

Supplier

quality guidebook

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Key supplier expectations:

Follow all general requirements and expectations discussed in this section.

This guidebook is arranged in the approximate order in which you will encounter activities.

Work with your Stryker representative to complete approval requirements.

Stryker partner functions: Procurement, Global Supplier Quality, New Product Introduction Quality, Advanced Operations

Establish solid process controls and maintain them throughout the product lifecycle. Complete Production Part Approval Process to qualify parts.

Stryker partner functions: Site Quality, New Product Introduction Quality, Advanced Operations, Research and Development

Establish and maintain an effective quality system meeting the expectations as outlined in this section. Conduct all notifications and approvals as required per your agreements with Stryker.

Stryker partner functions: Site Quality, New Product Introduction Quality, Global Supplier Quality, Advanced Operations, Manufacturing Engineering

Provide products or services that meet all specifications and agreements. Actively engage to implement improvements.

Stryker partner functions: Global Supplier Quality, Site Quality

Introduction:

Guidebook purpose and navigation

We are dedicated to developing and maintaining partnerships with our suppliers that enable us to sustain the highest level of reliability, quality and value.

Mission

**Together with our customers,
we are driven
to make healthcare better.**

Values

Integrity
We do what's right

Accountability
We do what we say

People
We grow talent

Performance
We deliver

Stryker is one of the world's leading medical technology companies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in Medical and Surgical, Neurotechnology, Orthopaedics and Spine that help improve patient and hospital outcomes.

At Stryker, quality is first in everything we do. Our focus on quality continues through our manufacturing and sourcing processes. Making a quality product starts with quality materials. We believe that fostering strong partnerships with our suppliers, with a shared focus on quality, delivers the best results.

This guidebook is intended to serve as a helpful resource and provide you, our supplier partners, with an overview of our quality requirements and expectations.

This guidebook is intended to be used for guidance only and does not take precedence in the event of any conflicts with agreements, drawings or specifications.

Introduction:

Quality policy

At Stryker, quality is first in everything we do. We are driven to make healthcare better for our customers by providing innovative products and services that meet regulatory requirements through our effective quality system.

Aligning closely with our mission and values, we define quality at our organization through this policy. To remain a leader in the medical technology industry, a company must have a passion for product quality and reliability. We are committed to meeting and exceeding global regulatory standards. We stand behind our products and address issues if they arise.

We hold our suppliers to the same standards. We will work closely together with you to continually improve the quality of our products.

Together, we make healthcare better.



Introduction:

Supplier Code of Conduct

Stryker is committed to conducting our affairs ethically and lawfully, and we expect that businesses we associate with will do the same.

Accordingly, we strive to select suppliers that share our commitment to honesty, integrity, accountability and corporate responsibility. We understand, while our suppliers are independent entities, their business practices and actions may impact us and our reputation.

Please review our Supplier Code of Conduct, available at stryker.com/potermis, which is intended to establish expectations for you and your employees, agents and subcontractors. In addition to any specific obligations under your agreements with us, we expect you to adhere to the Supplier Code of Conduct.



Introduction:

Purchase Order terms

Purchase Order (PO) terms and conditions are available at stryker.com/poterms and are required to be followed by all suppliers; provided, however, if a supplier and Stryker execute a Master Supply Agreement (MSA), the terms and conditions in such MSA govern the relationship between the supplier and Stryker, as well as prevail over Purchase Order terms and conditions.

Training

Stryker will share applicable specifications with our suppliers upon release or in the event of changes. It is the responsibility of the supplier to ensure all related specifications and requirements are transferred to their Quality Management System (QMS) and that personnel are trained to those specifications and requirements.

Stryker may periodically offer training to our suppliers. Examples of training topics include problem solving techniques, process controls and part qualification.



Supplier approval:

Approval process

Supplier approval is an essential element of our commitment to provide the highest quality products and services to our customers. Each supplier must be approved before being added to our Approved Supplier List (ASL). All suppliers impacting our product, process or quality system are categorized according to the type of products or services supplied, as follows:

- **Contract Manufacturer (CM):** manufactures a finished medical device (or an accessory to a finished device) to Stryker's specifications
- **Original Equipment Manufacturer (OEM):** provides a finished medical device (or an accessory to a finished device) where the supplier owns the Design History File or other equivalent product design ownership responsibilities
- **Component Supplier:** provides a "component" that becomes part of a finished medical device (or an accessory to a device)
- **Service Provider:** provides an outside routed process to a component, accessory to a finished medical device, finished device, chemical intermediate or pharmaceutical product
- **Contractor:** provides miscellaneous products and/or services based on either a specific need or a contractual agreement
- **Consultant:** provides expert or professional advice or opinions based on their technical knowledge and expertise
- **Manufacturing Material Supplier (MMS):** provides an item or substance used in or used to facilitate the manufacturing process of a medical device

Supplier approval requirements

Supplier approval requirements are dependent on a supplier's categorization and the level of risk (critical, major or minor) that the supplied product or service has on the patient.

Approval requirements may include the following:

- Supplier evaluation: initial assessment of supplier's business and capabilities
- [Change Control Agreement](#)
- [Quality Agreement](#)
- [Supplier audit](#)
- Provision of certifications and registrations, such as ISO certificates or FDA registration

Supplier approval: Change Control Agreement

To ensure the quality of products is maintained, change control is essential. Suppliers may be requested to enter into a Change Control Agreement with Stryker, agreeing that any changes proposed by suppliers or sub-suppliers meeting criteria listed in the agreement are submitted to Stryker in writing to sosicr@stryker.com. Items requiring approval include, but are not limited to, any changes to design, material, process, manufacturing location, equipment, sub-suppliers, systems, testing methods or certification of existing QMS. Refer to your Change Control Agreement for details.

Failure to obtain Stryker's written approval on the Supplier Initiated Change Request (SICR) form prior to change implementation results in a non-conformance against the supplier. Additionally, if product with unapproved changes is delivered to Stryker, Stryker reserves the right to reject and return such products at the supplier's expense.

You are expected to incorporate the terms of the agreement into processes and training programs to ensure consistent compliance with agreed terms. If you are concerned you may be unable to comply with any aspect of your Change Control Agreement, work with your Stryker representative to resolve the concerns prior to approval of the agreement.

Refer to the [Supplier Initiated Change Request](#) section for further detail on processing of changes.



Supplier approval: Quality Agreement

Quality Agreements define the quality management system requirements for the products and services purchased by Stryker from the supplier. The Quality Agreement is intended to ensure that the product and any other affected Stryker products, will be safe, effective and in compliance with applicable product and regulatory requirements.

Once the need for a Quality Agreement is determined, it is expected that you will work with Stryker to put the agreement in place. You are expected to complete the initial review of the agreement within the requested timeline. During the agreement process, supplier is to ensure the quality management system requirements for the product and communication channels are understood and clarification is requested as needed.

Stryker takes a global approach in which the Quality Agreement applies to all Stryker sites purchasing product from the supplier. The agreement will also specifically include and apply to all supplier manufacturing locations approved by Stryker.

The Quality Agreement commences upon the effective date and applies to all products or services provided by the supplier to Stryker. The agreement remains in effect as long as the supplier manufactures and/or supplies products to Stryker; however, any section which has a document retention or survival requirement will survive the termination for the specified time period. The agreement will be updated as needed to address, for example, changes in products, supplier manufacturing locations, quality management system requirements and/or other quality or regulatory areas.

The Quality Agreement is an early step in the relationship between Stryker and a supplier. Upon commencing the agreement, the communication pathways between the parties are expected to remain open and active as per the terms documented in the agreement. The supplier is expected to incorporate the terms of the agreement into processes and training programs to ensure consistent compliance with agreed terms.

Supplier approval:

Supplier audit

Stryker performs supplier audits to ensure compliance to quality, regulatory and Stryker-specific requirements. A supplier audit can be triggered for supplier approval, supplier re-evaluation or for-cause based on performance.

To ensure an audit goes smoothly, the supplier is expected to allocate time to the following:

- Align on scheduling, planning and preparation with the Stryker Auditor via discussion prior to the audit
- Allow Stryker to review the QMS, processes, records and facility, and ensure Subject Matter Expert (SME) availability to explain processes
- Follow up on non-conformances, as described below

After completion of the audit, an Audit Summary Report will be provided to you, which will include documentation of any non-conformances. You are expected to address any non-conformances within the timelines communicated in the Audit Summary Report and by your Stryker Auditor. When working to address non-conformances, take into account the considerations detailed in the [Supplier Corrective Action Request](#) section.



Qualification and process controls: Production Part Approval Process

The Production Part Approval Process (PPAP) collects objective evidence demonstrating that all specified requirements are clearly understood by the supplier and that the supplier's production processes have the capability to consistently meet all specifications.

Critical characteristics (part features and process specifications) should be established by Stryker and included in the PPAP workbook. These are referred to as Critical Quality Attributes (CQA).

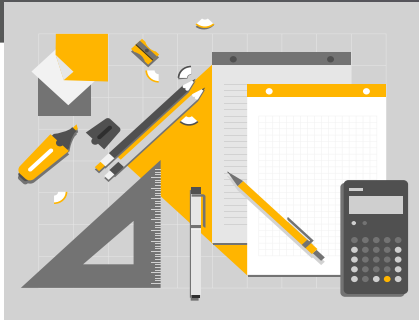
Stryker will notify you when a PPAP is required, such as for new production parts and when product or process changes are made to existing parts. Required deliverables vary dependent on the part being qualified. Stryker encourages early engagement in the PPAP process to allow for discussion on items such as process capabilities, supplier qualification process, timelines and PPAP tracking activities. You will be provided with a PPAP Workbook that communicates the expected deliverables for each part being qualified. Please review requirements to ensure understanding before beginning work and request clarification as needed from the PPAP originator.

Establishing solid risk-based process controls and maintaining them for the entire duration of the product lifecycle is an expectation for all suppliers. The tools described on the subsequent pages should be used not only during PPAP, but on an ongoing basis, to achieve positive quality outcomes.



Qualification and process controls:

Process controls expectations



1. Process Flow Diagram
2. Control Plan
3. Process Failure Mode Effects Analysis
4. First Article Inspection
5. Measurement Systems Analysis
6. Process capability
7. Validation

1. Process Flow Diagram

The Process Flow Diagram (PFD) is a type of flowchart that documents the relationship between manufacturing steps within a production facility. All manufacturing steps should be included to show material movement. This includes, when applicable, the process to send product to outside processing or through a validated rework loop, as well as its movement back through inspection. A process flow is usually the first step in creating a Process Failure Mode Effects Analysis (PFMEA) and a Control Plan. It is important to ensure that process steps are aligned on all three documents.

2. Control Plan

The Control Plan is a written description of actions required at each phase of the production process to ensure that all process outputs will be in a state of control. The Control Plan includes receiving, in-process and out-going requirements, as well as those conducted periodically (not conducted for every batch). Control Plans should provide safeguards that make sure the manufacturing process is adequately managed to achieve the desired product output.

It is expected that at a minimum, a Control Plan:

- Identifies each critical feature and defines the control measures to ensure the risks identified in the PFMEA are mitigated
- Identifies the measuring system that will be used and the frequency of the inspection
- Includes steps to be taken in the event a feature exceeds specification boundaries
- Has process steps aligning with those listed on Process Flow Diagram and PFMEA

Qualification and process controls:

Process controls expectations



Severity



Occurrence



Detection

3. Process Failure Mode Effects Analysis

A Process Failure Mode Effects Analysis (PFMEA) is a structured analytical tool to identify and evaluate potential failures within manufacturing or assembly processes. The PFMEA identifies the potential failure modes associated with processes and ensures that those potential failure modes are mitigated by preventive and/or control activities.

A PFMEA evaluates each process step and identifies potential failure modes, and then assigns ratings for severity (impact of issue should it occur), occurrence (likelihood of issue to occur) and detection (ability of your process to detect the issue should it occur). Controls should be implemented to reduce risks to meet the risk acceptability criteria.

PFMEAs should contain each step of the process and note where Critical Quality Attributes are produced. Where appropriate, PFMEAs can reference out to standardized PFMEAs for general processes such as material movement. The process steps in the PFMEA should align to those listed in the Process Flow Diagram and Control Plan.

The PFMEA is intended to be a living document and should be reviewed regularly and updated as new failure modes are identified, as well as with appropriate occurrence ratings based on failures that have occurred.

Qualification and process controls:

Process controls expectations

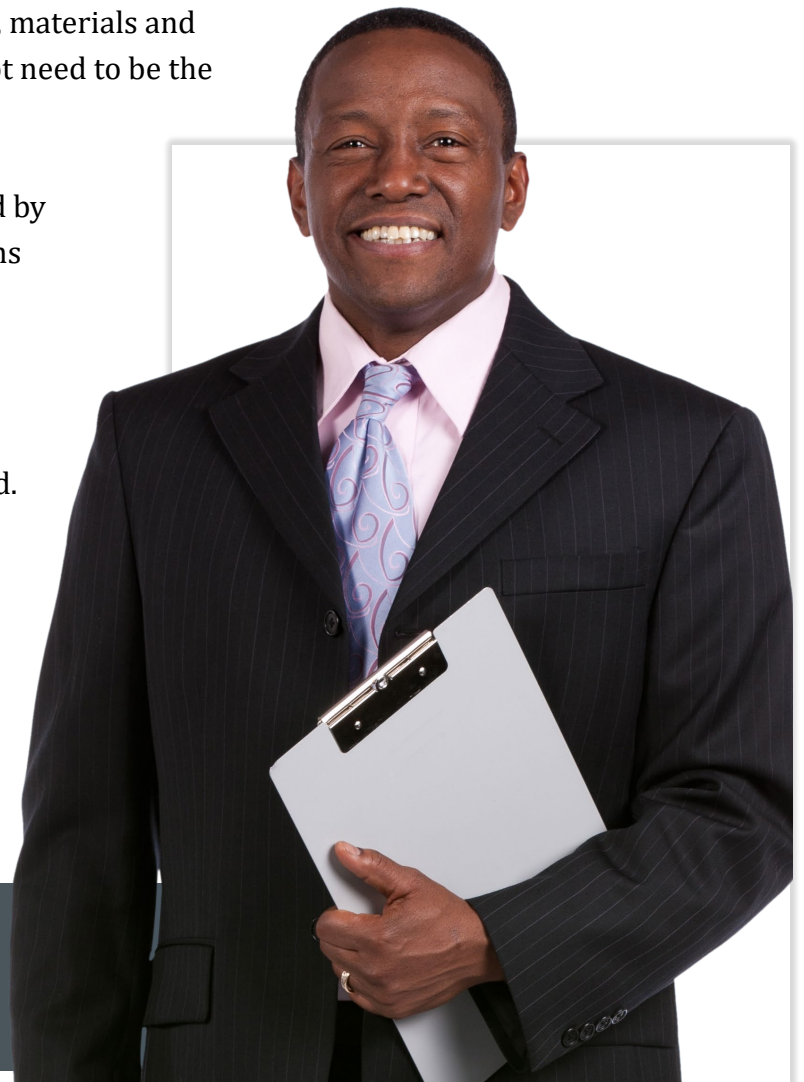
4. First Article Inspection

As part of the PPAP, a First Article Inspection (FAI) will be conducted. FAI is a formal method of providing verification that parts are produced to specification for a given manufacturing process. The method consists of measuring properties of initial sample items against specification.

First article parts need to be production-representative. This includes use of production-representative Operators, equipment, gauging, materials and manufacturing line. The inspected parts do not need to be the “first” produced.

An agreed-upon number of parts are inspected by both the supplier and Stryker for all dimensions and critical notes listed on the drawing/ specification. Document inspection results in the PPAP workbook. Care should be taken to ensure parts are tagged and labeled appropriately to be sent to Stryker, if requested.

If a drawing includes dimensions that cannot be inspected at final, in-process dimensions should be inspected. Communicate with Stryker when there are concerns over the ability to inspect product.



Qualification and process controls:

Process controls expectations

5. Measurement System Analysis

Measurement System Analysis (MSA) is a method to assess inspection and test methods used to measure critical part features to ensure repeatability and reproducibility.

The test method includes the process, method and equipment used for measurement. The resolution of a gage needs to meet the accuracy and precision required to measure the part feature repeatably and reproducibly. An MSA involves multiple Operators measuring a set number of parts multiple times and a statistical analysis of the results.

Work closely with your Stryker representative to ensure inspection methods are aligned and inspection results correlate with those obtained at Stryker.

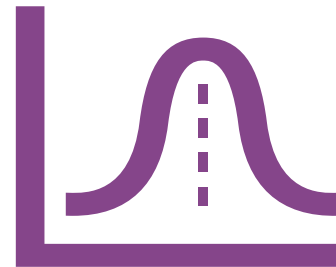
6. Process capability

Process capability studies provide statistical confidence that a process can consistently meet specification for critical part features.

Stryker's PPAP process requires initial process capability studies be completed for all CQAs, unless justification is provided and agreed by Stryker. Part features are required to meet a certain capability commensurate with their risk level.

Process capability studies can be performed using variable or attribute data; however, variable data is preferred as it provides a more accurate statistical representation of the process. The PPAP workbook establishes criteria for number of sample parts requested based on risk.

Suppliers are expected to conduct monitoring of process capability to ensure overall process stability.



Qualification and process controls:

Process controls expectations

7. Validation

Suppliers are expected to conduct validation when required. Examples of when validation is required may include, but are not limited to, the following:

- When new parts, equipment, manufacturing locations, test methods or processes are introduced
- When changes, modifications or repairs are made to qualified or validated systems
- When required per a Quality Agreement

Validation provides objective evidence that products, processes and equipment meet their specified requirements for their intended use and can be consistently fulfilled. Validation is the responsibility of, and conducted by, the supplier. Examples of required validations may include the following:

- **Installation Qualification (IQ):** Establishing by objective evidence that the key aspects of the equipment and ancillary system installation adhere to specifications
- **Operational Qualification [Equipment] (OQ):** Documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges
- **Performance Qualification (PQ):** Establishing by objective evidence that the process or sub-processes, under anticipated conditions, consistently produces a product which meets all predetermined requirements
- **Manual Process Qualification (MPQ):** The demonstration by objective evidence that a manual process is capable of producing product conforming to requirements/associated specifications

Suppliers are encouraged to follow the validation life cycle as illustrated in Figure 1 on the following page.

Qualification and process controls:

Process controls expectations

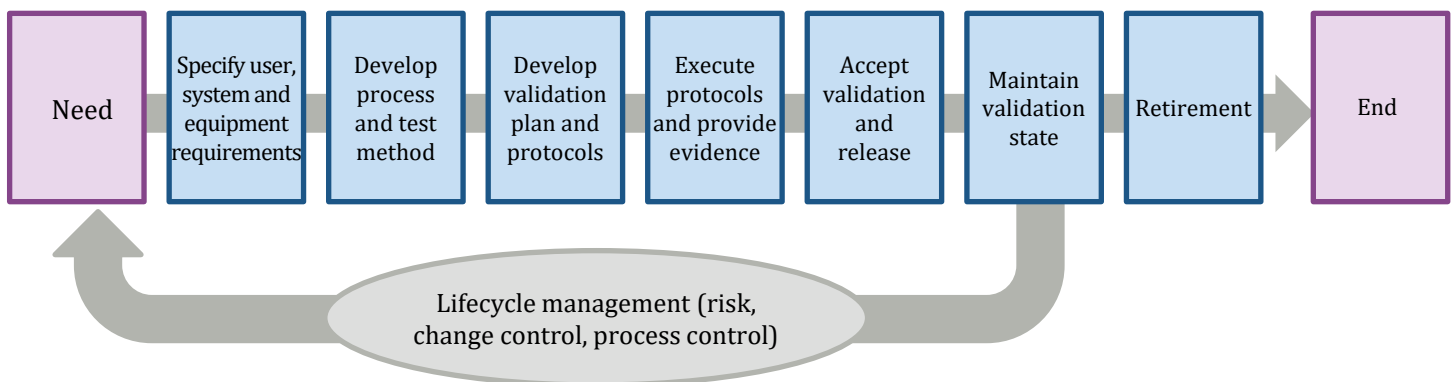


Figure 1. Validation life cycle

Suppliers are to develop and document a Master Validation Plan (MVP) prior to the start of validation activities. If you have entered into a [Quality Agreement](#) with Stryker, ensure the MVP meets all requirements documented therein.

Upon completion of all activities, a final report should be compiled and a conclusion drawn regarding the success of the study. Copies of all validation documentation are to be furnished to Stryker upon request.

The validated or qualified state must be maintained from initial qualification until the process/item is retired and taken out of production service. This includes controlling all changes to the validated or qualified system and performing revalidation or requalification, if the change would invalidate, or lie outside the scope of, the previous validation. Utilize Stryker's [Supplier Initiated Change Request](#) process for approval of changes.

Qualification and process controls:

Incoming inspection

Suppliers must conduct all necessary inspections to ensure product meets specification requirements. Certain types of products are subject to acceptance activities upon receipt at Stryker. Acceptance activities may include evaluations, inspections, tests or other verification activities. Stryker will ensure the acceptance or rejection of a component or product is based on pre-defined acceptance criteria.

Inspection sample sizes may be set based on process capability as established during the PPAP and may be adjusted upwards or downwards dependent on part performance.

Part certification

Part certification is used to qualify a supplier's inspection process for the purpose of optimizing Stryker's incoming acceptance activities. Stryker will continue to perform incoming acceptance activities utilizing documentation provided by the supplier. Depending on the risk profile of the product provided to Stryker, inspection data may need to be provided with each lot. Suppliers must conduct all necessary inspections to ensure product meets specification requirements, regardless of part certification status.

For a part to be selected for certification, a cross-functional team conducts a review of the part, considering items such as quality performance history, type of part qualification conducted and regulatory impacts of certification. Suppliers are encouraged to participate when identified as a candidate for part certification. This process may involve the following:

- Inspection protocols review/enhancement
- Review of product feature risks to determine a sampling plan
- [Process Capability](#) studies
- [Measurement System Analysis](#)

If an event occurs which has a potential impact to the certified part, a certification status review may result in the removal of the part's certified status. Event triggers may include items such as performance review demonstrating negative performance, NC/CAPA affecting the certified part, part revision change or transfer of manufacturing location.

Quality expectations: Quality system expectations

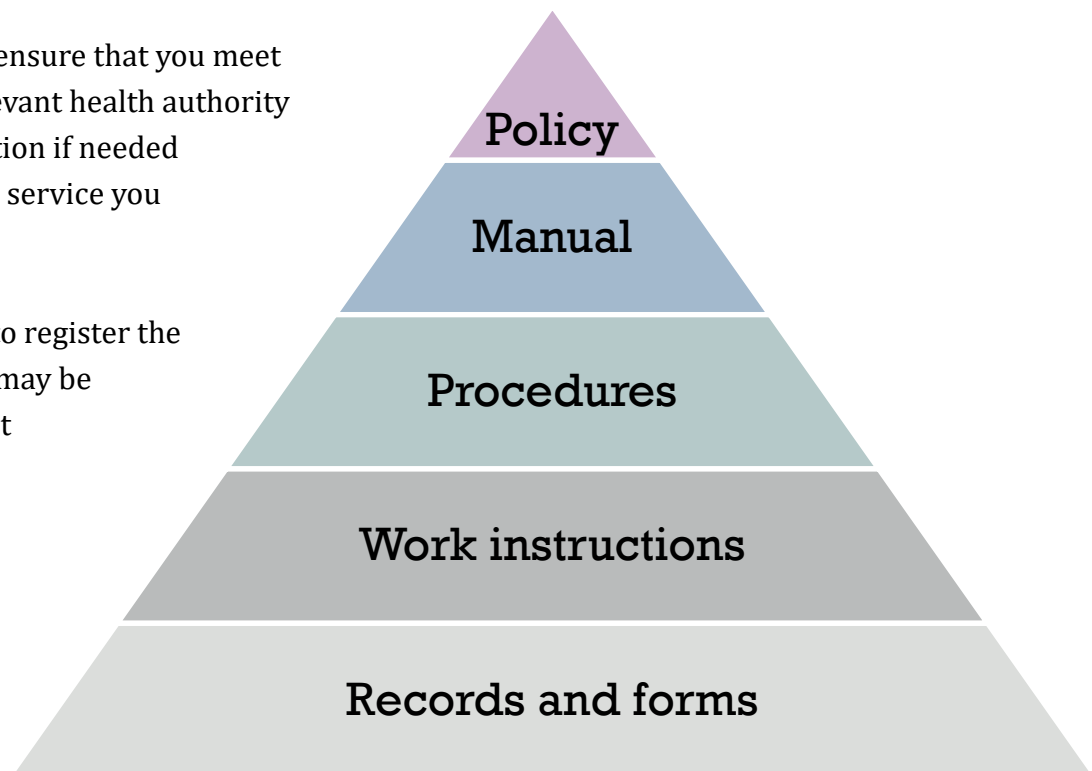
Stryker is a manufacturer of medical devices and is required to comply with applicable regulatory requirements and standards including ISO 13485. As a partner to Stryker, suppliers are expected to establish and maintain an effective Quality Management System (QMS) which, at a minimum, meets the expectations outlined in this section.

Suppliers are recommended to establish a QMS that complies with the latest requirements of ISO 13485. Expected QMS documentation includes a quality policy, quality manual, quality objectives, procedures, work instructions and records, in order to consistently meet customer and regulatory requirements. Each supplier is expected to continually improve the effectiveness of their QMS.

Stryker may verify a supplier’s QMS by means of a [Supplier audit](#), supplier self-assessment, review of supporting documentation or other verification process deemed appropriate by Stryker. Suppliers are to provide evidence of their certifications to Stryker upon request.

In partnership with Stryker, ensure that you meet requirements for FDA or relevant health authority registration and/or certification if needed dependent on the product or service you are providing.

In the event Stryker desires to register the product internationally, you may be requested to provide relevant documentation within a communicated timeline.



Quality expectations: Supplier Initiated Change Requests

As described in your [Change Control](#) or [Quality Agreement](#) with Stryker, changes requiring Stryker approval cannot be implemented until approved, in writing, by Stryker. This approval is granted through use of a Supplier Initiated Change Request (SICR).

We encourage suppliers to identify opportunities to improve quality, service or cost within their processes, and to submit proactive SICRs to Stryker for consideration. We understand that in addition to proactive SICRs, sometimes business circumstances necessitate changes. We require a minimum of 90 days for change approval, but ask that you submit SICRs as soon as you know about a prospective change to allow ample time for qualification and approval. This is especially important for high-impact changes such as manufacturing location changes, which require communication as early as possible. Please target approximately 12 months notice for manufacturing location changes.

SICRs are initiated by completing the SICR form and submitting to sosicr@stryker.com. When completing the form, please ensure that you conduct the following items:

- List all parts numbers affected by the proposed change. For parts under development, consult with your Stryker representative to determine whether an SICR is needed dependent on phase of development process.
- List all impacted Stryker sites
- Clearly describe the change and its expected benefits to you and to Stryker
- Detail the qualification or validation you intend to complete to evaluate the change prior to its implementation and the proposed timing of the change
- Use text entries (as opposed to an image of text) to allow processing of the form

Upon submission of the form, you will be notified of receipt, and later receive the name of the Stryker representative who will own the record. You can connect with this person directly with any questions or additional information about the proposed change.

Quality expectations: Supplier Initiated Change Requests

SICRs are reviewed by the Supplier Change Review Board (SCRB). SCRBR decisions are shown in Figure 2. Factors used to assess changes may include evaluation of the following:

- Regulatory impact
- Need for design testing or print update
- Impact to critical processes, special processes or CQA processes
- Increased process risk or need for control plan update
- Supplier’s quality performance

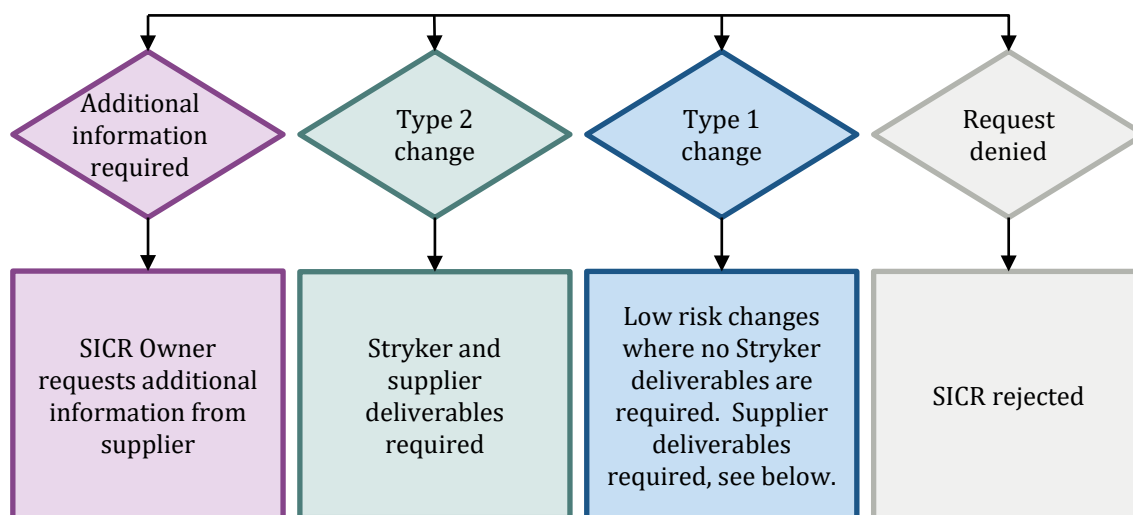


Figure 2. SCRBR decisions

If you receive the SICR form with “Type 1” selected and Stryker signature(s), you may proceed to qualify, validate (if required) and document the change in your QMS, and may implement the change without further Stryker approval.

If you receive the SICR form with “Type 2” selected and Stryker signature(s), work with your Stryker representative to execute Stryker and supplier deliverables to qualify, validate (if required) and document the change. Await final approval on the SICR form prior to implementing the change.

If a change impacts multiple Stryker sites, you will need an approved SICR form from each site prior to implementing.

Quality expectations:

Control of nonconforming product

Nonconforming product (or potential nonconforming product) must be controlled by the supplier. Suppliers are to have control systems implemented to segregate and prevent nonconforming product from mixing with conforming product.

Nonconforming product disposition:

Suppliers are to have documented processes regarding the disposition of nonconforming product. Dispositions may include use-as-is, rework or scrap. A disposition of use-as-is, or any deviation from product requirements or specifications, requires Stryker written approval.

Rework:

Suppliers are expected to establish and maintain a process for rework, to include re-testing and re-evaluation of the nonconforming product after rework, to ensure that the product meets its requirements. Rework and re-evaluation activities, including a determination of any adverse effects from the rework upon the product, must be documented.

- **Standard rework:** The supplier may re-perform processes, as long as those rework processes have gone through a Stryker PPAP or have been previously agreed by Stryker in writing and are consistent with repeating prior step(s) within the process, to bring a device into specification, without requesting approval from Stryker.
- **Non-standard rework:** Any rework that does not fit within the description of “standard rework” above is considered non-standard. Non-standard rework requires written approval by Stryker prior to the supplier performing or arranging for the performance of activities.

Quality expectations: Control of nonconforming product

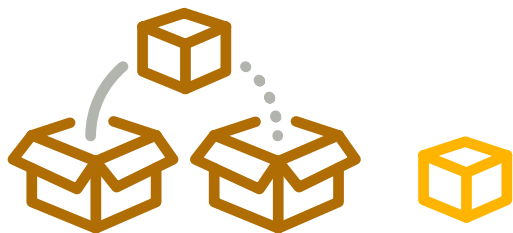
Escapes and field actions:

Suppliers are expected to immediately (less than 24 hours) notify all affected Stryker sites of:

- Escapes (or potential escapes) of nonconforming product shipped from the supplier's facility, including product shipped from sub-suppliers that could have an impact on product delivered to Stryker
- Product subject to any field actions such as correction and/or removal

This allows Stryker to implement containment action and initiate an investigation. Full cooperation is expected from the supplier in any investigation. Suppliers need to investigate and understand the full scope of the issue and establish and communicate a containment plan to quarantine non-conforming product which has not yet arrived at Stryker.

Nonconforming products or services reaching Stryker will be rejected and returned at the supplier's expense.



Escapes

Nonconforming items which
have left your direct control

Quality expectations: Corrective and Preventive Actions

Suppliers are expected to establish and maintain a Corrective and Preventive Action (CAPA) system that includes, at a minimum, the following:

- Documentation of CAPA activities and results
- Investigations to identify the root causes of non-conformances using one or more established problem-solving tools such as Pareto, 5-Whys, Cause and Effect, DDW, etc.
- PFMEA review to ensure failure modes are captured and classified appropriately
- Identification of actions needed to correct non-conformances and prevent recurrence
- Verification or validation of actions to assure effectiveness and no adverse affects
- Dissemination of information to personnel responsible for assuring product quality
- Analysis for trends to identify repeat issues
- Management review of identified quality problems and associated CAPA activities

Supplier Corrective Action Requests

Suppliers are expected to establish and maintain procedures to document, evaluate and, when appropriate, investigate complaints, including those received from Stryker in the form of a Supplier CAPA or Supplier Corrective Action Request (SCAR). This includes retaining written records of any investigation and the reasoning used to determine whether an investigation is, or is not, necessary.

If Stryker notifies you of a non-conformance, please consider the following:

- Confirm receipt of notification of non-conformance
- The information provided should identify if you are expected to implement a correction, a corrective action or both. Work alongside Stryker to identify appropriate actions.
- When a corrective action is needed, utilize root cause problem-solving tools
- When providing a correction or corrective action plan, include action due dates
- If intending to implement any changes that are subject to Change Control, submit a SICR to obtain written approval prior to implementing the change
- Provide evidence of corrective actions implemented

Quality expectations: Sub-supplier expectations

As a supplier to Stryker, it is your responsibility to manage anyone who provides products or services to you that have any effect on the products or services you are providing to Stryker (referred to as sub-suppliers). To do this, you are to establish and maintain written requirements for selecting, assessing, monitoring and re-evaluating your suppliers. You are responsible to keep all sub-suppliers adequately informed to ensure that the correct design, production or process controls are applied to ensure that the product conforms to its specifications. Additional expectations about sub-supplier management include the following:

- You are responsible to conduct appropriate process control, testing and inspection to ensure that any material received from any sub-supplier will function reliably for the intended purpose and in accordance with all product requirements
- Sub-supplier changes can only be made in accordance with your [Change Control Agreement](#) or [Quality Agreement](#), including supplier's submission and approval of an [SICR](#)
- It is expected that you have an agreement in place with your sub-suppliers to notify you of changes prior to implementation
- Nonconforming product identified by supplier attributed to sub-suppliers is to be handled in accordance with your QMS requirements
- Even if Stryker requests for you to use a specific sub-supplier, that sub-supplier must go through identical supplier controls as your other suppliers

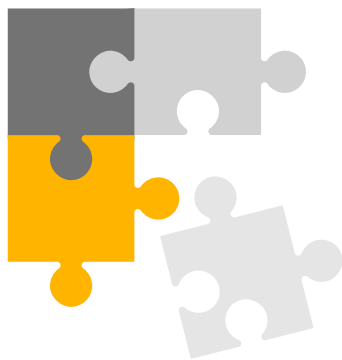


Quality expectations: Traceability

Suppliers are expected to establish and maintain a process for identifying and tracking product during all stages of receipt, internal processing, testing, storage, distribution and shipment. Maintain traceability to the unit, lot or batch level as required per regulation. This includes, but is not limited to, traceability for the following:

- Materials (including sub-supplier traceability)
- Process information
- Shipments

During production, suppliers are expected to perform a line clearance. Line clearance practice should ensure that equipment and work areas are free of products, documents and materials from previous processes to avoid mislabeling or cross-contamination of product. Additionally, suppliers should consider maintaining a 6s program as a best practice.



Traceability

The ability to verify the history, location and application of an item by means of recorded identification

Quality expectations: Packaging, labelling and delivery

Suppliers are expected to package products in accordance with any specifications defined by Stryker and good commercial practice to ensure that no damage results during transportation, including protecting any item or part thereof that may deteriorate during shipment or storage.

Suppliers are to meet any labeling requirements on the part specification, and additionally include with each shipment a Certificate of Conformance that complies with [PO terms](#) and [Quality Agreement](#) requirements, including items such as the following:

- Supplier name
- Stryker part name, number and revision level
- Stryker purchase order number and if applicable, release number
- Supplier's unique lot identifier (i.e. lot number, date code, sales order number or other traceable number), if applicable
- Quantity shipped
- Date manufactured
- Statement of Conformance to Stryker specifications, approved by an authorized Quality Representative (Including representative's name and title)



Record retention

Suppliers are to retain written records of all activities relating to the product, including but not limited to documents concerning the design, development, composition, manufacture, testing, quality, validation, traceability, remanufacture, packaging, labeling, inspection and shipping activities, as well as all training records for those entrusted with any work affecting quality. Records are to be retained compliant to regulation and/or for a time period specified by Stryker. Records are to be readily accessible upon request.

Quality expectations: Regulatory audits

Suppliers are to provide notification to Stryker within two business days of a Regulatory Agency (such as the FDA) notifying the supplier of any upcoming audit or inspection, or any communication such as a 483, warning letter or finding.

Suppliers may be subject to announced or unannounced audits by Notified Bodies or Regulatory Agencies. This may include suppliers providing critical or crucial products or services who are listed on the certificate of a Stryker site, where the listed supplier site is not certified to ISO 13485 from a Notified Body designated by a European Union member state. The audits may be conducted on Stryker's behalf in support of Stryker's product certifications and may assess the Quality Agreement and QMS elements. Suppliers are expected to accommodate and cooperate fully with any such audits, and to notify Stryker.

Notifications are to be sent to suppliernotifications@stryker.com. Notifications should include company name, location of audit, auditing organization, reason for audit and start/ finish dates of audit. Upon receipt, provide written observations and/or final audit report. A Stryker representative will partner with you to evaluate any potential product impact. Notifications are not necessary for supplier's Notified Body renewal and surveillance audits.

Product environmental compliance

Stryker and our suppliers must comply with environmental requirements regarding the materials that comprise our products, including the REACH Regulation, RoHs Directive and California Prop 65, among others. Suppliers are expected to inform Stryker of any restricted or declarable materials utilized. This information should be provided electronically by following instructions in the request email from BOMcheck or Assent. These are industry platforms designed to enable suppliers to provide declarations electronically in the form of a Full Material Declaration (preferred) or a Regulatory Compliance Declaration. The benefit of Full Material Declaration is that a supplier uploads the total chemical composition of parts only once (unless the formulation of the part changes), with automatic updates to the part's compliance status should future regulatory changes be introduced. Should you have any questions or require further detail, please contact BOMcheck or Assent via the contact information provided in the request email, or your Stryker representative.

Ongoing performance: Performance monitoring and re-evaluation

Stryker conducts ongoing monitoring of suppliers to assess quality performance and determine if additional action is needed. This may be conducted in forums such as nonconforming product review boards, CAPA review boards or Management Review.

Additionally, an annual Quality Performance Review (QPR) is conducted. During this review, each supplier is assigned a QPR score, which is calculated based on performance inputs such as those shown in Figure 3.

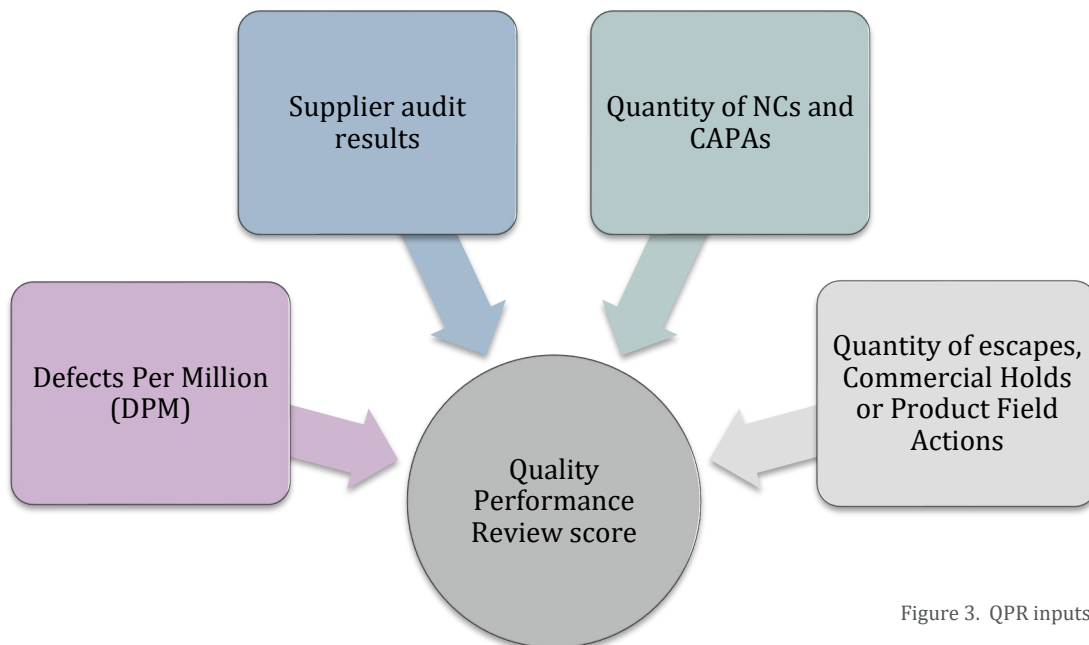


Figure 3. QPR inputs

Based on the QPR score and stakeholder input, actions may be initiated which can take forms such as a [Supplier audit](#) or a [Quality Improvement Project](#). In addition to being initiated as a result of performance monitoring, supplier re-evaluation can also be initiated on a set frequency (for suppliers providing higher-risk products or services), or for-cause at any time.

Ongoing performance: Quality Improvement Projects

In pursuit of our shared goal of continuous improvement, suppliers may get the opportunity to participate in a Quality Improvement Project, commonly referred to as a QIP. This program has proven to be effective and beneficial for suppliers.

This activity is supplier-driven with sponsorship/support from Stryker, and is based on an in-depth performance evaluation completed by a Stryker representative and the supplier. QIPs encourage direct engagement with Managers, Engineers, Operators and Shift Leaders to identify and implement solutions.

Commonly used QIP tools are [Process Control Plan Assessment](#), [Drill Deep and Wide](#) and [EQUIP](#).

Suppliers who are selected to engage in a QIP are responsible for the following:

- Defining project scope in partnership with Stryker
- Developing and owning an action plan tailored to systemic improvement activities that includes specific actions, action owners, due dates, completion statuses and mitigation activities if committed dates are at risk
- Defining key individuals within the organization for project monitoring and completion
- Providing consistent and timely updates to Stryker relative to the action plan
- Documenting evidence for completed action plan activities
- Monitoring effectiveness of completed action plan activities
- Conducting read across of improvement activities, if applicable

Success criteria will be set in partnership between the supplier and Stryker. QIP closure is accomplished once success criteria is met and action plan items are closed and deemed effective.

Ongoing performance: Process Control Plan Assessment

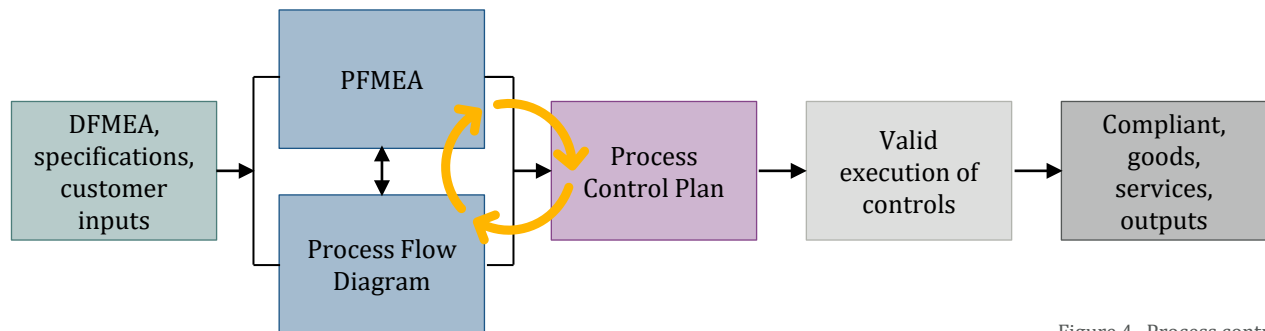


Figure 4. Process control

The Process Control Plan Assessment (PCPA) tool is designed to objectively evaluate the supplier's process controls against ideal process controls, as shown in Figure 4. The PCPA tool identifies process-centric problem statements and is a method of identifying improvement opportunities. A PCPA may be helpful when a supplier's process controls would benefit from assessment for the purpose of prioritizing improvement activities or to define a detailed problem statement when a problem in a supplier's process is not understood.

During a PCPA, the supplier and Stryker will work together to conduct an in-depth assessment of the following:

- Supplier process controls, including PFMEA, process Control Plan and Process Flow Diagram
- Implementation methods and controls
- Management responsibility in process controls

Upon completion of the assessment, the supplier and Stryker together create an action plan to enhance process controls. Upon completion of the action plan, a re-assessment will be conducted to ensure improvement.



Ongoing performance: Drill Deep and Wide

Drill Deep and Wide (DDW) is a root cause analysis tool used to determine occurrence, detection and systemic root causes, as shown in Figure 5. Once root cause(s) are determined for each leg, after the investigation, corrective action plans for each root cause should be brainstormed and determined.

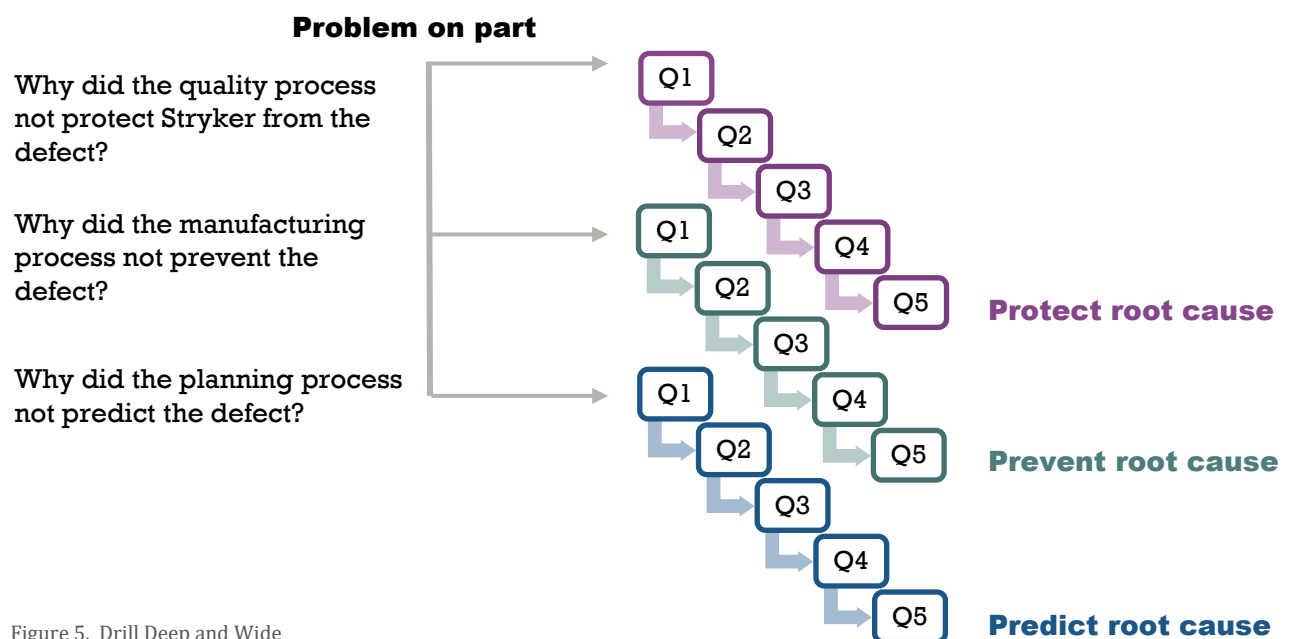


Figure 5. Drill Deep and Wide

It is important to note that multiple root causes may be discovered for each leg. A separate chain of 5-why's may be needed to ensure all possible root causes are identified. At the conclusion of the drill deep investigation and corrective action planning, a drill wide review will be conducted to determine preventive actions for other processes or products. The drill wide should consider other products, process lines, systems and plants. A read across plan should be created to address all potential opportunities outside of the scope of the non-conformance.

Ongoing performance: EQUIP

EQUIP is a continuous improvement program sponsored by top management at Stryker and the supplier which provides structured tools to assess and address the supplier’s process performance opportunities impacting quality, delivery and cost. The program commences with a shop floor assessment focused on twelve key areas to measure supplier’s practices against best industry practices, as shown in Figure 6. Assessment is focused on a selected process or product line. This program has proven to be effective and beneficial for suppliers.

The program provides for preventive as well as corrective intervention for any supplier at any stage of its lifecycle. Upon gaps identification, an action plan is defined and executed by the supplier and a re-assessment is performed to verify action implementation and sustainability.

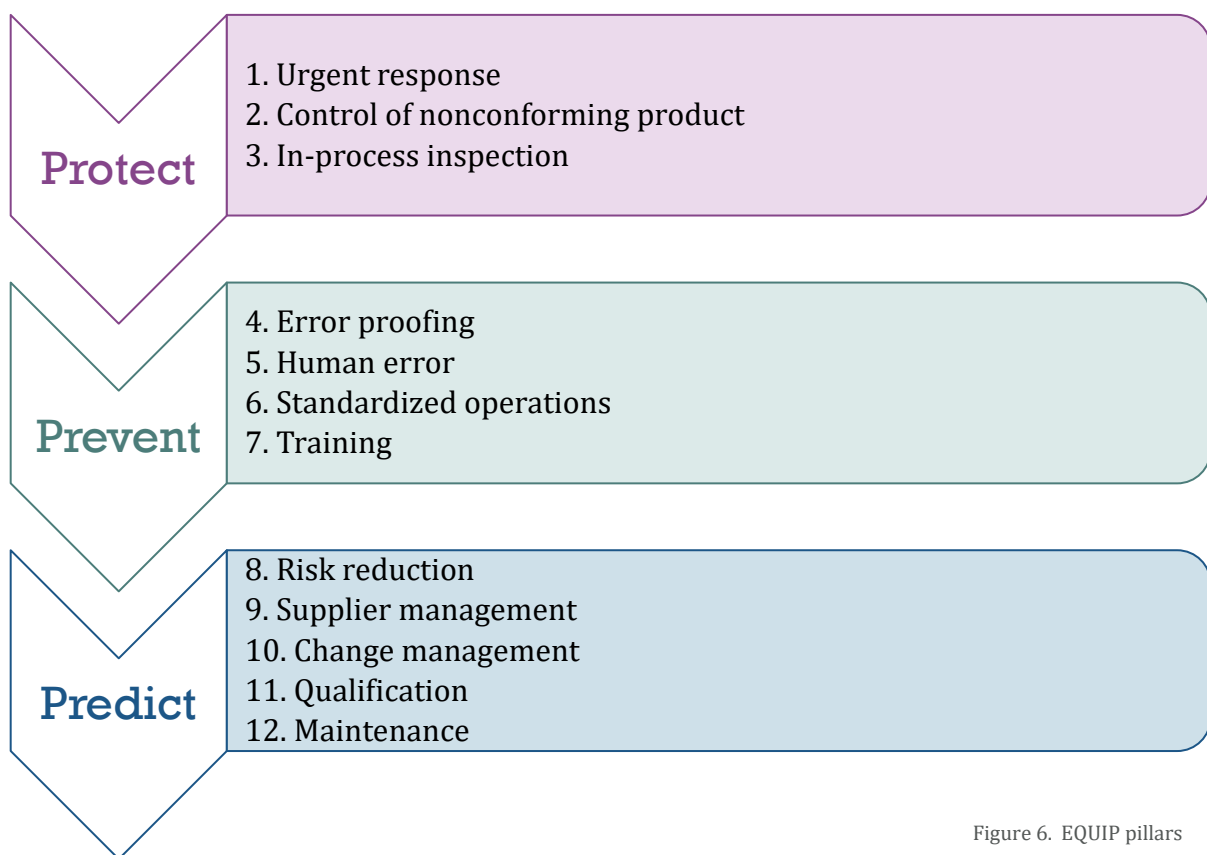
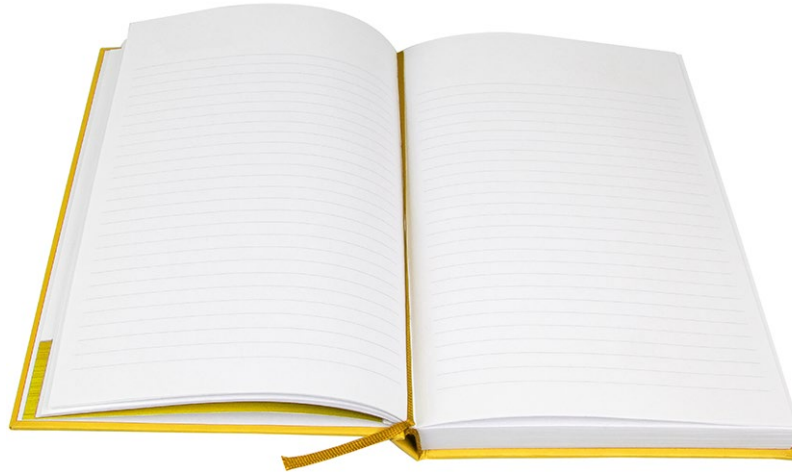


Figure 6. EQUIP pillars

Acronyms



AO: Advanced Operations	NPI: New Product Introduction
ASL: Approved Supplier List	OEM: Original Equipment Manufacturer
CAPA: Corrective and Preventive Action	OQ: Operational Qualification
CM: Contract Manufacturer	PCPA: Process Control Plan Assessment
CQA: Critical Quality Attribute	PFA: Product Field Action
DDW: Drill Deep and Wide	PFD: Process Flow Diagram
DFMEA: Design Failure Mode and Effects Analysis	PFMEA: Process Failure Mode and Effects Analysis
DHR: Device History Record	PO: Purchase Order
DPM: Defects Per Million	PPAP: Production Part Approval Process
FAI: First Article Inspection	PQ: Performance Qualification
FDA: Food and Drug Administration	QIP: Quality Improvement Project
GSQ: Global Supplier Quality	QMS: Quality Management System
IQ: Installation Qualification	QPR: Quality Performance Review
MMS: Manufacturing Material Supplier	R&D: Research and Development
MPQ: Manual Process Qualification	SCAR: Supplier Corrective Action Request
MSA: Master Supply Agreement	SCRB: Supplier Change Review Board
MSA: Measurement System Analysis	SICR: Supplier Initiated Change Request
MVP: Master Validation Plan	SME: Subject Matter Expert
NC: Non-Conformance	

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Thank
you

**for partnering with
Stryker to make
healthcare better.**