ADVANEX AMERICAS, INC
5780 Cerritos Ave Cypress CA 90630 | 714-995-4519 | sales@advanexusa.com | www.advanexusa.com

SUPPLIER

QUALITY MANAGEMENT SYSTEM

MANUAL

Revision: A Date: November 1, 2017

Introduction to the Supplier Quality Management System Manual

Purpose and Scope

The purpose of this section is to introduce the Supplier Quality Assurance Manual (SQMSM), outline its goals, and explain the responsibilities in regards to the administration of the document itself.

This manual applies to all suppliers providing material or services to Advanex Americas, Inc. (ADVANEX).

Explanation

The goals of the SQMSM are as follows:

1. Promote ADVANEX supplier development through the use of quality improvements based upon ISO 9001:2015 and ISO/TS 16949:2009 technical requirements and to encourage certification to these quality management system standards.

2. Communicate to the supplier ADVANEX's expectations, common goals and minimum requirements to assure the quality of supplied material or services, including documentation requirements.

3. Communicate supplier awareness to the following points:

- Supplier contribution to product and service conformity
- Supplier contribution to product safety
- Supplier expectations pertaining to ethical behavior

4. Encourage open and free communication of ideas, information and notification of problems among suppliers in the spirit of teamwork and cooperation.

5. Develop an overall plan to assure a smooth production start-up at both ADVANEX and the supplier based on effective planning and communication.

6. Define the quality assurance (QA) procedures and documents suppliers must follow and use to assure application of an effective quality system that is based on continuous improvement, built-in quality, and quality problem prevention.

7. Improve the performance of ADVANEX suppliers through continuous process improvement and monitoring of supplier performance indicators.

Document Administration

1. ADVANEX

A. Update and ensure distribution of the SQMSM and its revisions to the supplier.
One manual will be provided to each manufacturing location.
B. Maintain a record of when and to whom the manual / revisions are sent, as well as, track the acknowledgement letter returned by the supplier.

C. Educate suppliers on application of SQMSM and its revisions.

D. Maintain control of the SQMSM master and its revisions. All manuals will contain a revision level and date specifying the revision level. Suppliers are issued the latest revision.

2. Supplier

A. Control the manual and revisions provided by ADVANEX.

B. Ensure distribution of copies to the appropriate persons and develop a document tracking method.

NOTE: Dissemination of this manual outside the supplier's organization is prohibited. However, requirements, activities or forms contained within may be shared with sub-suppliers.

C. Understand the appropriate application of this manual as a working tool to improve processes and build-in quality into production operations.

D. Assure all related departments are trained in regards to ADVANEX SQMSM requirements.

E. Unless otherwise notified, the manual (and any revision) becomes effective upon issuance to the supplier. All forms impacted by a revision must be used at new job start or when submitted for the first time.

F. If there are any questions concerning the administration of this manual, please contact:

Advanex Americas, Inc.
Attn: Quality Manager
Phone: 1-714-995-4519
Fax: 1-714-995-7294

G. In regards to SQMSM documentation (Forms) the supplier must use the format provided in this manual. However, the supplier may substitute non-ADVANEX forms if they do the following:

1) Negotiate and receive agreement for substitution from their quality contact at ADVANEX. This must be done on a form-by-form basis. The ADVANEX Quality Assurance Contact reserves the right to refuse any request to substitute forms.

2) The new format meets all requirements and contains all the information found in the ADVANEX form.

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SECTION I: DOCUMENTATION REQUIREMENTS

Purpose

To explain supplier's responsibilities pertaining to management and control of documents, including records, determined by Advanex Americas to be necessary to ensure the effectiveness and control of its processes.

Scope

This shall apply to all suppliers and support personnel acting on behalf of suppliers. Furthermore, requirements specified by an external body (regulatory or customer) will take precedence over applicable requirements.

Supplier Responsibilities

1. Supplier is responsible for ensuring that the documents and records related to their processes are controlled and up to date, in accordance with established quality procedures.

1.1 2. Controlled Documents are maintained to the extent that they affect conformance to regulatory, customer or industry requirements; or to the extent that they affect performance or effectiveness of the Advanex Americas QMS. These documents include, but may not be limited to, the following (per applicability):

- Policies Manual
- Standard Operating Procedures
- Charts, Diagrams and Checklists
- Internal Specifications
- Work Instructions
- Process Control Documentation (Control Plans, PFMEAs, Setup Instructions, etc.)
- Training Documentation (including video, pictures, and samples, as applicable)
- Customer Supplied Drawings and Specifications
- Industry Specifications and Standards
- Equipment Calibration and Maintenance Documents
- Blank Forms and other Templates

1.2 Records shall provide evidence of results achieved or activities performed, which include:

- Management Review Records

- Contract Review Records
- System Performance Records
- Document Change Requests
- Inspection Records
- Calibration Records / Gauge R&R Studies
- Calibration Certificates
- Nonconforming Product Reports
- Corrective Action / Preventive Action Reports
- Internal Audit Reports
- Training Records
- Re-validation of Special Processes, where appropriate
- Records of traceability, where appropriate

2. Supplier shall adhere to Advanex Americas Record Retention matrix requirements as specified in Appendix A. Furthermore, supplier shall communicate disposition of records when applicable.

SECTION II: SAFETY AND SECURITY

Purpose

To explain supplier's responsibilities regarding compliance with safety and security requirements when visiting ADVANEX.

Scope

This shall apply to all suppliers and support personnel acting on behalf of suppliers.

Supplier Responsibilities

1. Prior to visiting ADVANEX, the supplier should contact ADVANEX and inquire as to the specific safety and security requirements of the facility. Contact and numbers are as follows:

Advanex Americas, Inc.
Attn: Purchasing
Phone: 1-714-995-4519
Fax: 1-714-995-7294

2. Suppliers must follow all safety requirements presented to them by ADVANEX.

General requirements typically include:

A. It is the supplier's responsibility to assure that their personnel come equipped with the appropriate safety equipment and information.

1) The supplier may be required to **bring proof of insurance and worker's compensation documentation,** or confirm the applicable information is on file at ADVANEX prior to arriving (e.g. to perform onsite inspection), if applicable.

2) **Safety glasses with side shields** are required in the manufacturing areas. Safety glasses are not required in the office areas. ADVANEX may provide one if supplier representative does not have their own.

3) **Steel toe safety shoes** may be required for all personnel working in the manufacturing areas. Safety shoes are not required if supplier personnel are only touring ADVANEX facilities, however, closed toe shoes are required with one inch or lower heels. Open toed shoes and spike heels are not permitted in the manufacturing areas.

4) **Hearing protection** may be advised in certain areas of the manufacturing facility. An ADVANEX representative will provide supplier representatives with the appropriate type if the supplier does not bring any with them.

B. **Visiting personnel** are not permitted to tour the manufacturing facility unless accompanied by ADVANEX personnel for safety and security reasons.

C. While in the plant watch for vehicles, etc. **Be very careful.** Be sure to stop and yield the right of way to oncoming traffic before proceeding across all aisle ways and intersections. Visitors must remain in designated isles and walkways.

D. While in the plant visitors must stay in the yellow pathways.

E. In case of an emergency evacuation, visitors should follow the evacuation route of team members in the area where the visitor is working. After exiting the building the visitor should check in with their host ADVANEX member, so that an accurate head count can be taken to insure the safety of all ADVANEX employees and visitors.

F. Reporting Accidents/Injuries:

All accidents and injuries must be reported immediately to the ADVANEX representative or the Purchasing department indicated above. A written report describing the incident must be signed by the supplier's supervisor and submitted to the ADVANEX Purchasing department indicated above.

G. First-Aid:

1) Incidental first-aid (i.e. bandages) may be the responsibility of the supplier.

2) Emergency first-aid treatment will be provided for supplier personnel injured on site. Ambulance service for transportation to outside medical facilities will be made available at the supplier's expense.

H. Requirements for bringing in and taking out parts, tools, etc.:

1) Suppliers may bring in parts, tools, gages, etc., to the ADVANEX facility without any special paperwork. However, to take them out of the ADVANEX facility, they must be inventoried upon arrival, by the ADVANEX Production department. Having an itemized list to give to Production will facilitate entering and leaving the ADVANEX facility.

2) Suppliers may bring in chemicals as needed, but they must be pre- approved by ADVANEX and identified in accordance with ADVANEX requirements. The supplier must provide proper documentation to the Purchasing department as indicated above, as well as any other department specified by ADVANEX.

3) The supplier is responsible for ensuring compliance with applicable laws regarding the transportation, packaging, storage, handling and disposal of hazardous materials.

SECTION III: SUPPLIER APPROVAL AND PERFORMANCE

Purpose

To outline ADVANEX's methods for evaluating supplier performance and approving suppliers.

Scope

Applies to all ADVANEX material and service suppliers.

Initial Approval

The supplier is responsible for completing a Quality Survey and to provide the requested information for initial review and approval by ADVANEX Quality and Purchasing personnel.

On-site assessment by ADVANEX at supplier facility may be performed, as needed, prior to approval in order to verify information indicated on the Quality Survey.

Approval may be granted to the supplier based upon the following criteria:

Certification to a minimum of ISO 9001:2008 and/or
Satisfactorily completion of the Quality Survey of Supplier form # 7.4-5
75% of questions on survey answered 'Yes' with supporting documentation.

If supplier is ISO 9001:2008 or ISO/TS 16949:2009 registered, a copy of the certificate is required for supplier approval.

If supplier gains approval status, they will be placed on the Approved Supplier List (ASL) for a one-year period.

Disapproval of Supplier

ADVANEX may remove a supplier from our Approved Supplier List, as necessary.

Criteria for removal could be:

A trend in the unsatisfactory or untimely completion of corrective actions,
A trend of low Quality and/or Delivery ratings, or
Failure to maintain a minimum of ISO 9001:2008 certification.

Suppliers are notified when they are removed from ADVANEX's Approved Supplier List.

Evaluation of Supplier Performance

Supplier performance is monitored in the effort to determine and evaluate the continuous suitability of supplier to provide products or services to Advanex Americas, Inc. (ADVANEX).

The performance indicators used to evaluate the supplier performance are:

Rejections form supplier,

On-time delivery performance, and

Trends in the unsatisfactory or untimely completion of corrective actions.

A formal corrective action is sent to supplier when a rejection is detected on received material or serviced product in receiving. Also see Section V for Corrective Action procedure.

ADVANEX monitors supplier delivery performance through reviewing receiving reports and purchase order records, and comparing the promised delivery date with actual delivery date.

This data is maintained electronically and presented on Supplier Performance Report and analyzed quarterly by ADVANEX Quality and Production personnel to determine continued suitability of approved suppliers.

It is important for the supplier to make improvements in these performance areas (quality, delivery and corrective action/improvements), as ADVANEX's goal is to aid in the improvement of our suppliers and encourage quality management system effectiveness.

SECTION IV: CUSTOMER FOCUS

Purpose

To provide guidelines of satisfying customer (ADVANEX) needs and expectations by maintaining customer communication and utilizing a customer complaint management system.

Scope

Applies to all ADVANEX material and service suppliers.

Customer Representative

The supplier shall have a designated ‘Customer Representative’, who has the responsibility and authority to ensure customer (ADVANEX) satisfaction through taking necessary actions to improve or correct processes and identified performance concerns.

Customer Complaints

When a customer complaint is communicated to supplier, verbal or written, Customer Representative shall document the complaint in a suitable form (also see attached sample).

Customer (ADVANEX) complaint shall be addressed and followed up with the ADVANEX representative for correction.

A formal corrective action may be issued to supplier for documenting to ensure that the concern is addressed.

The supplier shall review Complaint data at specific intervals to determine how improvements can be made in the supplier’s processes. This review shall ensure that the processes involved are effective in meeting customer (ADVANEX) expectations and **resolving the issues**. If there are any changes in the process the supplier must notify A\Advanex immediately of such change.

SECTION V: NONCONFORMING PRODUCT

Purpose

To describe the guidelines used to control nonconforming product with the aim of preventing recurrence.

Scope

Applies to all ADVANEX material and service suppliers

Control of Nonconforming Product

The supplier shall established processes to control nonconforming product, which includes:

1. Dimensional problems derived per incurred process and established as failing applicable requirements per Advanex requirements

2. Contamination such as mix products, uneven surface finishes, and visual nonconformance that was previously established per process approval by Advanex (initial run/sample)

3. Where applicable, counterfeit parts, the supplier shall implement and control processes for the prevention of providing Advanex with counterfeit or suspect part. Furthermore, the supplier is to immediately communicate Advanex of unsatisfactory process findings. Satisfactory preventive requirements by the supplier can include the following (where applicable):

- Awareness and prevention of counterfeit parts (material)
- Monitoring program
- Traceability and control of authorized distributors
- Segregating and reporting suspect or detected counterfeit parts
- Verification and testing to detect counterfeit parts

Process Control Documentation

The supplier shall ensure that product which does not conform to product requirements and specifications is identified and controlled to **prevent its recurrence** and unintended use or delivery.

The supplier shall handle nonconforming product by one or more of the following ways:

by taking action to eliminate the detected nonconformity;
by authorizing its use, release or acceptance under concession by ADVANEX,

by taking action to preclude its original intended use or application.

The supplier shall maintain records of the nature of nonconformities and any subsequent actions taken, including concessions obtained by Advanex Americas, Inc. (ADVANEX).

When nonconforming product is corrected it may subject to re-verification to demonstrate conformity to the requirements by ADVANEX representative.

When nonconforming product is detected after delivery or use has started at Advanex Americas, Inc., the nonconforming product will be returned back to supplier. The supplier shall take action appropriate to the effects, or potential effects, of the nonconformity.

A Corrective Action may be sent to the supplier in the event that ADVANEX has detected nonconformity. Supplier shall complete the corrective action promptly and take appropriate action to improve or correct the process(es) involved that caused the condition.

SECTION VI: CORRECTIVE ACTION

Purpose

To describe the process and guidelines used to evaluate the need for actions to ensure that nonconformities, including customer (ADVANEX) complaints, do not recur.

Scope

Applies to all ADVANEX material and service suppliers.

Supplier Corrective Actions

Suppliers shall maintain a corrective action program. All corrective actions shall be implemented and documented utilizing ADVANEX prescribed Corrective Action form (attached).

Failure to promptly respond to a request for Corrective Action may result in negative Performance Evaluation ranking and possibly disapproval of supplier.

The corrective actions program shall address the following requirements, as appropriate:

reviewing nonconformities (including ADVANEX complaints),
determining the causes of nonconformities,
evaluating the need for action to ensure that nonconformities do not recur,
determining and implementing action needed,
records of the results of action taken, and
reviewing corrective action taken.

The following are guidelines for implementing Corrective Actions. Supplier may utilize their own process as long as the intent of the following steps are fulfilled:

Review and Evaluate Cited Discrepancy

Answer all of the following (5W & 2H) against the cited discrepancy:

What happened? Where did it happen?
To Whom did it happen? Why did it happen?
When did it happen?

How did it happen? To How Many did it happen?

Determine Any Necessary Interim Actions

If processes are out of control or provide an unacceptable output, halt process or modify process to provide acceptability.

Continuously verify process outcome to preclude or eliminate deficiency recurrence.

Continue this action until corrective action investigation determines cause and corrective action and is implemented.

Investigate and Determine Root Cause

Systematically review and eliminate process elements not applicable to the cited discrepancy by means of SPC, Brainstorming, Cause and Effect Diagrams, Flow Charts or any statistical tools necessary. Systematically evaluate the following:

- METHODS
- EQUIPMENT
- PEOPLE
- ENVIRONMENT
- MATERIALS

Identify and Categorize Cause

Determine if cause is "assignable", meaning that it can be identified and eliminated.

Determine if cause is "common", meaning that it is not inherent to the process, but can affect the performance.

Determine if cause is "special", meaning that it is unpredictable or random.

Consistency of categorizing causes of discrepancies will assist in adequately identifying recurrences and isolating root cause.

Investigate Cause Recurrences

Determine number of known occurrences. Evaluate recurrence timeframe and investigate any trend evidence showing previous ineffective corrective action(s).

Investigate and implement improved corrective action against previous one, re-instruct and follow-up.

Implement Corrective Action

Correct the deficiencies, such as rework, re-document, or re-train.

Remove any interim actions previously applied.

Document Corrective Action(s)

Document all cited discrepancies, root causes, and corrective actions.

Distribute findings and results of corrective actions to all cognizant departments or personnel.

Follow Up Effectiveness

Follow up with verification methods such as, process or internal audits, analysis of compiled data, or designated (scheduled) monitoring of process.

SECTION VII: TRAINING AND QUALIFICATION

Purpose

To specify the minimum supplier requirements in regards to training and qualification of team members.

Scope

Applies to ADVANEX material and service supplies who are ISO 9001:2008 and/or ISO/TS 16949:2009 registered.

Training and Qualification Requirements

The supplier shall effectively manage a comprehensive training program for all employees. Department training needs shall be identified through a multi- disciplined approach.

Individual needs shall be identified through an evaluation process that includes references to retained employee training records. An individual or a department should be designated to administer the training program.

The supplier is expected to continuously develop its employees' capabilities through various activities including on-the-job training (OJT), collective education, etc.

When training or awareness activities are conducted, the supplier shall evaluate the effectiveness of the action taken. Effectiveness should be documented appropriately.

Qualification criteria shall be established for all employees whose work affects product quality and supplier shall ensure that employees are qualified based upon that criterion.

The supplier should develop a method for documenting team members' progress and capability.

To improve performance and productivity of employees, the supplier should utilize empowerment and motivation programs to encourage and reward outstanding performance, as appropriate.

SECTION VIII: PROCESS IMPROVEMENTS

Purpose

To describe the process and guidelines used to monitor and measure continual improvement efforts.

Scope

Applies to ADVANEX material and service supplies who are ISO 9001:2000 and/or ISO/TS 16949:2002 registered.

Continual Improvement

The supplier shall define a process for strategic continual improvement of the organization in order to enhance its performance and customer (ADVANEX) satisfaction. The supplier should conduct continual improvement through either two methods: Breakthrough Projects and Small-step ongoing improvement.

Breakthrough projects should either lead to revision and improvement of existing processes or the implementation of new processes. An appropriate Management Representative should be responsible for managing breakthrough projects and ensuring internal communication is maintained with appropriate functions.

Breakthrough project phases may typically include:

Objectives and outlines of the improvement project,

Determining existing processes and realizing opportunities for change,

Planning of improvement to the process,

Implementation of the improvement,

Verification and Validation of the process improvement,

Evaluation of the results and lessons learned.

Tools such as timelines, progress charts, and agenda reports may be used to monitored project progress.

Appropriate supplier management representative should periodically update supplier top management regarding progress and any needed resources.

Small-step ongoing improvement activities may be carried out and monitored, as appropriate. These improvement activities may be random and performed by anyone in the supplier organization. Appropriate authority is obtained, when needed, to make small improvements in processes and are documented for follow up.

Continual Improvement activities or projects may be documented to describe the following:

Reason for the improvement (reactive or proactive),

Current situation of existing process (existing data),

Analysis of the existing situation or problem (Root cause),

Identification of possible solutions (Brainstorming),

Evaluation of affects, if the solution treated the root cause, or improvement was made,

Implementation and Standardization of the new solutions,

Evaluation of the effectiveness and efficiency of the process with the new improvement action completed.

This guideline provides a organized process for implementing continual improvements with the organization. Although other methods may be used, it is highly recommended by ADVANEX that the general intent of the guideline be followed.

SECTION IX: INFRASTRUCTURE

Purpose

To identify the Infrastructure and Work Environment needed to consistently meet manufacturing responsibilities, planned plant efficiency and delivery performance guarantees in order to ensure customer (ADVANEX) satisfaction.

Scope

Applies to ADVANEX material and service supplies who are ISO 9001:2000 and/or ISO/TS 16949:2002 registered.

Infrastructure

The supplier shall maintain the infrastructure needed to achieve conformity to product requirements and specifications. Supplier shall determine and reviews these needs through reviewing:

buildings, workspace and associated utilities,
process equipment. May include both hardware and software, and
supporting services such as transport and communications, and computers.

Plant, Facility and Equipment Planning

The supplier shall develop plant, facility and equipment plans, as applicable. The supplier should identify plant layouts in order to optimize material travel, manage handling effectively, identify value-added use of floor space and facilitate synchronous material flow, as applicable. Methods should be developed and implemented to evaluate and monitor the effectiveness of existing systems.

Lean Manufacturing principles are encouraged, as appropriate, to facilitate optimization of the plant, facilities and equipment.

Contingency Plans

The supplier should establish contingency plans in order to satisfy customer (ADVANEX) requirements in the event of an emergency such as utility interruptions, labor shortages, key equipment failure and field returns, as applicable.

Work Environment

The supplier shall review, determine and manage the work environment needed to achieve conformity to product requirements.

The following areas are identified for supplier review, as applicable, to ensure conformity to product requirements, as applicable:

Lighting
Water, coolants and oil mist
Cleanliness and Dust
Hazardous chemicals
Any damage to instruments including inspection devices and fixtures

Personnel Safety to Achieve Product Quality

The supplier shall ensure that employees can perform their duties in a safe working environment. Additionally, supplier should be committed to product safety to ensure both internal and external customers are safe from any potential risk. The means to minimize potential risk are addressed, especially in the design and development process, as applicable, and in manufacturing process activities.

SECTION X: CALIBRATION

Purpose

To provide a method that ensures that all monitoring and measuring devices used for product acceptance is maintained within acceptable tolerances.

Scope

Applies to ADVANEX material and service supplies who are ISO 9001:2000 and/or ISO/TS 16949:2002 registered.

Calibration

The supplier shall determine the monitoring and measurement to be undertaken and the devices needed to provide evidence of conformity of product to determined requirements.

The supplier shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall be:

calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,

adjusted or re-adjusted as necessary,

identified to enable the calibration status to be determined,

safeguarded from adjustments that would invalidate the measurement result,

protected from damage and deterioration during handling, maintenance and storage.

Additionally, supplier shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Supplier takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

Verification Records

The supplier shall ensure that records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee-owned and customer-owned equipment will include:

equipment identification, including the measurement standard against which the equipment is calibrated,

revisions following engineering changes,

any out-of-specification readings as received for calibration/verification,

an assessment of the impact of out-of-specification condition,

statements of conformity to specification after calibration/verification, and

notification to the customer if suspect product or material has been shipped

SECTION XI: MEASUREMENT SYSTEM ANALYSIS

Purpose

To describe the process and methods to assess the stability of the measurement system used by supplier.

Scope

Applies to ADVANEX material and service supplies who are ISO/TS 16949:2002 registered.

Measurement System Analysis (MSA)

The supplier shall conduct statistical studies to analyze the variation present in the results of each type of measuring and test equipment system.

This applies to measurement systems referenced in the control plan. The supplier shall adopt the following implementation methods for measurement system assessment, as applicable. Other analytical methods and acceptance criteria may be used as long as it fulfills the intent of the following requirements. Verification may be requested as part of the Production Part Approval Process required by ADVANEX (see section XIII).

MSA Implementation

The supplier shall determine, identify and assess the **key characteristics** to measure per **customer** (ADVANEX) and **industry standard** material or service **specifications**.

The devices used for measurement of ADVANEX products are assessed in three cases:

When there is a new device introduced for measuring ADVANEX products.

When there is a change in the characteristics of the device that warrants a new assessment (Gage R&R) such as a discovery of an out of tolerance condition, etc.

When there is a change in the environment in which the device is maintained and controlled that may affect the capability of the device.

When there is a new/revised product or service requested by ADVANEX.

The supplier shall assess whether environmental factors such as the temperature and humidity are significant in affecting the quality of the measurement. If assessment reveals it is not significant, MSA (Gage R&R) assessments may be performed anywhere suitable within the facility to undertake the assessment in an effective manner.

Assessments

"Repeatability" is determined, by identifying variation in measurement obtained with one measurement device when used repeatedly by one inspector while measuring the identical characteristics on the same part.

> The inspector, using the specified device (such as a caliper, micrometer, or optical comparator), shall take the subject part and measure its length 5 times in 3 different trials. Each measurement is documented on the appropriate inspection data form.

"Reproducibility" is determined, by identifying the variation in the average of the measurement made by different inspectors using the same measuring device when measuring the identical characteristics on the same part.

> 3 different inspectors, using the specified device (such as a caliper, micrometer, or optical comparator), shall take the subject part and measure its length 5 times in 3 different trials. The results are documented on the appropriate inspection data form.

Once all of the data is collected, the supplier shall input the data into a spreadsheet that calculates the ranges, averages and ultimately the Repeatability %, Reproducibility % and Gage R&R variation %.

If forms and spreadsheets are not available, it is the supplier's responsibility to request samples from ADVANEX to assist supplier.

Standards

In order to ensure the accuracy of the measurement systems, supplier shall only use devices traceable to national standards when performing MSA (Gage R&R) assessments.

The standards may be based upon NIST (National Institute of Standards Technology) or national equivalent. Other approved standards may be used upon Customer (ADVANEX) consent with written customer approval obtained.

Analysis & Acceptance

The supplier shall review and analyze the MSA (Gage R&R) data upon completion. The criteria used in this review are based upon the **percentage of the part tolerance** or the process variability that is consumed by measurement system variation. Acceptability is based upon the following variation:

> Under 10% error - Acceptable measurement system.

10% to 30% error - May be acceptable based upon importance of the application, cost of the device, cost of scrap, etc.

Over 30% - Considered not acceptable

If MSA (Gage R&R) variation % is over 30%, every effort shall be made to improve the measurement system. A Corrective Action may be generated if deemed appropriate to investigate the issue. A determination is made as to the cause of the significant variation (such as training, environment, calibration, etc) and the necessary action should be taken to improve measurement system.

At the conclusion of the assessment, and upon acceptance of the results, the MSA (Gage R&R) results shall be documented and a part of the PPAP documentation package to be submitted to ADVANEX, if required (also see section XIII).

SECTION XII: INVENTORY MANAGEMENT

Purpose

To describe the process and guidelines to improve and manage material inventories.

Scope

Applies to ADVANEX material supplies who are ISO/TS 16949:2002 registered.

Inventory Management

Stocked materials shall be properly segregated and identified in bins, racks, or shelves as befitting the physical characterization of the material.

Storage locations shall be secured and controlled as practical, to preclude unauthorized use of materials.

Supplier shall ensure that appropriate documentation is established prior to entering or drawing material from designated inventory areas.

An inventory management system shall be used to ensure that customer (ADVANEX) jobs that are shipped from inventory are done so as efficiently as possible.

First-in-first-out (FIFO) efforts should be utilized when appropriate.

The intent of this requirement is for optimization of turn over time and **timely stock rotation**. The guideline for maximum inventory turn over time should not exceed 6 months, or per customer (ADVANEX) request.

Inventory areas for material shall be assessed at minimum, annually, in order to detect deterioration of the material stored as well as to detect accuracy of inventory. This assessment is documented appropriately.

Storage and Inventory areas shall be maintained orderly and clean in order to prevent damage or deterioration of the material stored, pending use or delivery.

Lean Manufacturing techniques (such as Just-in-Time, Error Proofing, Visual Controls, etc) should be utilized, as appropriate, to improve the efficiency of production and materials flow.

SECTION XIII: INTERNAL AUDITS

Purpose

To provide a process and method for the assessment of the supplier's quality management system, production processes and manufactured products, as applicable.

Scope

Applies to ADVANEX material and service supplies who are ISO/TS 16949:2002 registered.

Quality Management System Audit

The supplier shall ensure that the quality management system is audited to verify compliance with ISO/TS 16949:2002 and any additional quality management system requirements.

Manufacturing Process Audit

The supplier shall ensure that each manufacturing process is audited to determine its effectiveness.

Product Audit

The supplier shall ensure that products at appropriate stages of production and delivery are audited to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labeling, at a defined frequency, as applicable.

Internal Audit Plans

The supplier shall ensure that internal audits cover all quality management related processes, activities and shifts, and are scheduled according to the annual plan. When internal/external nonconformities or customer (ADVANEX) complaints occur, the audit frequency shall be appropriately increased. Internal audit checklist should be developed and used for each audit.

Internal Auditor Qualification

The supplier shall ensure that internal auditors are qualified to audit the requirements of ISO/TS 16949:2002. ADVANEX may request documented evidence of qualification criteria and results, in the event that supplier has negative performance trends.

SECTION XIV: FMEA, CONTROL PLANS & PPAP

Purpose

To describe the minimums requirements of the Advanced Product and Quality Planning process for use by supplier.

Scope

Applies to ADVANEX material and service supplies who are ISO/TS 16949:2002 registered.

Exemption & Disclaimer

The supplier may only be required to conduct APQP and PPAP documentation when ADVANEX ha identified “Automotive Job” on the purchase order sent. Supplier should contact Purchasing at ADVANEX if clarification is needed.

The supplier may be waived of the requirements for APQP and PPAP upon request to ADVANEX. ADVANEX will evaluate the request and determine approval or rejection based upon the complexity and implications of the material or service procured.

It is the supplier’s responsible to determine the submission level requirements requested by ADVANEX.

Specific guidelines to the FMEA, APQP, PPAP & Control Plans may be found in the 5 core Automotive Manuals controlled by the AIAG (www.aiag.org) and Chrysler, Ford and General Motors.

Process Failure Mode Effects Analysis (P-FMEA)

As the initial steps in the planning process the following shall be taken by the supplier’s planning team to review and develop the PFMEA study.

Identify the application of the study on specific part number.
Identify the processes involved from Receiving to Shipping with a process number.
Brainstorm and define a list of potential failures of those processes and identify one or two primary failure modes.
Define the potential effects of those failure modes and determine severity rating and classification for that process.
Brainstorm and determine the possible causes of the identified potential failures.
Determine the occurrence rating for that process.
Define the current process control methods used to prevent the identified failure modes and decide upon a detection rating.

Perform study and analysis to validate the FMEA information.
Review results of the study to determine the Risk Priority Number (RPN). If the RPN number exceeds **60** (60 is ADVANEX's recommendation) then the section related to Recommended Actions, Responsibility & Target Completion Date, and Actions Taken is completed.
Verify that this corrective process reduces the RPN below 60.
Supplier's team reviews activities to identify additional Action Plans and opportunities for improvement.

PFMEA's shall be tracked, as it is a living document. Old revisions of the PFMEA's should be identified as 'Obsolete' and segregated as appropriate.

The Supplier shall develop for Pre-launch or Production runs:

Process Flow
Characteristic Worksheet, as appropriate
Process FMEA
Action Plan (if needed)
Control Plans

Control Plans

The Control Plan, depending upon customer (ADVANEX) request, is identified as Pre-launch or Production.

Pre-launch:

Supplier may develop pre-launch Control plans, for use in production as a means of identifying the controls for pre-production runs.

Typically, this Control Plan is developed for customer (ADVANEX) review and approval via PPAP, prior to initiating mass production Job Orders and Control Plans.

Production:

Production Control Plans may be developed for mass production runs. This Control Plan is initiated for ADVANEX Job Orders specified an "Automotive Job". This Control Plan accompanies the Job order throughout all stages of production.

Elements of the Control Plan:

The following elements are to be completed by supplier, as applicable, pending determination of the application of the Control Plan (Pre-launch, or Production):

General Data

Control plan number,
Issue date, and revision date, if any,
Customer (ADVANEX) information,
Supplier name/site,
Part number(s),
Part name/description,
Engineering change level,
Phase covered,
Key contact,
Part/process step number,
Process name/operation description.

Product Control

Product special characteristics,
Other characteristics for control,
Specifications/tolerances.

Process Control

Process characteristics and parameters,
Process-related special characteristics,
Machines, jigs, fixtures, tools for manufacturing.

Methods

Evaluation measurements techniques,
Error-proofing, as applicable,
Sample size and frequency,
Control methods.

Reaction Plan and Corrective Action

Reference to Reaction plan (Corrective action, as applicable

Production Part Approval Process (PPAP)

Once the Control Plan (Pre-launch) is developed, the appropriate documentation is sent to Production for a sample run (AIAG PPAP Guidelines specify a minimum of 300 pieces run) as applicable.

Inspection results, SPC data (typically on critical characteristics) and MSA (Gage R&R) should be generated for the PPAP documentation.

Once sample run is complete and all of the APQP documentation is collected, supplier may send prepare the Parts Submission Warrant as a coversheet for the PPAP.

The submission level is typically Level III, or per customer (ADVANEX) request.

Documentation is prepared for level III (typically) submission to the customer (ADVANEX) that includes:

Sample run (300 parts)
Material Certificate (If applicable)
Parts Submission Warrant
Drawings/specifications, as applicable
Inspection Results (when applicable)
Laboratory and Functional Results (when applicable)
Appearance Approval Report (when applicable)
Process capability results (when applicable)
Control Plans
MSA (Gage) studies
Process Flow and PFMEA

Receipt of ADVANEX approval is required to validate supplier production process.

Typically, once PPAP approval is obtained, the Control Plan indicating ‘Production’ should be released with the Job Order to complete the production run.

The supplier shall maintain all of the APQP, FMEA, Control Plan and PPAP files for a minimum of 5 years.

RECORD RETENTION MATRIX – APPENDIX A

Record	Retention Period		
	Commercial	**Auto**	**Aerospace**
Process Control Records	5 years	EOP + 20 years	7 years
Inspection Records	5 years	EOP + 20 years	7 years
Calibration/Gage R&R	5 years	EOP + 20 years	7 years
Process Design records	5 years	EOP + 20 years	7 years
Management Review and Data Analysis	5 years	EOP + 20 years	7 years
Sales Order Records	5 years	EOP + 20 years	7 years
Purchasing Records	5 years	EOP + 20 years	7 years
Training Records	5 years	EOP + 20 years	7 years
Personnel Records	5 years	EOP + 20 years	7 years
Internal/External Audits	5 years	EOP + 20 years	7 years
Corrective/Preventive Action	5 years	EOP + 20 years	7 years
Nonconformance	5 years	EOP + 20 years	7 years
Document Change Requests	5 years	EOP + 20 years	7 years
Shipping Records	5 years	EOP + 20 years	7 years

Supplier is to communicate disposition of records to Advanex Americas, Inc. where applicable