

**SUPPLIER QUALITY REQUIREMENTS MANUAL
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1.0 QUALITY POLICY /CUSTOMER SATISFACTION

Stryker Instruments Kalamazoo

Commitment to customer satisfaction must be the passion and responsibility of every individual at Stryker Instruments.

We must relentlessly seek to understand, serve, and respond to our customers!

We must understand the trust we earn when we enable our customers to succeed and the confidence they lose in us when we fail to meet their expectations.

**Customers Must Win... We Must Win
Otherwise, No Deal!**

Stryker Instruments Puerto Rico

**Quality if our Way of Life...
...Delight of our Customers.**

“We are a different kind of company. We are a family of talented associates, with no limits to our efforts in ensuring the satisfaction of our customers.

We are committed to maintain a positive work environment
Developing our capabilities and improving our quality of life.

Through our continuous improvement we will be at the cutting
Edge of technology, providing innovative quality products.

Our success will result in economic security and mutual benefit
To our **Customers, Associates, Community and
Stockholders.**

Stryker Puerto Rico,
Committed to Excellence.

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Stryker Instruments Ireland

“Our products reflect our people”

We are a dedicated team of talented individuals committed to excellence in manufacturing, product development and customer service.

We form lasting relationships by understanding, meeting and satisfying our Customer needs.

Our working environment is both flexible and dynamic.

We are committed to the concept of Personal Quality as the basis of our culture of excellence.

Our efforts will ensure continued prosperity for ourselves, our customers and the community.

We are proud of our products and the Trust that our customers place both in them and in us.

ACHIEVING EXCELLENCE

Product quality excellence is the result of excellence in materials, product design, manufacturing processes, and the performance of our people. We along with Our customers jointly contribute to the achievement of this objective through close cooperation and mutual effort.

Our suppliers play a critically important role in achieving quality excellence. They will be selected and developed to advance our effort at continuous quality improvement.

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2.0 INTRODUCTION

This Supplier Quality Requirement Manual is intended to provide valued Stryker Instruments suppliers and potential new suppliers with the basis for understanding the quality expectations of Stryker Instruments.

The manual establishes the minimum quality requirements for all suppliers of production materials and services, whether the products and services being furnished are provided by the supplier directly or are purchased from sub-suppliers for use in Stryker Instruments products.

These quality requirements are a supplement to and do not replace or alter other terms and conditions covered by purchase documents or contracts, specified warranty agreements and requirements of engineering drawings or specifications.

Stryker Instruments, a division of Stryker Corporation, provides the worldwide medical profession with high-quality, cost-effective technology—technology that restores people more rapidly to independent lives, reduces the time and complexity of surgery and recovery, decreases the need for revision surgery, shortens hospital stays, and helps hospitals operate more efficiently. Stryker Instruments is dedicated to building on this reputation through continuous improvement and unsurpassed customer satisfaction. You, as a member of our supply base, are essential to the continued achievement of this goal.

This Supplier Quality Requirements Manual represents a strategy for partnership in continued growth, cost reduction, productivity, market penetration and profitability through quality.

It is the goal of this Manual to develop a clearer picture of our requirement and to insure that both Stryker Instruments and our suppliers become committed to a continuous industry-pacing quality improvement program.

This manual was designed with the intent to address current industry standards and the International Organization for Standardization (ISO) Quality Systems Guidelines and 21 CFR Part 820 Quality System Regulation.

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3.0 PLANNING FOR QUALITY

3.1 EQUIPMENT CONTROL AND MAINTENANCE

All production equipment, including fixed machinery, jigs, fixtures, tooling, templates, patterns and gauges, should be proved for bias and precision prior to use. Special attention should be paid to computers used in controlling processes, and especially to the validation of commercial software.

Equipment should be appropriately stored and adequately protected between use, and verified or re-calibrated at appropriate intervals to ensure continuing process capability. The calibration plan must be documented and fully enforced

3.2 SUB-SUPPLIER CONTROL OF QUALITY

It is the responsibility of the supplier to insure all materials and parts used in the production of Stryker Instruments products conform to required quality standards. The supplier and sub-supplier should establish a system that will insure all materials are properly stored, segregated, handled and protected throughout the production process. The supplier will be responsible for assuring continuous quality improvement of materials, process supplies, parts, and services that are purchased from sub suppliers for use in the supplier's products and must establish and maintain procedures related to this responsibility.

3.3 SPECIAL PROCESSES

The supplier with products that involve special processes is responsible for compliance to the applicable specification whether the operation is performed within its facilities or by subcontractors. Examples of special processes include parlene coating, welding, heat-treating, plating, priming and painting and any other surface finishes that may apply.

Special process controls should include the monitoring of those parameters (temperatures, speed, etc.) that are applicable to that process. When performed in-plant, a review of this data should be routine for both control and improvement. When these processes are subcontracted, control plans should be developed with subcontracted sources that include regular submission of control data and test results, preferably in a statistical format. This process control information should be readily available for review by Stryker Instruments' Supplier Quality Assurance Representative.

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4.0 ASSURANCE OF PRODUCT & PROCESS QUALITY

These key points of a supplier's quality system are the areas that reflect the execution and control of either manufactured or procured product quality.

4.1 SOURCE INSPECTION

Stryker Instruments reserves the right to inspect, at the supplier's facility, any material or parts furnished to Stryker Instruments by purchase agreement. Stryker Instruments also reserves the right to perform periodic audits and appraisals of a supplier's quality system, inspection/testing operations, quality records and any information associated with the production of Stryker Instruments parts.

A Stryker Instruments Supplier Quality Assurance Representative may conduct source inspection. Source inspections and appraisals do not constitute or imply acceptance of a supplier's material, service, or parts. They do not relieve suppliers of the responsibility for maintaining quality system and inspection procedures to ensure acceptable product and service quality.

Stryker Instruments' normal receiving inspection sample size is based on ANSI/ASQC's Z1.4 1993 published C=0 plan. Therefore, any lot with at least one non-conforming part is subject to rejection. Stryker Instruments reserves the right to change the type of sampling plan employed and sample parameters as deemed necessary. Products failing Stryker Instruments' receiving or assembly inspections are subject to return to the subcontractor in accordance with the Non-Conformance Policy outlined in Section 4.3.

Stryker Instruments uses an attribute chart for selection of inspection equipment. These techniques are not intended to dictate subcontractor inspection, but rather to provide the subcontractor with insight into Stryker Instruments' standard techniques. Stryker Instruments reserves the right to change or disclose the inspection method as deemed appropriate.

Special inspection techniques or procedures are documented in Quality Inspection Procedures (QIP) for specific parts. If a QIP exists for the part, it will be referenced on the print.

4.2 DESIGN/PROCESS CHANGE CONTROL

In the event a supplier wishes to make significant changes to any stock and/or proprietary part supplied under a Stryker Instruments part number, the supplier **must**

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notify Stryker Instruments Purchasing. If the change is acceptable, the Buyer should submit the change to Stryker Instruments Engineering for concurrence and updating of the related Stryker Instruments document.

Written authorization must be obtained from Stryker Instruments Purchasing prior to incorporating any design or process changes on any product or component part supplied to Stryker Instruments. It is the supplier's responsibility to notify Stryker Instruments of any process change that affects Stryker Instruments designed parts. Stryker Instruments will determine if a first article sample inspection or validation is required. Shipments incorporating such changes may not be made on those parts where Stryker Instruments has design control until a first article sample inspection has been performed and approved by Stryker Instruments.

Control of manufacturing processes in every supplier tier is crucial. Minor changes in processes can cause extreme harm in the finished products and should be reviewed by Stryker Instruments for approval. In the event a process is changed without notification to Stryker the supplier will be held liable.

The supplier must complete all verifications and tests necessary to ensure that products continue to meet Stryker Instruments specifications. The supplier must provide documentation on any change to cost, planning and appropriate proof of good reliability.

4.3 NONCONFORMING MATERIAL

If the sample(s) from a lot of supplier's material or parts are rejected, Stryker Instruments reserves the right to reject the entire lot.

Every component is individually evaluated during the assembly process at Stryker Instruments and at any point a component may be rejected. A Material Review Board (MRB) evaluates non-conforming components identified in the assembly area. The MRB generally consisting of a Buyer, Quality Assurance Engineer and Manufacturing Engineer will determine if the component deficiency is attributable to the subcontractor and should be returned for repair, replacement, or evaluation. Any questions regarding returned defective material should be addressed to the appropriate buyer.

In the event of a rejection, Stryker Instruments issues a Defective Material Report (DMR/NCR/RTV form) to the appropriate supplier. This rejection notice requires the supplier to provide a written corrective action and preventive action plan.

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Nonconforming material found at Stryker Instruments is subject to several possible dispositions, dependent on the nature of the nonconformance and supplier:

- Supplier to rework and/or sort at Stryker Instruments facility or mutual site at supplier's expense
- To rework and/or sort at Stryker Instruments facility at supplier's expense
- Scrap at facility at supplier's expense
- Return to supplier at supplier's expense
- Use with a Stryker Instruments deviation (approved by appropriate Stryker Instruments Engineering Group).

A supplier must immediately notify the Stryker Instruments Quality Department and the appropriate buyer if it is discovered that defective material may have been shipped. Stryker reserves the right to charge a \$75 handling charge for materials that are defective.

Reference Documents:

13fm401 Subcontractor Defective Material Report (Instruments/Ireland)

NCR Form/ RTV Form (Puerto Rico)

4.4 TOOLING CONTROL

The following guidelines are in effect for suppliers that use Stryker Instruments proprietary tooling:

All tooling purchased by Stryker Instruments will remain the property of Stryker Instruments. Maintenance and repair of tooling is the responsibility of the supplier unless otherwise negotiated. Major repairs to tooling are the responsibility of Stryker. Approval must be obtained before any major maintenance is completed.

Suppliers are to advise Stryker Instruments Purchasing in advance when the condition of tooling will not allow the production of a part in conformance to established quality requirements. This should provide adequate time to rework or repair tooling and assure continuity of supply without the need for deviation from the specifications. This should be accompanied by a capability study that identifies the capability, or lack of capability, of the current tool.

All Stryker Instruments tools should be permanently identified with Stryker Instruments tool numbers.

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Upon request the supplier will submit a report, which includes the following:

- Description of available tooling.
- Condition of tools (cost of rework, if required).
- Date tooling was last used.
- Revision level to which tool was made.
- Insurance coverage of Stryker Instruments property (tools).
- Tooling location if not at supplier plant.

All tooling and/or equipment used in the manufacture of products purchased by Stryker Instruments should be maintained in a condition which will assure conforming parts will be produced and expected tool life will be achieved.

The supplier should maintain formal procedures addressing tool handling, storage, preventive maintenance and documentation.

Tooling and checking fixture changes should be documented and traceable.

4.5 CALIBRATION/MAINTENANCE OF GAUGES, PROCESS INSTRUMENTATION, AND TEST EQUIPMENT

All inspection measuring, process instrumentation, and test equipment, including production tools and fixtures used as a medium of inspection, must be inspected and calibrated at established intervals. The equipment's function, service conditions, use and maintenance, and recognized industry standards determine the frequency of calibration.

Calibration should be performed under controlled conditions of temperature; cleanliness and humidity based on the type of product provided. Service conditions should be similarly controlled to ensure accuracy of measurement.

Supplier's measuring and test equipment should be calibrated by either the supplier or a commercial facility in accordance with recognized measurement standards, i.e., the National Institute of Standards and Technology.

Reports or data sheets certifying the date and accuracy of each instrument should support calibration performed by a commercial facility and/or in-plant. These reports must be maintained on file by the supplier and made available for review by Stryker Instruments 's Supplier Quality Assurance Representatives.

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4.6 STRYKER INSTRUMENTS SUPPLIED MATERIAL (if applicable)

The supplier should establish and maintain procedures for verification; storage and maintenance of purchaser supplied product provided for incorporation into the supplier's product. Any such product that is lost damaged or is otherwise unsuitable for use should be recorded and reported to the purchaser.

NOTE: Verification by the supplier does not absolve the purchaser of the responsibility to provide acceptable product. Methods for implementing this requirement are the same as those Stryker Instruments is requiring for the primary supplier.

Product that is supplied to a subcontractor may be done in one of two ways. Stryker will issue parts to the supplier and, the supplier will be debited the cost of the product. The component cost should then be included in the finished product cost and billed to Stryker Instruments. If the component is a reoccurring item supplied by Stryker, the subcontractor should place an order with Stryker using a SUP order type so the components supplied will be picked and shipped to the customer based on need date. The subcontractor will then be invoiced for the product with a net 30 days payment term.

4.7 HANDLING, PACKAGING AND SHIPPING CONTROL

If applicable, parts may be required to be packaging in accordance with an ES Engineering specification. If no ES exists the following guidelines apply.

The handling of materials requires proper planning, control and documented system for incoming materials, materials in process and finished goods; this applies not only during delivery, but also up to the time of being put into use.

The supplier must ensure that products, when complete, are rust and corrosion free and packaged in such a manner as to provide adequate protection for expected or specified shipping and storage conditions.

The supplier must maintain a system that ensures adequate control of the quality of the packaging and shipping phase. The contents of each container must be clearly marked and identified on the outside in accordance with the requirement of Stryker Instruments.

Handling and Storage- The method of handling and storage of materials should provide for the correct pallets, containers, conveyors and vehicles to prevent damage due to

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vibration, shock, abrasion, corrosion, temperature or any other conditions occurring during handling and storage including specified levels of cleanliness. These handling and storage procedures are subject to approval by Stryker Instruments. Items in storage should be checked periodically to detect possible deterioration.

Identification- The marking and labeling of materials should be legible, durable and in accordance with the specifications. Identification should remain intact from the time of initial receipt to delivery to the final destination. Marking should be adequate to identify a particular product in the event that a recall or special inspection becomes necessary. If Bar codes are used the labels should be in accordance with Stryker Instruments "Bar Coded Shipping/Parts Label Specification" available through Stryker Instruments Purchasing.

Each package sent to Stryker Instruments should include the following information on the packing slip:

- Subcontractor Name
- Stryker Instruments purchase order number
- Stryker part number
- Quantity shipped
- For blanket parts the release of the purchase order
- If the product is reworked please indicate with DMR purchase order number
- I Supply includes the packing slip number
- Puerto Rico Only- certificate of compliance

*Component received after 3:30 may not be received in until the following business day.

Packaging- the methods of cleaning and preserving, and the details of packing, including moisture elimination, cushioning, blocking and crating, should be specified in written instructions either on the print or the purchase order.

Delivery- Items with limited shelf life or requiring special protection during transport or storage should be identified, and procedures should be maintained to ensure that deteriorated items are not put into use. Provision for protection of the quality of product is important during all phases of delivery.

4.8 PRODUCT REQUIREMENTS

Raw Materials- Stryker Instruments requires that the subcontractor retain certification records of all material used in manufacturing of components. As a verification check,

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Stryker Instruments reserves the right to request certifications to verify material by way of in-house or independent laboratory tests. Additional process requirements (i.e. hardness, passivity, sterility, etc.) may also be specified and subject to verification. Certification records must be maintained and available for review for the expected life of the finished device, but in no case less than two years.

Dimensional Requirements- Subcontractors are required to manufacture product in accordance with print specifications. Inspection systems to assure part to print conformance are required and are the sole responsibility of the subcontractor. When the component or assembly is being manufactured for the first time, first article samples may be requested and must be approved by Stryker Instruments either prior to the shipment of production runs or with the first production release as specified by the buyer. All efforts should be made to utilize the same inspection equipment.

Gaging - Standard gaging is the sole responsibility of the subcontractor (i.e. calipers, micrometers, thread gages, optical comparator, etc.). Responsibility/requirements for custom gaging must be addressed with the buyer during the initial purchase order negotiations. Stryker Instruments-owned gages and tooling used by the subcontractor must be used only for Stryker parts, labeled with an identification number if designated by the buyer, and maintained as agreed upon in the purchase order for the gage or tool. A photograph of the tool or gage may be required for verification purposes. If the Stryker-owned tool requires repair or replacement, the subcontractor should contact the appropriate buyer. Calibration should be scheduled and maintained by the supplier.

Visual Requirements- The physical appearance of a product is very important in the medical industry. External parts must have a consistent finish and be free of blemishes. Sample blocks displaying Stryker Instruments' blasting specification are available upon request and may be obtained by contacting your buyer. Other visual aids (sample parts, finish blocks, paint samples, ES specifications etc.) may be provided on subjective visual characteristics. Quality Assurance will address any other questions regarding finish.

Products submitted to Stryker Instruments for acceptance must be provided clean and free of dirt and manufacturing fluids. (ES may be applicable) Product submitted dirty will be rejected and returned to the subcontractor for cleaning.

Product packaging is the responsibility of the subcontractor unless otherwise specified by Stryker Instruments. Corrosion protection for parts should be addressed on an individual basis with the appropriate buyer. Where a product is static sensitive, it is the subcontractor's responsibility to package the product with the appropriate static

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protective packaging. Where possible parts should be packaged in quantities per our request. Products damaged in the shipping phase of delivery will be returned to the subcontractor for repair or replacement at the subcontractor's expense.

Product Liability - In all cases, Stryker Instruments will hold contracted subcontractors liable for product conformance to specification. Non-conforming product, which is the result of subcontracted/third party involvement, is the responsibility of the subcontractor under contract to Stryker Instruments

4.9 PART CERTIFICATION/DOCK TO STOCK

In order for product to be certified which would allow it to come directly to stock each supplier has to pass an audit, which is geared toward traceability and quality records. After a supplier is certified each part will be reviewed on an individual basis and if process control is demonstrated that part may be certified. Stryker reserves the right to decertify product if necessary. The certification audit is required annually.

Reference Documents:

10fm007 Stryker Instruments Supplier Audit Form

4.10 ELECTRONIC FILE TRANSFER

Approved communication methods include e-mail, fast fax, I supply and the traditional phone and fax. Documents that need signatures will still need to be faxed, as we have not yet implemented electronic signatures.

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5.0 SUPPLIER MANAGEMENT

5.1 SUPPLIER MANAGEMENT MEETINGS

Supplier management meetings will be conducted with those suppliers that most directly affect overall supplier performance. Topics of supplier management will cover performance trends, including quality and any open corrective actions, cost reduction opportunities and other issues that may be affecting performance. Often during supplier management meetings the unit-manufacturing engineer or quality engineer will attend to support. Often it is required to communicate with the engineer in the units to resolve engineering issues and going straight to the engineer is acceptable. Please do not negotiate price, delivery or requirements of purchase orders with anyone other than the buyer. In general the buyer or vendor management team (PR) in the unit should be the main point of contact for all issues.

5.2 SUBCONTRACTOR AUDITS

Prior to the placement of new business, a supplier survey will be conducted to determine if proposed or existing suppliers are capable of producing products that consistently meet the expectation and specifications of Stryker Instruments.

A Stryker Instruments Audit Team will be formed and may contain representatives from the following departments, Materials, Quality, Manufacturing, and Regulatory. The purchasing department will be the chairperson of the team and will be responsible for supplier contacts and arrangements.

In determining which companies are qualified Stryker Instruments will be considering quality, timeliness, business reputation, productive capabilities, financial stability, engineering skill and competitive pricing. The subcontractor assessment form will be used during the audit of the facility. An “acceptable” rating is the minimum requirement for new business.

Prior to the assessment Stryker Instruments may request the supplier submit their quality manual and a financial statement and or Dun & Bradstreet Number. The assessment will be sent to the supplier and based on any findings the subcontractor may submit written response with a corrective action plan and time frame for completion.

Reference Documents:

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- 06fm012 General Phone Assessment
- 06fm013 Phone Assessment Machining
- 06sm015 PC Board Supplier Phone Assessment
- 06fm016 Plastics/Clean room Molding Phone Assessments
- 06FM017 On Site Assessment

5.3 SUBCONTRACTOR PERFORMANCE AND RATING SYSTEM

To aid in the subcontractor selection and retention, a rating system is used to manage our subcontractors. A rating will be given to a subcontractor based on their historical performance.

Instruments/Ireland: Performance evaluated every 6 months
Subcontractors will be classified into one of five categories: A, B, C, X or N.

- A Supplier- 6 mths perf > 94.9%
- B Supplier- 6 mths perf 92.5 to 94.9%
- C Supplier- <92.4%
- N Supplier- new supplier without 6 mths of history
- X Supplier- Obsolete Supplier

Monthly Performance Calculations

- Quality 55%
- On time 40 %
- Quantity 5 %

Puerto Rico: Performance evaluated every 3 months
Subcontractors will be classified into one of the four categories.

- A Supplier- 3 mths perf > 94.9%
- B Supplier- 3 mths perf 92.5 to 94.9%
- C Supplier- <92.4%
- X Supplier- New Supplier

Monthly Performance Calculations

- Quality 50%
- On time 37.5 %
- Quantity 12.5 %

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5.4 PURCHASE ORDER

Purchase orders from Stryker Instruments come in a few different formats. We utilize a standard purchase order form with standard delivery dates, quantities and terms and conditions. A blanket purchase order may be used to purchase materials up to a year with a rolling twelve month forecast. (Consult Blanket PO guidelines) The last method of a purchase order consists of vendor management inventory. A web-based system is used to indicate inventory levels and is based on replenishing stock and keeping inventory in between the min and max, which were set with the supplier. Terms and conditions are applicable to all forms of purchase orders.

Reference Documents:
06fm009 Purchase Order

5.5 BLANKET PURCHASE ORDER SYSTEM

Stryker utilizes a blanket purchase order system, which is based on a yearly forecast. Stryker will commit to purchase six months worth of product based on a rolling forecast. The system works off of a reorder point and will trigger a release to the subcontractor. The optimal inventory level will be set with the supplier and it is recommended that only parts that have excellent quality history and stable demand be put onto this program. Blanket PO guideline explain the necessary requirements for blanket PO.

5.6 I SUPPLY®

I supply® is our web based inventory management system that is utilized in conjunction with blanket orders and supply of product. I supply® allows the individual users (subcontractors, Stryker division, international subs) to see inventory levels and manage their inventory to their discretion. A minimum and maximum inventory level are determined and the user has complete control over maintaining the agreed upon level of inventory.

5.7 RAW MATERIAL ORDERING BOARD (KANBAN) PUERTO RICO

Raw material ordering board is Kanban replenishment system that is used in conjunction with blanket orders in supply orders. Supplier will replenish when they receive an empty Kanban notification from Stryker.

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6.0 QUALITY DOCUMENTATION AND RECORD RETENTION

Quality Documentation- The subcontractors quality system should require that sufficient documentation be available to follow the achievement of the required product quality and the effective operation of the quality system. All documentation should be legible, dated (including revision dates), clean, readily identifiable and maintained in an orderly manner. Data forms may be paper or electronic.

In addition, the quality system should provide a method for removing and/or disposing of documentation used in the manufacture of products when that documentation has become out-of-date.

The following are examples of the types of documents requiring control:

- Drawings
- Work Instructions
- Specifications
- Operation Sheets
- Blueprints
- Quality Manual
- Inspection Instructions
- Operational Procedures
- Test Procedures
- Quality Assurance Procedures
- Assembly Procedures

Quality Records- The system should require that sufficient records be maintained to demonstrate achievement of the required quality and verify effective operation of the quality system.

The following are examples of the types of quality records requiring control:

- Inspection Reports
- Audit Reports
- Test Data
- Material Review Reports
- Qualification Reports
- Calibration Data
- Validation Reports
- Quality Cost Report

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Quality records should be retained, for a specified period, in such a manner as to be retrievable for analysis in order to identify quality trends and the need for, and effectiveness of, corrective action.

Stryker Instruments recommends that quality records be retained for a minimum of 5 years. Quality records on parts and materials affecting Stryker Instruments 's ability to meet government mandated standards, i.e., Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and other legislative type records should be kept a minimum of seven (7) years.

While in storage, quality records should be protected from damage, loss and deterioration due to environmental conditions.

6.1 FIRST ARTICLE REPORT PROCEDURE

Stryker Instruments requires its suppliers to submit a first article sample on most components to ensure acceptable process results. No production parts are to be shipped until first article sample approval is obtained.

Initial production sample approval is required under the following conditions:

- Upon initial production of a part.
- A new supplier for an existing part.
- A significant change in a supplier's process (example: new or revised tooling; process method change; moved production location; new plant or subcontractor). In this instance, the supplier must notify Stryker Instruments Purchasing of the change and obtain the necessary approval and sample report forms.
- An engineering revision to an existing part. (FAR in this case is at the discretion of the buyer)

The supplier should certify that the samples conform to all drawing and related specifications. The supplier should also certify that the samples are representative of the quality that the supplier will manufacture on a continuing production basis. Actual inspection and test data results with comparison to drawing/specification required values must be included.

If tooling involves duplicate fixtures or multiple cavity molds, dies, etc., samples from each of these operations are required. Any layout lines or reference marks used to perform the layout inspection must be left on the submitted samples.

The Stryker Instruments purchase order for first article samples requires the supplier to notify Stryker Instruments Supplier Quality Assurance when a sample is ready for verification. Samples, at the discretion of Stryker Instruments Supplier Quality Assurance, may either be audited by a Stryker Instruments Supplier Quality Assurance Representative at the supplier's plant or be shipped to a Stryker Instruments receiving location for validation of the supplier's results.

Samples that are to be forwarded to a designated Stryker Instruments receiving location or specified individual for validation must be shipped in a separate container addressed to the "Receiving Inspection Department" and clearly marked as "First Article." The required completed forms must be included with the samples. Validation of initial production samples by Stryker Instruments will not take place without the properly completed forms accompanying the sample. Stryker Instruments FAR forms can be used as well as an acceptable equivalent.

Suppliers are encouraged to visit Stryker Instruments facilities to audit the storage, handling, installation and testing of the production material provided by the supplier. The supplier must be satisfied or, if not, provide written comments requesting corrective action to be taken to insure that the material provided is being efficiently and correctly utilized by Stryker Instruments. Recommendations and suggestions for improvement are requested. Arrangements for the supplier visitation should be made through Stryker Instruments Purchasing.

Reference Documents:
06fm004 FAR Report

6.2 *FAST FAX AGREEMENT*

Stryker utilizes an automatic faxing system when sending out new orders. The fax will be a copy of the purchase order with the part numbers, PO number delivery requirements etc. The fast fax agreement is a controlled form that needs to be signed by all suppliers in order to utilize the fast fax system. This agreement contains the same terms and conditions that are located on our standard Purchase Order form.

Reference Documents:
06fm040 Fast Fax Agreement

6.3 *ENGINEERING CHANGE ORDERS*

This form alerts the subcontractor that Stryker Instruments has approved a permanent blueprint change or serves as a notification of an accepted deviation. The following information will be furnished: part number, part description, ECO/Deviation number and

new revision level. Please make special note to the disposition section of the ECO. This section will indicate whether the stock in process should be scrapped or if the change is a running change and parts in production or in a stocking program are acceptable. Rev control is very critical on all components, labels and literature.

A copy of the ECO or deviation and blueprint will be attached. A written acknowledgement is to be completed and submitted to the appropriate buyer within two weeks. Upon receipt of the ECO notification, the attached blueprints will not always have the approved changes incorporated on the parts. This print may be the old revision level and should be used only as a reference for specification not changed by the ECO. Purchasing is responsible for assuring this notification form is provided and acknowledged by the subcontractor and will forward an updated print (new revision level) to the subcontractor when available. ECO's/Deviation may be forwarded to the supplier via e-mail. In this case receipt of the e-mail constitutes as notification. All Stryker prints will have revision level, which starts at rev none and moves through the alphabet. An ECO is not required if the prints are not officially released for production and are in new product development.

Reference Documents:

05fm016 Engineering Change Order Form

6.4 DEBIT MEMO PROCESS (if applicable)

A debit memo is completed and issued by Stryker Instruments accounts payable when product is being returned to the subcontractor. The memo will reference part number, quantity, handling fee (if applicable), DMR number and DMR purchase order number. It is imperative that the subcontractor reissues an invoice for any parts returned to Stryker Instruments unless otherwise specified by the buyer. Credit memos are not necessary from the supplier when product is being returned.

6.5 MATERIAL CERTIFICATIONS

Material certifications are required for some components or finished goods and will be specified on the print. If a certification is required please include the following criteria:

- Passivated components require passivation certification
- Sterilized components require sterilization certification
- Raw Material requires material certification
- Electrolyzed components require electrolyzing certification
- Anodized components require anodized certification
- Plastic molded part requires material certification per ES 450.

Please include on the certification part number, quantity of parts and purchase order number. Certification paperwork must accompany the parts in the shipping container. Additional certification may be required upon request by Stryker Instruments. (Puerto Rico components require certification of compliance)

6.6 *INVOICES*

Invoices must be sent to Stryker Instruments, attention accounts payable after the delivery of the product. To assure prompt payment please include the following information: invoice date, Stryker Instruments purchase order number, Stryker part number, part description, quantity shipped, Shipping method, shipping ID/packing list number and the buyers name. If the part is a blanket order part please include the release number along with the purchase order number.

7.0 NEW PRODUCT PROCESS

Stryker Instruments invests heavily in new products and they are a critical aspect of our business each year. During product development there will be a materials representative that will be responsible for the quoting, supplier selection and procurement of materials. In order to protect design and development each supplier will be asked to sign confidentiality agreements before any prints are reviewed. Which include non disclosure agreements. It is common for Stryker to host a print review with selected suppliers to discuss form, fit function of the part, manufacturability, quality inspection, cost drivers and other design input. It is very common to work directly with the design engineers during new products but please make sure to communicate with the purchasing resource on the project.

There may be many different prototype drawings that are used while the design is in process. A print is official when it has all signatures in the title block of the print. All prototype (non released) prints should be marked to indicate status and typically they have numeric codes to indicate revision changes. Prior to production a First Article Report (FAR) may be required. It is critical to verify proto-type revisions with the new product team before production.

Reference Documents:

Reference documents are listed at the end individual sections in the manual. If you would like a copy of any of the documents listed please contact your purchasing contact.