblies)
d. Disposal/replacement costs (Supplier's product/material)
e. Manufacturer line down costs
f. Production over-time costs
g. Sorting costs (Including supervision of third party sorting)
h. Re-inspection/rework costs
i. Re-labeling costs
j. Transportation/expedite costs
k. Travel costs
l. Non-Conformance investigation, issuance & handling costs - $50 per hour with a minimum charge of 1 hour.

"Additional costs" related to each Quality Problem Report (QPR) issued are indicated on each Supplier Returns which is sent to the Supplier. Suppliers will be invoiced for these "additional costs" by Myotek Accounting.

3.4 In-Process/Final Inspection

The Supplier is required to perform adequate inspection/verification to ensure that required product quality conditions are being met. Mistake-proofing, automated inspection, 100% visual inspection and/or inspection sampling shall be implemented as indicated on the approved control plan. The methods used shall ensure that acceptable products are being produced and shipped in accordance with Myotek quality and delivery requirements.

3.5 Re-inspection/Rework - Third Party Sorting

Upon receipt of a Quality Problem Report (QPR), the Supplier shall immediately replace, re-inspect and/or rework existing inventory of the designated product (refer to Section 18.0). Unless otherwise agreed upon, the Supplier shall re-inspect and/or rework suspect nonconforming product at Myotek the same day the request is made. If the Supplier is unable to re-inspect and/or rework product at Myotek, a third party sorting firm may be used on the Supplier's behalf. The Supplier shall coordinate and supervise all activities performed by a third party sorting firm while at Myotek. The Supplier is required to pay the third-party sorting firm directly for all related charges.

4.0 PERFORMANCE

The Supplier is required to continue to meet and/or exceed Myotek Supplier performance requirements.

Failure to meet these requirements may result in the following actions being taken:

a. Controlled shipping
b. Third-party controlled shipping (inspection/sorting)
c. Suspension of quotations for new business
d. Reduction in current business with Myotek
e. Termination per Myotek General Requirements

4.1 Quality Performance

The Supplier is expected to meet or exceed the following quality performance levels, unless designated otherwise:

a. PPM (Parts per million) – Zero PPM's.
b. QPR (Quality Problem Report) - Receive no NC's.

4.2 Cost Performance

The Supplier is required to initiate value-added (VA) or value engineering (VE) activities to increase product value or reduce product costs, over the life of the product.

The Supplier is required to present continuous improvement (CI) and cost-reduction plans/results to the responsible Myotek Purchasing Representative on an annual basis.

4.3 Delivery Performance

The Supplier is required to provide 100% on-time delivery in accordance with Myotek order release requirements.

5.0 IMPROVEMENT/DEVELOPMENT

The Supplier shall continually develop and improve its quality systems based on Customer satisfaction levels and performance trends/goals.

5.1 Performance Tracking

The Supplier shall monitor, record and periodically report/analyze the following types of performance data:

a. Warranty/field claims
b. Customer complaints/returns
c. Customer disruptions
d. Delivery performance
e. Transportation expedite costs
f. Special status customer notifications
g. Others (as necessary)

5.2 Quality System Analysis/Review

The Supplier shall focus efforts on improving its quality systems that directly relate to customer satisfaction and company performance. Quality system reviews will focus on analyzing and improving methods/practices in the following areas:

a. Quality planning (new product development)
b. Mistake proofing
c. Tool development/capability
d. Preventive maintenance
e. Process control (process set-up and verification)
f. Inspection/test methods and equipment
g. Control of nonconforming product
h. Operator training
i. Corrective and preventive action

5.3 Continuous Improvement

In addition to corrective action activities, the Supplier needs to establish formal methods for continuous improvement. These methods will include the following types of activities:

a. Development of annual improvement targets and projects
b. Establishment of quality improvement teams
c. Monitoring/reporting of implementation status and actual results vs. targets
d. Revision/addition of activities based on performance results

Continuous improvement activities will result in increased product value, improved delivery and/or lower costs.

6.0 QUOTATION DEVELOPMENT

6.1 Cost Detail Records

The Supplier is required to detail all costs associated with producing a new product.
The following information/costs shall be <u>itemized</u> on each quotation submitted to Myotek:

a. SG&A information
b. Capacity information (cycle times, yield/scrap ratios, capacity hours, manpower/shift)
c. Assembly/sub-assembly costs
d. Initial process costs (molding, stamping, extruding, etc…)
e. Secondary process costs (painting, coating, curing, etc…)
f. Tooling costs (including tool size, material, # of cavities, etc…)
g. Jig, fixture and test stand costs (including quantity and type of each)
h. Material costs (including material coverage/usage per part)
i. Machine costs
j. Special testing or validation costs

k. Detailed list of Packaging Cost (box, dunnage, bags, pallets, labels, foam, skid, etc.).
l. Delivery costs (including delivery/payment terms)
m. Trial costs (if applicable)

Additionally, if the quote is contingent on new capital equipment or processes, this shall be noted on the quote documents.

7.0 NEW PRODUCT DEVELOPMENT

7.1 Initial Process Development/Capability

Prior to mass production, the Supplier is required to establish optimal process parameters and operating conditions. The Supplier is required to conduct necessary internal production trials until best obtainable dimensional, functional and appearance product levels have been obtained.

The Supplier shall perform an analysis/comparison of actual process set-up and performance compared to the final quotation. The following items will be determined prior to Customer pre-production trials.

a. Initial production yield
b. Material usage (type, quantity, price)
c. Manpower usage (number, shift(s))
d. Cycle times
e. Process and material flow
f. Process parameter conditions/ranges (optimum)
g. Part quality capability to drawing/standard requirements:
    1) Dimensional - key part drawing characteristics
    2) Appearance - optimal appearance level
    3) Functional - testing compliance
h. Packaging/labeling methods
i. Deviation from standard requirements (Appearance, dimensional and/or test)

7.2 Initial Process/Product Evaluation

During the development phase, the Supplier shall submit the First Article Inspection Report (MYO-PUR 7-1-2) within 3 days of every new or revision trial. This applies to all components and product assemblies.

During the pre-launch phase, the Supplier shall conduct an internal pre-production PDR run of 300 pieces or a 2hour run, whichever is less, to finalize initial process/part capability. The hourly output must meet the quoted weekly production requirements.

Unless otherwise specified, the following analysis shall be performed using parts from the trial:

a. Thirty (30) samples shall be randomly pulled for dimensional analysis of key drawing characteristics.

b. If destructive testing is required, an additional thirty (30) samples shall be pulled to conduct the appropriate reliability tests.
c. One (1) piece from each cavity from the same shot shall be randomly pulled for layout inspection of all drawing dimensions.

7.3 Initial Product Appearance Capability

All parts from the pre-production trial shall be 100% visually inspected to determine part appearance capability. The following information shall be recorded/analyzed:

a. Number run
b. Number rejected
c. Cavity # of rejected parts (if applicable)
d. Type/cause of rejects

Based on the impact of rejects to overall yield, the Supplier is required to implement process improvements/changes.

7.4 Initial Production Concerns

During the new product development process, accurate records shall be kept of all production trials and corresponding results. Any concerns regarding the following items shall be reported to responsible Senior Management at Supplier for assignment of appropriate actions:

a. Material problems and/or shortages
b. Equipment problems/delays
c. Processing/yield problems
d. Production bottlenecks and/or flow problems
e. Manpower problems and/or shortages
f. Part appearance or function nonconformance
g. Packaging/labeling problems

Any problems/concerns that may affect the Supplier's ability to meet Myotek pre-production or production order requirements shall be documented and forwarded to the appropriate Myotek Purchasing Representative immediately after being detected.

7.5 Internal Mass Production Review/Approval

Prior to the start of mass production, it is the Supplier's responsibility to audit/review all new product manufacturing processes to confirm that all requirements have been met.

Responsible Senior Management will conduct the final internal process review and approve/authorize mass production start-up. Final internal approval for mass production will not be given until all deficiencies are resolved and approval status is documented.

8.0 INITIAL PRODUCT TESTING/VALIDATION

The Supplier is required to ensure product compliance to applicable government, regulatory and Myotek customer standards. Product testing/validation requirements are specified on the Myotek part drawing(s), QA Part Function Requirements sheet and/or Inspection Standard.

8.1 Testing Facilities

The Supplier is required to have internal testing/validation capability or to use an independent laboratory to perform necessary product testing. Independent laboratory facilities used shall be accredited to ISO/IEC 17025 or national equivalent. A copy of the lab's certificate and scope shall be retained in Supplier's project file.

8.2 Test Planning

As a part of new product development activities, the Supplier is required to develop a formal test schedule indicating the planned completion date of all required product testing. Any delays or testing nonconformance's must be reported to the responsible Myotek Quality Representative immediately after being detected.

8.3 Reporting

For each test conducted, test results shall be recorded on a test report. The test report will include the following information at a minimum:

a. Supplier Name
b. Commercial Independent Laboratory (If used)
c. Part Number
d. Part Name
e. Test Standard
f. Description/Detail of Test Performed
g. Date Started/Completed
h. Lot #/Mfg. Date of Product Tested
i. Actual Test Results
j. Statement of Compliance/Noncompliance

Test reports shall be submitted to Myotek in accordance with Section 9.2 of this Manual.

9.0 INITIAL PRODUCT SUBMISSION/APPROVAL

The Supplier is required to receive written approval prior to the shipment of mass production product to Myotek. The Supplier shall receive an approved (temporary or full) *PSW* for each new product or change to the existing product. (Refer to latest AIAG PPAP manual for complete detail.)

To receive this approval, the Supplier shall submit documents, data and/or parts as indicated on the *PSW*.

The documents, data and parts shall be sent to the responsible Myotek Quality Representative at least 10 days after PDR / Run @ Rate has been completed with acceptance.

Note: If temporary approval is received, the Supplier must complete all open requirements until full approval is obtained.

9.1 Document Submission

Unless otherwise stated or indicated as not applicable (N/A), a copy of the following documents shall be submitted as part of each PPAP submission package:

a. *PSW*
   (Signed and dated)
b. Control Plan,
c. PFMEA
d. Inspection Standard(s)
e. Process Flow
f. Approved Packaging Specification
g. Standard Operating Condition Sheets (For parts molded on Myotek/Customer molds/tools)
h. Other documents as designated by the Myotek Quality Representative

Documents must be submitted in a white binder with dividers reflecting the sections on the *PSW Document.*

9.2 Data Submission

The Supplier is required to submit dimensional and functional test data for detailed requirements on the Myotek Part Drawing(s), QA Part Function Requirements sheet and/or Inspection Standard.

Unless otherwise stated or indicated as not applicable (N/A), a copy of the following data shall be submitted as part of each new product submission package:

a. Capability studies (30 pieces from each cavity; specified critical dimensions)
b. Layout report (One piece from each cavity; all drawing dimensions)
c. Product testing/validation results for each test performed
d. Material certifications (including those for materials received from Myotek)
e. Statistical data (yield/rejects) from the pre-production trial (300 piece or 8 hour run, whichever is less).

9.3 Product Submission

Unless otherwise stated or indicated as not applicable (N/A), thirty (30) samples/sets that comply with appearance, dimensional and functional requirements shall be submitted as part of each new product submission package.

Note: Layout inspection samples will be kept by the Supplier while the product is active.

9.4 Appearance Deviation Samples

In order to obtain appearance deviation approval, the Supplier is required to complete and submit a *Request for Deviation* for each type of appearance deviation, in accordance with Section 17.0 of this Manual.

10.0 MASS PRODUCTION SHIPMENTS

The Supplier is required to produce product according to approved processes and methods as indicated on the approved control plan.

10.1 Additional Inspection - Initial Mass Production Shipments (First 90 days or until Myotek criteria has been met)

The Supplier is required to set up an offline inspection plan for the first 90 days or until Myotek's criteria has been met on all shipments of product to Myotek. This inspection is in addition to the on-line (standard) operator inspection. The offline inspection plan is agreed upon in advance

11.0 PROCESS CONTROL

The Supplier is required to implement effective methods to ensure that production processes are operating or being carried out as required.

11.1 Mistake Proofing

Mistake proofing methods shall be used (where feasible) to control manufacturing process conditions that are critical to product appearance or function.

11.2 Set-up Verification

At the start of each shift, the Supplier is required to verify and record that each production process is set up according to established requirements. Set-up shall also be verified if there is a material changeover, a job change and/or a process/machine adjustment.

11.3 Machine Process Parameter Ranges

The Supplier is required to establish and document ranges for all machine process parameters critical to part appearance or function. Internal Quality and/or Engineering approval(s) by Myotek are required to operate outside of established process parameter ranges.

Whenever process parameter ranges are changed, verification of acceptable part quality shall be performed and recorded.

11.4 Process Control Documents

At a minimum, the Supplier is required to develop/maintain the following documents for each product:

a. Pre-Launch and Launch Control Plans. (Unless otherwise specified, the control plan will meet the requirements of the IATF 16949 Requirements.)
b. Inspection Standard(s)
c. Process Flow
d. *Packaging Specification*
e. Standard Condition Sheets (For parts molded on Myotek molds/tools)
f. A DFMEA (if design responsible) and a PFMEA

Refer to the *PSW Sheet* for additional documentation requirements.

11.5 Operator Instructions/Training

The Supplier is required to develop operator instructions that detail set up, operator, process, inspection and packaging/labeling requirements.
Operator instructions will include/detail the following information:

a. Part name and part number
b. Operation/activity name
c. Process/assembly instructions
d. Inspection/test instructions
e. Packaging/labeling instructions
f. Required tools/gages
g. Visual aids
h. Reaction plans to nonconforming conditions
i. Revision date(s) and approval(s)
j. Significant characteristic symbols for those operations that impact designated significant characteristics

The operator instructions shall be available for use at each work station. **All operator(s) shall be trained each time the instructions are changed. Records of operator training shall be maintained.**

11.6 Preventive Maintenance

The Supplier is required to perform preventive maintenance on machines/equipment according to an established schedule. Preventive maintenance activities and manufacturing downtime status will be reviewed on a periodic basis. Preventive maintenance frequencies and checks will be adjusted based on machine/equipment downtime and efficiency levels.

12.0 PACKAGING

The Supplier is required to design and develop packaging for all products shipped to Myotek, in accordance with specified requirements.

12.1 Packaging Approval

The Supplier shall complete and submit a *Packaging Specification* to the responsible Myotek Purchasing Representative. The Supplier shall submit samples as requested. After approval, the Supplier is required to ship product in accordance with the Packaging Specification unless otherwise instructed.

The Supplier shall reevaluate the packaging and make any necessary improvements whenever product is found to be damaged during transit. Prior to making any changes, however, the supplier must resubmit a Packaging Specification to the responsible Myotek Purchasing Representative detailing the proposed changes.

12.2 Packaging Materials

a. Packaging materials that minimize dirt, dust, static electricity and other contaminants must be used.
b. Foam wrap, plastic bags, dividers, etc. will be used only when needed to protect the product from being scratched and/or damaged during transit.
c. Loose-fill materials such as polystyrene peanuts or shredded paper are forbidden.
d. Boxes will be taped on top and bottom seams; no folding of flaps.
e. The Supplier shall have an approved back up packaging system when returnable containers are the primary packaging.

12.3 Packaging Size/Weight

a. No individual containers/boxes shall weigh more than 35 pounds (lb.).
b. Containers/boxes must not overhang the edge of the pallet.

12.4 Pallet Sizes

Pallet size must be approved for use by Myotek.

12.5 Securing Pallet/Product

a. Pallets of product that are shipped to Myotek are required to be secured with plastic banding.
b. Plastic wrap will be used instead of banding if detailed on the approved Packaging Specification.
c. The plastic wrap shall be wound around the product from the bottom of the pallet to the top of the boxes/containers, overlapping each layer of plastic.
d. Pallets of product that are double-stacked shall be plastic wrapped from the bottom of the first pallet to the top of the boxes/containers on the 2nd pallet.

e. Do not use metal or steel banding straps to secure the load.

12.6 Pallet/Product Stacking

a. Containers/boxes will be stacked so they do not damage product beneath them.
b. Pallets of product will be stacked so that lighter loads are on top of heavy loads and product beneath them is not damaged.
c. Pallets of product must be properly secured during transit.

13.0 LABELING

13.1 Barcode Label Requirements

The Supplier is required to identify all shipping units with barcode labels that can be scanned by Myotek Receiving sites. Barcode labels are required to meet Code 39 symbology and conform to the AIAG Bar Code Symbology Standard (AIAG - B1). The Supplier shall submit a sample label to the responsible Myotek Purchasing Representative during APQP launch. After approval, the Supplier is required to ship product using only the approved label.

Each label needs to contain the following minimum information:

a. PART NO. (P) (This is Myotek's specified #)
b. QUANTITY (Q)
c. SUPPLIER (V)
d. SERIAL (S)
e. DESCRIPTION
f. CODE (This is for color only, if specified by Myotek)
g. U/M (U)
h. PO# (K)
i. MFG DATE & SHIFT (OR OTHER LOT TRACEABILITY INFORMATION)
j. SHIP DATE
k. AUDITOR

If possible, the Supplier name will be placed on the bottom of the label.

13.2 Barcode Label Placement/Usage

a. Labels shall be placed on the upper corner of two adjacent sides of the box/container or as specified.
b. Labels may not be placed on the top of the box/container under any circumstances.
c. All exterior container labels shall be clearly visible from the outside of the pallet.
d. If interior bags, boxes, reels, etc. are used to break a larger lot into smaller lots, each interior bag or box shall be labeled with the PART NO. (P), QUANTITY (Q), and MFG DATE & SHIFT (OR OTHER LOT TRACEABILITY INFORMATION).

13.3 Packing Lists

a. For each shipment of product, there shall be one packing list unless otherwise stated on the pallet (e.g. Sample parts).
b. The packing list shall be placed on the shipment so as to be readily visible and accessible without having to tear down the shipment configuration.

14.0 ENGINEERING/PROCESS CHANGE CONTROL

14.1 Initial Change Approval

The Supplier is required to receive approval from the responsible Myotek Quality Representative before implementing any internal or external engineering or process change (See Appendix I for a list of PSW required changes). The Supplier shall submit an Engineering Change Notification to the responsible Myotek Purchasing Representative.

The Supplier is required to coordinate the following activities with the responsible Myotek Purchasing Representative:

a. Build-up of inventory to allow the change to be made
b. Die/tool preparation and transfer (If the change is not made at the Supplier)
c. Verification that the change was made correctly

If clarification of the submission requirements is needed, the Supplier shall contact the responsible Myotek Quality Representative.

14.2 Document Submission/Approval

After completion of an engineering or process change, the Supplier is required to receive written approval from the responsible Myotek Quality Representative before starting, or continuing with, mass production. To receive approval, the Supplier shall submit documents, data and/or parts as indicated on the PSW Sheet or as otherwise required by Myotek. Where the OEM has supplier product and process approval requirements, the Supplier shall follow those requirements too.

Upon Myotek approval, the Supplier shall receive a signed PSW Approval.

14.3 Product Identification & Segregation

Prior to the initial shipment of product after a change, the Supplier shall segregate inventory and, at Myotek's request, ship all pre-change product to Myotek. When Supplier ships post-change product, pre-change product cannot be shipped without written authorization by the responsible Myotek Quality Representative.

15.0 DIE/TOOL REPAIR CONTROL

Any problems/concerns that may affect the Supplier's ability to meet Myotek pre-production or production order requirements shall be documented and forwarded to the appropriate Myotek Purchasing Representative, immediately after being detected.

The Supplier is required to coordinate all major die/tool repairs with the responsible Myotek Purchasing Representative, including any repair that affects the tool surface. The Supplier shall send a Mold Repair/Improvement Notification to the responsible Myotek Purchasing Representative. Sample submission documents may also be required (Refer to Appendix I for guidelines). If sample submission is required or if you need further clarification, please contact the appropriate Myotek Quality Representative.

After the tool repair is completed, the Supplier is required to evaluate the repair by producing product and inspecting it for acceptable condition according to established standards. At a minimum, this includes dimensional checks, appearance checks and others as required with results forwarded to the Myotek Quality Representative.

If the die/tool is in need of additional repair, the Supplier shall contact the responsible Myotek Purchasing Representative for further direction.

For all Myotek dies/tools, the Supplier is required to internally document all minor and major repairs in the Myotek Single Tool Report and the tool tracker report and log. These records shall be available for review upon request.

15.1 Document Submission

The Supplier is required to submit documents as requested by the Myotek Purchasing Representative and/or Quality Representative prior to the first shipment of parts off the repaired tool unless prior agreements have been made.

15.2 Product Identification

For the first shipment after the repair is complete, a label stating "CHANGE" (with brief description) must be attached to each box next to the barcode label stating the reason.

16.0 RAW MATERIAL CONTROL

16.1 Material Verification/Storage

The Supplier is required to ensure that raw material is properly received, identified, stored and used in the production process. Raw material refers to all raw material and components used in the manufacturing process such as paints, chemicals, resins, adhesives, metal, etc.

The Supplier shall have a system in place for controlling raw material with shelf-life requirements and ensuring that expired material is not used.

16.2 Material Usage & Lot Traceability

The Supplier shall have a material rotation system in place that ensures material is used on a first-in first-out (FIFO) basis.

The Supplier shall have a lot traceability system in place so that finished product can be traced back to the raw material lot numbers used.

The Supplier shall not change raw material, raw material Suppliers or Supplier manufacturing locations without approval from the responsible Myotek Quality Representative (see Appendix I).

16.3 Return of Myotek Supplied Material Found to be Defective

Defective material received by the Supplier from Myotek, whether raw or molded, shall be handled as follows:

a. Verify that the material is in fact defective, using Inspection Standards, Limit Samples, etc.
b. Contact the appropriate Myotek Purchasing contact with part number, defective condition, etc.
c. Email to Myotek Purchasing Representative with details of suspect shipment.
d. Myotek Quality Control will contact the Supplier with the disposition of the defective stock and will arrange for any necessary sorting at the Supplier. Myotek QC will issue an RMA # to allow the return of the stock within three (3) working days. The Supplier must not dispose of or return the stock until contacted by Myotek QC.
e. Returned parts must include the original SRF, with RMA #, and be clearly labeled “Defective Material Return –RMA #XXXX”.

17.0 SUPPLIER PROCESS/PRODUCT DEVIATION APPROVAL

17.1 Deviation Approval

The Supplier is required to quarantine/hold any product that does not meet established standards for part appearance, dimension or function.

If the Supplier finds they have potentially shipped nonconforming product to Myotek, the Supplier must first place a call to the appropriate Myotek Quality Representative notifying them of the concern. Then the Deviation Approval process is to be followed.

Myotek will start any sort activity necessary with the understanding that the Supplier will be responsible for any costs incurred by Myotek for the sort activity.

In order to ship any product to Myotek beyond established standard levels, the Supplier must receive approval from the responsible Myotek Quality Representative. To receive this approval, the Supplier must complete and submit an Application for Deviation (PSW form).

In critical inventory/production situations, the Supplier must contact the responsible Myotek Purchasing Representative and notify them of the urgency of the situation.

17.2 Deviation Notification/Submission

The Application for Deviation (use PSW Form), along with three (3) marked samples of the deviation, shall be sent to the responsible Myotek Quality Representative. The Supplier shall fax/e-mail a copy of the Application for Deviation (#5) prior to the shipment of the deviation samples. If the deviation is approved, the Application for Deviation is signed and returned to the Supplier along with one of the deviation samples.

For the shipments of deviated parts, the Supplier is required to include a copy of the approved Application for Deviation with the packing list.

18.0 SUPPLIER CORRECTIVE ACTION

Upon notification of Supplier nonconforming product or improper delivery, the Supplier is required to take immediate action(s) to provide acceptable product to Myotek.

18.1 Notification/Corrective Action Reporting - Quality Problem(s)

Upon detection of defective Supplier product at Myotek or its Customers, the Myotek Quality Representative issues a Quality Problem Report (QPR) detailing the defect condition, inventory status and action(s) required.

Upon receipt of a QPR, the Supplier is required to complete the following items:

a. Sort/rework stock at Myotek (see Section 3.5).
b. Replace and/or certify Myotek inventory within 24 hours or sooner (depending on inventory and production status).
c. Send a Quality representative to review the defect condition at Myotek as requested by the Myotek Quality Representative.
d. Complete a detailed internal investigation to identify root cause(s) and necessary countermeasure activity.
e. Complete Corrective Action Reports as detailed below.
f. Certify all existing internal stock for the defect condition(s) and mark each box with a "Certified" label (see Appendix II).
g. 100% inspect the next three (3) production shipments for the defect condition(s) noted on the QPR and place the "Certified" label on each box.

For each Problem Report received, the Supplier is required to complete a PDCA.

The initial report (including items a - h listed below) is due within three (3) working days. The final report (including all items listed below) is due within ten (10) working days.

The Corrective Action Reports will be signed by the Supplier's Quality and Manufacturing Managers and then sent to the responsible Myotek Quality Representative.

Supplier Corrective Action Reports are required to contain the following (minimum) information:

a. Supplier name
b. Myotek part name and part number
c. Date opened and date closed
d. Initiator
e. PR number
f. Problem description (Details of actual defect condition, quantity found, type of defect, along with reasons why the condition was not detected.)
g. Temporary Countermeasures (Details of temporary actions such as sorting, re-inspecting, reworking etc… Plans for permanent actions such as machine/tool repair, process modifications, additional detection methods, etc…
h. Root causes (Details of actual or potential causes for the problem such as machine failure, processing error, detection failure, etc…)
i. Permanent Countermeasures (Details of permanent actions such as machine/tool repair, process modifications, additional detection methods, etc…Details will include date(s) of implementation)
j. Verification activities (Inspection, test or evaluation results (data) that indicate the defect condition has been eliminated; including date(s) verification was performed)
k. Recurrence prevention activities (Additional machine detection capability, error-proofing, improved inspection detection or improved process controls to prevent the defect condition from being produced again)
l. Verification and recurrence prevention activities for similar product lines

18.2 Notification/Corrective Action Reporting - Delivery Problem(s)

The responsible Myotek Purchasing Representative notifies the Supplier of delivery issue(s) either by issuing a Monthly Report Card or verbally (as required).

If deficient delivery status has been indicated, the Supplier is required to complete a PDCA and submit it to the responsible Myotek Purchasing Representative.

Corrective action is due within 10 days, unless otherwise agreed upon.

19.0 COMMUNICATION/DOCUMENTATION

The Supplier is required to record/document all correspondence with Myotek related to quality, delivery, cost and/or production issues.

After meeting at Myotek or the Supplier's facility, the Supplier shall issue a report to the Myotek Purchasing Representative detailing the following items (as applicable):

a. Supplier name
b. Meeting date
c. Meeting members
d. Meeting agenda/subject
e. Items discussed
f. Present status
g. Open items with completion dates and responsible persons

The Supplier is required to <u>immediately</u> notify the responsible Myotek Purchasing Representative, whenever there are discrepancies/problems regarding the following items:

a. On-time delivery
b. Die/tool condition or function
c. Production capacity
d. Packaging
e. Invoices/payment

Appendix I – PSW Required Changes

No.	Item	Explanation/Examples
1	Design Change	The part drawing changes, altering the physical structure or number of the part. A design change is done when a new part drawing or an M/I is issued. • New part design • Design change that affects the part • Design change that does not affect the part such as part name or part number
2	New Supplier	A supplier or sub-supplier, who has never produced the part or component, begins manufacturing the part for Myotek. • Addition of a new supplier or sub-supplier • Changing the supplier or sub-supplier • New delivery location • Change from in-house production to outside supplier (or vice versa) • Change in factory location
3	Material Change	The material(s) used to manufacture the part is changed • Change of material supplier or supplier manufacturing location • Material supplier changed from outside to self-supplied (or vice versa) • Change in material composition
4	Manufacturing Method Change	A process method, setting or condition used in manufacturing the part is changed or modified. This includes any change which effects the way the parts are produced as reflected in the PQCT, MQC, control plan, etc. This applies when the normal control range changes, not for routine adjustments. • Plating or coating condition change • Machining or cutting condition change • Process standards or setting method change • Stamping • Associate change on a critical process
5	Process Order Change	The manufacturing process order is changed or deviates from the PQCT, MQC, control plan, etc. • Change to the order of the process, or adding or deleting process steps • Change a temporary process to a permanent one (or vice versa) Note: If the PPAP process cannot be completed before parts are to be shipped (e.g. a welding robot breaks down and the process is done by hand) contact QC immediately. QC will provide instructions and requirements to suppliers in this situation.

Appendix I – IP (Initial Part) Required Changes (Continued)

No.	Item	Explanation/Examples
6	Machine Change	When the machine initially used to produce the parts during approval process has been changed or replaced by another machine. (Machine examples: stamping press, assembly line, injection molding, etc.) • Initial use of a new machine • Modification or major repair of a machine • Equipment relocation within the same plant
7	Jig/Tool Change	The primary or secondary tooling or jigs are changed, potentially affecting the quality, function, appearance, or reliability of the part. (Jig and tool examples: welding or assembly fixtures used in manufacturing process, cooling fixtures, sonic or heat welding, etc,) • Change in machining master for all parts • New or modified jigs
8	Die/Mold Change	A die or mold that is used in the manufacturing process is new or changed. • New or renewed die or mold • Revision or major repair of the die or mold
9	Inspection Method Change	The inspection method of the parts has changed, potentially resulting in either an improvement or changes in the part's quality performance. This may require a revision to the PQCT, MQC, control plan, etc. • New or modified inspection equipment • Measuring method change or measuring instrument type change
10	Packaging Change	The packaging of the part deviates from the initially approved method. The change could adversely affect the quality of the part or parts handling at Myotek. • Any change in packaging materials or containers
11	Sort	Only to be used as directed by Myotek Quality Department

Note: For clarification contact your Quality Representative.