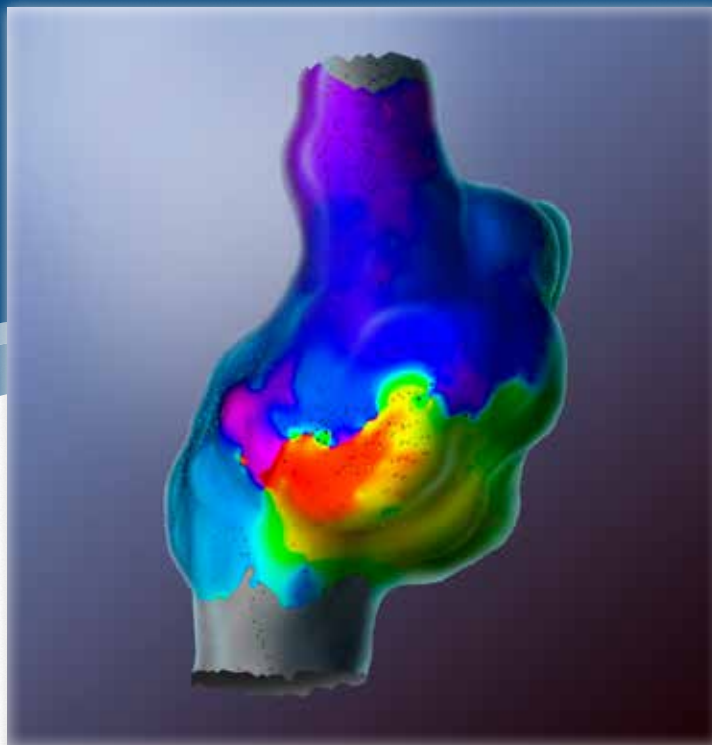


Boston Scientific

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Supplier Guidebook

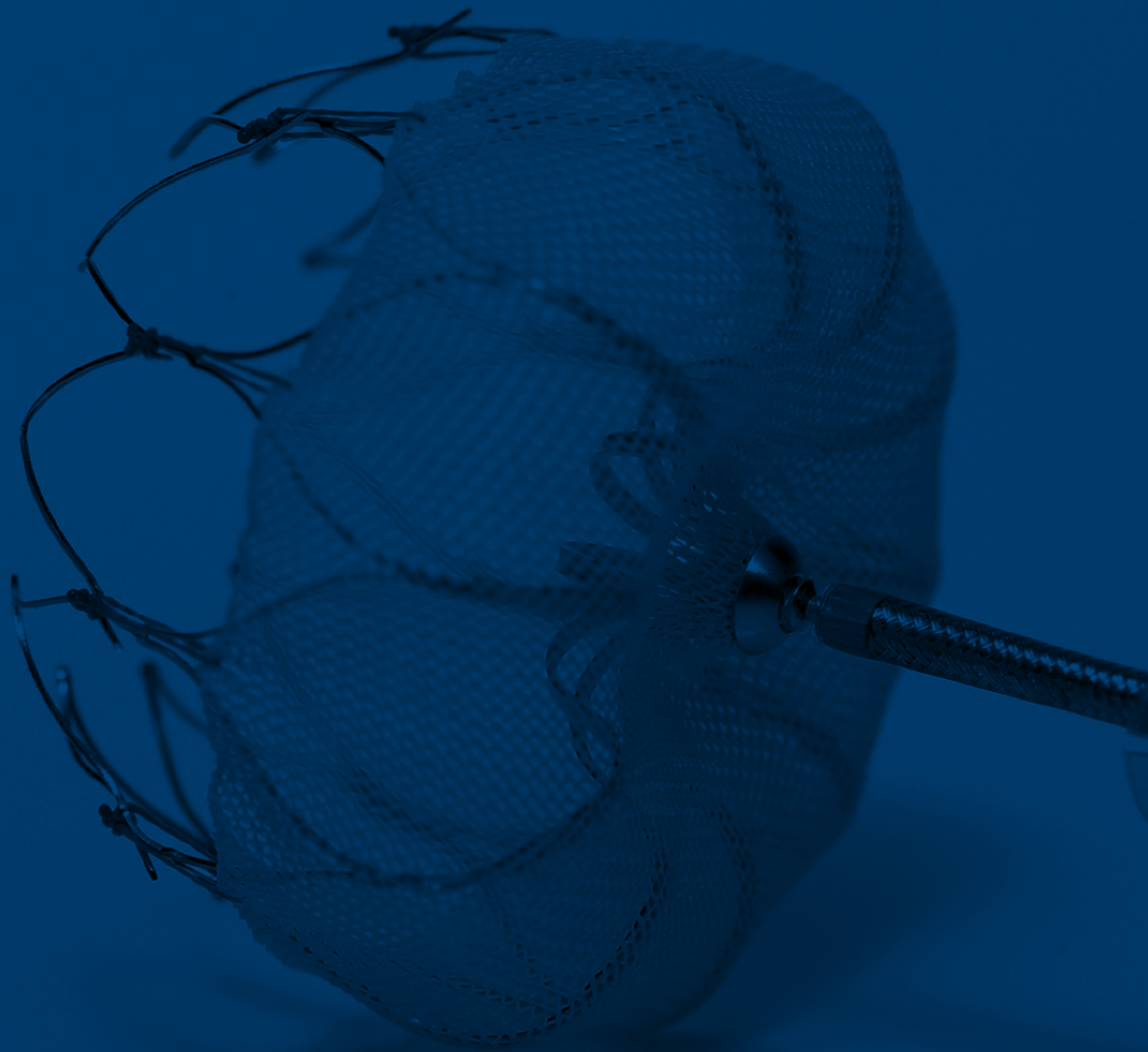
Guidelines for a successful partnership with Boston Scientific



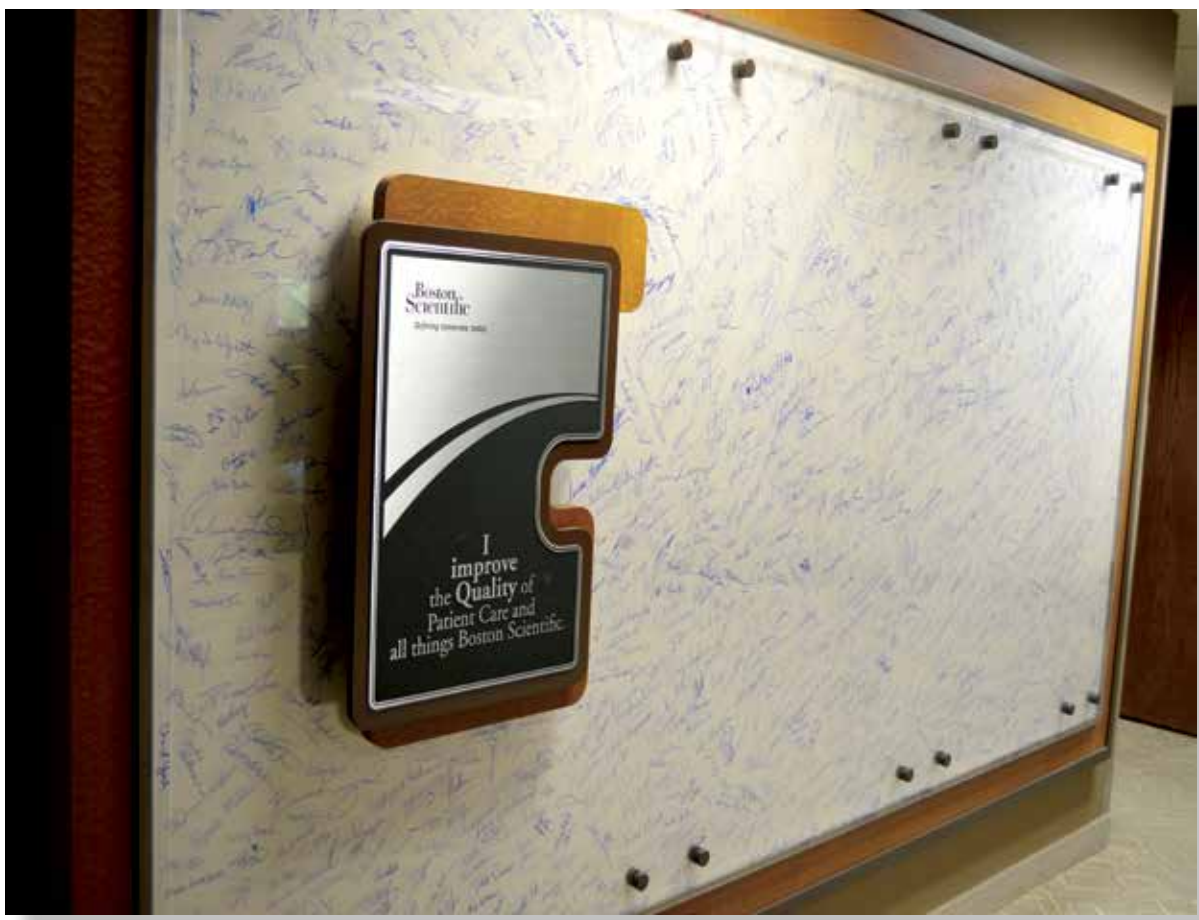
Copies of this Supplier Guidebook can be accessed at:
<http://www.bostonscientific.com/en-US/supplier-resource-center/doing-business.html>

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I
Improve
the Quality of
Patient Care and all things Boston Scientific.



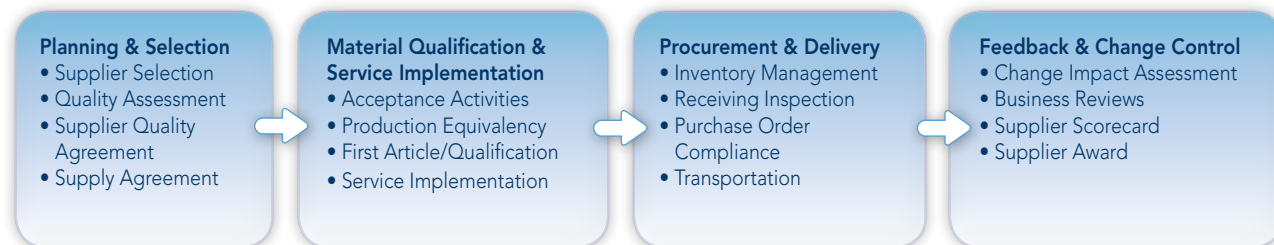
Supplier Management Overview

Supplier Management Overview

Boston Scientific strives to be the highest performing medical solution provider. To realize this vision, the mission of Boston Scientific's global supply chain organization is to establish world-class practices for all purchased materials, products and services. We are committed to developing and fostering supplier relationships that will deliver industry-leading quality, reliability, and value to our patient and physician customers.

In pursuit of this mission, we have developed a comprehensive supplier management program, as illustrated in the Supplier Controls Lifecycle. The Supplier Controls process ensures that the quality of the supplied materials, products, or services meets Boston Scientific's specified purchase requirements. Boston Scientific uses a systematic approach to manage the Supplier Controls process. Each step in the process comprises various activities as shown below.

Supplier Controls Lifecycle



Boston Scientific will select and partner with suppliers who are committed to working together toward a common goal and who share our commitment to the best practices outlined in this Supplier Guidebook. These are continuously monitored with Business Reviews, Supplier Scorecards, and Assessments. Outstanding performance is recognized by the Boston Scientific Supplier Award. Any purchasing agreement or supplier quality agreement that the supplier has in place with Boston Scientific will supersede this Supplier Guidebook.





Planning and Selection

Supplier Selection

The process of selecting suppliers for materials, components, finished medical devices or services is an integral part of Boston Scientific's commitment to highest performing global medical solutions for our customers.

Our principal interest is to ensure that our selected suppliers are aligned with Boston Scientific's quality, technology and business goals. The supplier selection process is also used to identify potential risks in the supply chain, such that risks can be mitigated or eliminated prior to production.

When selecting a supplier, Boston Scientific will evaluate existing and new suppliers. The key areas evaluated are:

- **Quality:** Capability to repeatedly produce product which meets or exceeds the technical and quality requirements of Boston Scientific
- **Technology:** Technical capability and commitment to advancing process technologies in support of Boston Scientific's strategic direction
- **Service:** Capability to meet Boston Scientific's production, delivery and service requirements with a demonstrated high level of support and responsiveness
- **Value:** Competitive pricing, year over year cost reduction capabilities and active participation in inventory management initiatives
- **Corporate Responsibility:** Commitment to responsible business practices

The level of evaluation within the selection process is based upon the potential risk of the sourcing decision, which is determined by supplier history and by the particular material, component, assembly, service or finished medical device to be purchased.

Strategic suppliers will be considered first for new business. When a strategic supplier cannot meet Boston Scientific's **Quality, Technology, Service** and **Value** expectations, then other suppliers with a proven track record of meeting these expectations will be considered.



Boston Scientific's Supplier Expectations

Quality

Boston Scientific requires world-class quality for all purchased materials and services that are supplied to our patient and physician customers. Our suppliers directly share in the responsibility to ensure the highest degree of care is taken to meet or exceed all specified quality and reliability requirements. Boston Scientific expects:

- Suppliers provide data to demonstrate compliance to applicable external regulations
- Materials, components, assemblies, services and finished medical devices supplied to Boston Scientific meet or exceed all specified requirements
- After production equivalency has been established, all changes must be submitted to Boston Scientific for approval prior to implementation
- Suppliers have a robust Quality System that meets Boston Scientific's supplier assessment requirements
- Suppliers review and sign a Supplier Quality Agreement (SQA) when required
- Suppliers maintain a manufacturing environment with appropriate temperature, humidity or other environmental controls. Systems shall be in place to prevent damage, deterioration, contamination or other adverse effects from occurring during the manufacture or delivery of products.
- Suppliers have a documented process for line clearance and process/product changeovers to prevent mix-ups, to prevent use of incorrect materials/components, and to ensure traceability.
- Suppliers provide data to support Boston Scientific regulatory audits and suppliers support on-site audits from external governing bodies.
- Supplier shall use best practices in performing root cause analyses, in a prompt fashion, to resolve issues related to its products.

Technology

Boston Scientific seeks to partner with suppliers with demonstrated technology leadership and a commitment to investing in continued technology development.

Boston Scientific also expects all suppliers to:

- Implement formal, management-sponsored continuous improvement initiatives; examples include Six Sigma, Lean, or Total Quality Management initiatives
- Perform PFMEAs (Process Failure Mode Effect Analysis) during manufacturing process development to identify key or high risk characteristics. As a result of the PFMEA activity, a Control Plan shall be developed to control these characteristics. Reference AIAG industry standards for guidance on PFMEA and Control Plans. The PFMEAs and Control Plans shall be living documents and should be reviewed/updated whenever there is a product or process change.
- Implement Statistical Process Controls (SPC) for all critical input and output process variables
- Achieve process capabilities exceeding $P_{pk} = 1.33$ for all critical input and output process variables

For suppliers providing electrical components, Boston Scientific encourages implementation of a statistical electrical test program leveraging JEDEC standard JESD50B.01. Suppliers that manufacture, process, assemble, or otherwise handle electronic parts, assemblies, and equipment susceptible to damage by electrostatic discharge shall maintain an ESD control program (based on applicable standards including ANSI/ESD S 20.20 or IEC 61340-5-1).

Strategic suppliers are expected to invest in the technologies and capabilities that will allow Boston Scientific to direct more spending toward those strategic suppliers.

Service

Boston Scientific uses a variety of tools and metrics to set service expectations and to evaluate suppliers' abilities to meet them:

- Supply Agreement – this sets service level expectations
- Relationship – the quality of interactions, measured by supplier responsiveness, level of support, and open/effective communication
- Delivery Performance – the ability to ensure an appropriate level of production/finished goods and on-time completion of services
- Customer Inventory – participation in Boston Scientific inventory programs, such as consignment, i-Supply and/or forward-positioned inventory hubs
- Capacity/Flexibility – the ability to quickly respond to changes in demand
- Supplier Controls – a robust supplier management program articulating expectations consistent with those expressed in this Guidebook
- Business Continuity – clear disaster recovery plans addressing potential natural and man-made business interruptions, including critical Tier 2 suppliers and raw material replacement

Value

In a focused effort to reduce health care costs, Boston Scientific is actively striving to deliver products that provide increasing value to patients and physicians.

Boston Scientific expects suppliers to competitively price new materials/services, minimize development costs and support ongoing cost reduction initiatives. Price reductions can be proactively achieved through lean initiatives, process/yield improvements or technology development. A demonstrated willingness to invest in cost reduction initiatives which enable Boston Scientific to realize its goals is highly regarded.

When conducting Supplier Selection, Boston Scientific evaluates suppliers' history of proactively reducing material/service purchase price year over year and reducing development costs with each successive product.

New Product Development

Boston Scientific offers a broad portfolio of market-leading products and is committed to delighting patients, physicians and healthcare providers. Key to this effort is a focused and effective new product development process. It is expected that Boston Scientific suppliers play an active part in the development of new products and technologies by:

- Properly planning and staffing new product development projects
- Investing in new technologies to improve product features/performance/capability/cost
- Being an active partner in development of new product solutions
- Supporting best-in-class material delivery time to help bring new products to market sooner
- Providing clear and regular communication through the development process
- Quickly implementing changes to support new product development needs
- Meeting all commitments for new product development



Corporate Responsibility

Boston Scientific recognizes that Corporate Responsibility extends beyond compliance and therefore Boston Scientific seeks partnerships with suppliers who share our commitment to strong ethics and full compliance with all applicable laws. Boston Scientific also considers the demonstration of responsible practices as an indicator of a supplier's long-term sustainability and we consider partnerships with responsible suppliers to be a fundamental component of our business continuity and risk mitigation strategy.

Boston Scientific is committed to promoting the following (basic expectations) in our supply chain:

- **A safe and healthy workplace.** Safety of workers is paramount. This includes appropriate attention to occupational safety, emergency preparedness, industrial hygiene, procedures and systems to deal with occupational injury and illness, appropriate attention to physically demanding work, appropriate machine safeguarding, access to clean facilities and potable water, and when applicable, appropriate dormitory and canteen.
- **Upholding human rights.** All workers must be treated with dignity and respect as recognized and understood by the international community. This includes freely chosen employment, avoidance of child labor, reasonable working hours, fair wages and benefits, humane treatment, nondiscrimination, a workplace free of harassment, and freedom of association.
- **Human Trafficking and Slavery.** Boston Scientific adheres to the California Transparency in Supply Chains Act of 2010.
- **Conflict Minerals.** Suppliers are expected to provide pertinent information regarding "conflict minerals" to allow Boston Scientific to comply with section 1502 of the Dodd-Frank Act of 2010, even if they are not subject to the regulation themselves. Boston Scientific will consider conflict minerals status as an input to the supplier selection process.
- **Business integrity.** Corruption, bribery, extortion, and embezzlement are prohibited.
- **Supplier diversity.** Boston Scientific is committed to the sustained support of small, minority-owned and women-owned businesses who share our dedication to improving the quality of patient care.
- **Environmental responsibility.** We seek partnerships with suppliers who are committed to the continuous improvement of their environmental sustainability programs and who share our goal of zero harm. Adverse effects to the community, environment, and natural resources are to be continuously minimized, while safeguarding the health and safety of the public. This includes appropriate environmental permits and reporting, pollution prevention and waste reduction, hazardous substance management, wastewater and solid waste controls/processes, air emissions controls/procedures, and adherence to all applicable laws and regulations regarding materials restrictions.



Regulated Materials

Together, Boston Scientific and its suppliers are required to comply with all relevant environmental and medical device regulations relating to materials within products. This may be achieved by restricting, labeling, or controlling materials and/or by implementing collection and waste reduction programs. Failure to comply with geography-specific laws may prohibit sales of a device in that geography. Regulations that restrict the use of certain materials include, but are not limited to, the Medical Device Directive, the RoHS Directive, the REACH Regulation, and rules concerning materials safety and materials of animal origin. Therefore, suppliers shall have knowledge of, and inform Boston Scientific of, restricted and regulated materials that are used to manufacture, process, or package products for Boston Scientific, using an electronic component material assessment form, submitted through the BSC Corporate Portal.

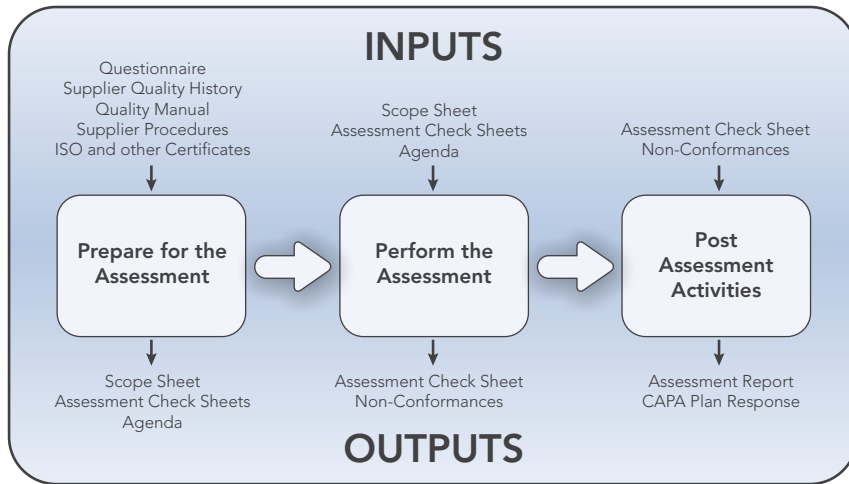
- **Electronic Component Material Assessment (eCMA) Form.** Boston Scientific requires that suppliers complete documentation on material composition and regulation compliance for all supplied components and products. This documentation will be used by Boston Scientific to provide declarations of compliance and information to patients, physicians, and regulators as required.
- **Full Material Disclosure.** Suppliers are expected to provide disclosure on 100% of the material composition. Due to the ever-changing landscape of materials regulations, obtaining full material composition from suppliers will allow Boston Scientific to automatically evaluate materials against new regulations and reduce the need for future declaration requests.
- **eCMA Form Submission.** The eCMA Form, Conflict Minerals Reporting Templates and supporting documents for regulated materials can be submitted through the eCMA module of the BSC Corporate Supplier Portal. The submission of an eCMA Form through the BSC portal using the suppliers' unique username and password is certification that the content being submitted is valid and true.

Supplier Quality System Assessments

All production-impacting suppliers to Boston Scientific are required to establish and maintain a robust quality system. Boston Scientific uses a risk-based approach to determine the type of assessment to be performed (on-site or off-site) and the assessment frequency. In addition to normally planned assessments, quality signals may arise which prompt Boston Scientific to conduct an issue-specific assessment. Quality history, including Lot Acceptance Rate (LAR) and Corrective Actions, combined with past assessment results and Acceptance Activity (AA) risk, may influence the frequency of assessments.

Supplier assessments are based upon applicable regulations including ISO 9001/13485/17025/11138 and FDA Regulation 21-CFR-Part 210/211/820 quality principles.

In addition to maintaining a robust quality system, it is expected that suppliers establish adequate supplier controls of their supply base (Tier 2 suppliers). In certain cases based on risk, Boston Scientific has established Tier 2 supplier assessment requirements.



The supplier assessment process consists of three steps:

1) Prepare for the Assessment

- Boston Scientific will review supplier quality history and other quality information, which may include questionnaires and/or forms to be completed, copies of Certifications (e.g., ISO 13485), Supplier Quality Manuals, Procedures, and Work Instructions.
- For on-site assessments, an agenda will be provided in advance.

2) Perform the Assessment

- On-site assessments are either "Initial" or "Surveillance".
 - **Initial Assessments:** A broad focus of the entire quality management system is used to assess new suppliers
 - **Surveillance Assessments:** A detailed review of a limited number of quality system elements through direct observation and the collection of objective evidence

3) Post-Assessment Activities

- Upon completion of an assessment, any observations will be identified and categorized as:
 - **Minor Non-Conformances:** A low risk, isolated non-compliance to a regulatory standard or quality system requirement
 - **Major Non-Conformances:** Serious, systemic or repeat non-compliance to a regulatory standard or quality system requirement; a collection of Minor Non-Conformances may indicate systemic non-compliance, resulting in a Major Non-Conformance
 - **Major Non-Conformance with Product Control:** Non-compliance where product is found unfit for use, adulterated, mislabeled, etc. (creating risk to patient safety), resulting in the need for a secondary action to physically or electronically control product
- The assessment outcome will either be "Approved" or "Failed." A "Failed" outcome may derive from a Major Non-Conformance with Product Control and/or 3 Major Non-Conformances.
- An assessment report will typically be provided within 30 calendar days of the assessment date.

Retention of Records

Suppliers are expected to retain quality records for all provided materials for the period defined by the Supplier Quality Agreement or if not defined, for a period of seven years (or 15 years for products that are, or are incorporated in or used in conjunction with, implantable Medical Devices) after delivery to Boston Scientific. After this period has elapsed, Suppliers will notify Boston Scientific prior to destroying any records and provide a copy of such records upon Boston Scientific's request.

Service Implementation

Expectations of production-related service suppliers (i.e. calibration, analytical/inspection labs, translation, sterilization, media, etc.) are focused on the supplier's ability to effectively follow and perform test protocols, maintain compliance to test standards and compliance/certification to ISO 17025, while meeting responsiveness expectations and reporting requirements. In some cases, results and data provided by Service Suppliers are used to support a regulatory submission or product release. Boston Scientific considers adherence to standards and record-keeping to be critical elements in every supplier's quality system.

Logistics and transportation service providers are expected to demonstrate value, performance (on-time and undamaged delivery) and compliance with all applicable transport and security regulations: TSA, DOT, IATA, etc. Transportation suppliers are also expected to partner with Boston Scientific in mitigating fuel price fluctuations and mitigating risk of damage/loss to shipments.

Non-production services suppliers (i.e. consulting, facilities, management, etc.) are expected to perform to their applicable Statements Of Work, complete all deliverables on time and provide the highest quality service at competitive pricing.

Finished Medical Device Suppliers

In addition to expectations articulated elsewhere in this Guidebook, suppliers of finished medical devices suppliers have responsibilities for the following:

- Design Control Process – initiation (Design History File/Device Master Record), verification/validation activities and maintenance
- Product Literature and Labeling – labeling requirements and Instructions For Use (IFU)
- Product Approval – clinical requirements and regulatory submissions/approvals/maintenance
- Post-Market – external event reporting, complaint handling and device tracking

Specific responsibilities and requirements are defined in applicable agreements depending upon the nature of the supplier relationship.



Material Qualification

Acceptance Activities

Boston Scientific ensures that specifications are met via ongoing Acceptance Activities (AA's). An Acceptance Activity is defined as the inspection or test of material for conformance to design specifications.

Acceptance Activity Verification Process

Materials are grouped by risk:

- Group 1 – materials/components that have increased patient safety risk, are implantable, or may come into contact with the patient
- Group 2 – Finished Medical Devices or materials/components that have reduced patient safety risk

In Group 1, all specifications with patient risk (deemed Critical to Control - CTC) require an Acceptance Activity, which should be implemented by the supplier. Group 2 parts do not require AA's.

Boston Scientific utilizes Failure Modes and Effects Analysis (FMEA) techniques to evaluate the risk of the part to the patient. Boston Scientific evaluates risk using either patient Severity (S) or Risk Index (RI) terminology.

The Severity or Risk Index identified in the FMEA process will determine the AA verification requirements. Verification of each AA consists of setting up appropriate sampling and acceptance criteria using Lot Tolerance Percent Defective (LTPD), measurement system analysis (Gage R&R), and a system to ensure on-going control.

For instances where suppliers perform AA's, suppliers are responsible for verifying and documenting compliance in an AA verification report. Boston Scientific is responsible for the completion and final approval of supplier AA verification reports.

AA Verification

The AA Report will contain either Risk Index or Severity		AA Sampling Plan minimum			Measurement System Gage R&R	
Risk Index (RI)	Severity (S)	Tightened LTPD	Normal LTPD	Reduced LTPD	Variable	Attribute
N/A	0	No AA Required				
0	1	10%	20%	25%	N/A	N/A
1	2	5%	10%	15%	30%	0.7 Kappa 20% LTPD
2	3 or 4Low Occurrence	2.5%	5%	7.5%	30%	0.8 Kappa 15% LTPD
3	4High Occurrence	100% inspection			10%	0.9 Kappa 10% LTPD

Any change after approval of the AA Verification Report that affects the Report's content must be communicated to, and approved by, Boston Scientific personnel prior to implementation of the change.

Components of AA verification:

- **Gage Repeatability & Reproducibility (Gage R&R)**
Gage R&R studies identify the proportion of overall variation due to the measurement system, demonstrating measurement precision. Reference documents on how to perform and analyze a Gage R&R are available upon request.
- **Calibration**
Calibration of equipment used in AA's is vital to equipment accuracy. The calibrated range of the equipment must encompass the entire range of the specification that it is measuring.
- **Monitoring Requirements**
Documentation and monitoring of measurement data provides greater confidence that shifts in process parameters which impact Boston Scientific will be identified and resolved in a timely and consistent manner.
- **On-going Requirements**
Suppliers must ensure operator certifications and calibrations are current and regularly maintained. Suppliers must also maintain a system to record and store measurement data.

Acceptance Activity Review

For suppliers with Acceptance Activities, assessments will periodically review those Acceptance Activities. This review is performed by collecting objective evidence that Acceptance Activities are being performed and ensuring that any associated requirements are in place and functioning properly (e.g., equipment, calibration, and monitoring).



First Article/Qualification

First Articles/Qualifications are used to demonstrate that a supplier is capable of consistently meeting specifications.

In Group 1, the acceptance criteria to meet qualification requirements are based upon LTPD levels determined by patient risk. Statistically significant sample sizes are determined by Boston Scientific. Data are used to demonstrate suppliers' capability of meeting the acceptance criteria.

Prior to First Article/Qualification, the following requirements must be met:

Group 1 Parts	
Pre-Qualification	Qualification
<ul style="list-style-type: none"> Supplier Assessment Production Equivalency Form – Supplier agrees to inform and gain approval from Boston Scientific prior to implementing any changes from this point forward Acceptance Activity Verification Report Evaluation data for each specification to determine capability (goal $P_{pk} > 1.33$) 	<ul style="list-style-type: none"> Test Statistical sample size, based on LTPD levels shown in the table above Completed Electronic Component Materials Assessment (eCMA) Form

Group 2 Parts	
Pre-Qualification	Qualification
<ul style="list-style-type: none"> Supplier Assessment 	<ul style="list-style-type: none"> Test each essential specification Completed Electronic Component Materials Assessment (eCMA) Form

Supplier Testing and Data Collection Requirements

In many cases, Suppliers collect qualification data. Supplier-generated data must be produced on calibrated and controlled equipment. The following must be provided to Boston Scientific or available for review at the Supplier's facility:

- Test data
- Person who conducted the test
- Test date
- Test equipment used (i.e. equipment number)
- Identification of actual test articles: lot number, serial numbers, sample numbers, date code, raw material lot number

Procurement & Delivery

Total Cost Management

Suppliers are expected to apply a continuous improvement approach to establish world-class pricing. Boston Scientific expects suppliers to develop cost structures that are fair, reasonable, and available for review upon request.

Customer Service and Delivery

It is expected that Suppliers provide timely delivery of materials and services in the most cost-efficient manner and that Suppliers have the ability to support Boston Scientific around the globe. This includes on-time delivery, timely responsiveness and flexibility to requests for order placement and material returns.

Agreements and Purchase Orders

It is the intention of Boston Scientific to establish written Supply Agreements with key suppliers. The goal of these Agreements is to establish terms and conditions for both Boston Scientific and the Supplier that will build and grow the businesses together. Boston Scientific purchase orders also contain key terms regarding the relationship.

Written Agreements

Supply Agreements and Supplier Quality Agreements contain the terms and conditions by which Boston Scientific and Suppliers agree to conduct business, addressing:

- Payment terms
- Pricing and annual cost reductions
- Shipping and delivery terms
- Supplier-managed inventory programs
- Lead times
- Purchase order change and revision terms
- Length of agreement
- Supply assurance agreement
- Penalties for nonconformance
- Supplier change request expectations
- Design controls, regulatory and post-market responsibilities for Finished Medical Devices

Purchase Order Requirements

Purchase orders contain the basic requirements associated with all orders placed by Boston Scientific. These requirements include:

- **Material** – Boston Scientific material number, revision, and quantity
- **Product/Services Description**
 - Product requirements properly documented, including drawing numbers and other requirements
 - Comprehensive description of product/services (greater detail is necessary if no Statement Of Work is in place)
- **Payment terms** – net 45 days after receipt of material and invoice or net 60 days for some services; Boston Scientific also has a prompt payment discount program:
 - Discount terms are 2%/15 days
 - Payments are made by ACH
- **Delivery**
 - Shipments are required to arrive at the shipping destination point specified on the Purchase Order within the allowed delivery window
 - The supplier and Boston Scientific will agree to the terms that regulate the cost of freight as well as transfer of title & risk of loss; “Incoterms 2010” will be used to facilitate agreement of delivery terms
 - It is Boston Scientific’s preference to have full visibility of shipping costs; if and where possible, freight/shipping costs should be excluded from the item’s price and itemized on the invoice
- **Certificate of Conformance (CofC) or Certificate of Analysis (CofA)** – A signed Certificate must accompany each shipment made to Boston Scientific or be submitted electronically if eCert has been enabled, acknowledging that all material requirements that are quality-system related have been met
- **Flexibility** – To meet normal demand variability inside of lead-time, suppliers must maintain raw materials and production capacity to support a minimum of 20% upside flexibility

Payment

When invoices are required, a valid invoice referencing the Boston Scientific purchase order number initiates the payment process. To minimize payment disruptions, suppliers should follow all Boston Scientific invoicing guidelines. ACH is Boston Scientific’s preferred method of payment. Materials and labor should be itemized on the invoice to ensure proper tax calculations. Evaluated Receipt Settlement (ERS) and Consignment are programs that may eliminate the need for an invoice to be submitted.



Inventory Management

Collaborative Inventory Management

i-Supply is an internet-based inventory management tool that promotes collaboration between customers and suppliers providing real-time inventory, forecast, and consumption rate data. Boston Scientific has implemented i-Supply for reducing inventory levels, freight, and other supply chain costs, as well as supporting inventory replenishment programs.

Consignment

Boston Scientific defines supplier-consigned inventory as products that have been furnished to Boston Scientific but remain the property of the supplier until consumed by Boston Scientific or sold to a third party. The consignment program requires a signed consignment agreement between both parties. Timing details and requirements for the payment process are included within this agreement.

Forward-Positioned Inventory Hubs

Boston Scientific defines forward-positioned inventory hubs as inventory managed and owned by the supplier but stored in a location near a BSC factory to assure a consistent flow of material. The payment process is initiated at the time of consumption.

Risk Based Incoming Acceptance (RBIA) Process

Boston Scientific utilizes a risk-based material acceptance process referred to as RBIA. The process establishes acceptance methods to determine if purchased material lots are acceptable for production. The acceptance methods are based on material grouping and Risk Index/Severity level.

Acceptance methods

- **Certificate of Conformance (CofC)/Certificate of Analysis (CofA)** – material lots are accepted/rejected based on information on the CofC or inspection data on the CofA
- **Sampling Inspection** – material lots are accepted/rejected according to a sampling plan and acceptance criterion determined by material grouping and specification Risk Index/Severity level
- **Same Supplier Lot (SSL)** – allows acceptance of child lots based on acceptance of a defined quantity of random samples selected from the parent lot

Boston Scientific reserves the right to inspect/test any specification, performance, or reliability requirements to verify a material is suitable for use. Suppliers are expected to work with Boston Scientific to resolve discrepant materials and handle material returns in a timely manner.

Electronic Certification - eCert

Materials suppliers are expected to provide electronic certifications via eCert. Minimum requirements include:

- PO Number
- Part Number
- Material Revision
- CofC and/or CofA
- Vendor batch number

Note: The vendor batch number on the eCert must match the vendor batch number shown on the packing slip attached to the package.

Access to the eCert system is through the BSC Corporate Supplier Portal.

Feedback & Change Control

Open Communication

Fundamental to the partnership between Boston Scientific and suppliers is a willingness to collaborate and communicate effectively at all levels. Open and direct access to personnel and facilities is expected. Information exchange will include the following areas:

- **Quality Data** – Traceability and other processing data available to Boston Scientific when addressing quality or compliance concerns
- **Strategic Planning** – Executive-level communications to ensure alignment of vision, strategy, and execution, including strategies regarding supplier locations, technology investments, and capacity investments
- **Commercial Initiatives** – Business planning to meet material cost, supply agreement, forecast, purchasing, and logistics requirements
- **New Product Development** – Product roadmap, technology integration, and next-generation product research and development
- **Financial Viability** – Changes in financial status including 1) changes in ownership, 2) downgrades in credit score, Paydex, D&B rating, 3) major lawsuits, judgments or bankruptcies, 4) other activities that may impact financial indicators relating to solvency or financial stress
- **Sustainability Initiatives** – Sustainability projects/initiatives planned or underway

Strategic suppliers enjoy increased visibility across all of Boston Scientific, and receive first consideration for new business. Going forward, Boston Scientific aspires to direct 80% of spending to strategic suppliers.



Supplier Quality & Compliance Signals

Supplier quality signals are derived from receipt of non-conforming material, Supplier Quality System Assessments, or any other quality signal requiring action. Boston Scientific leverages internal corrective/preventive action tools (CAPA), as well as the Suppliers' corrective/preventive action system to address and rectify quality and compliance signals. Supplier commitment to timely acknowledgement of issues and implementation of solutions is critical to the business relationship as a whole.

If a quality signal is identified, the Supplier is expected to provide the following documentation within 1- 2 days:

- Problem/defect description
- Containment action performed
- Initial Investigation and Conclusions

Within 14 days, the supplier will provide an action plan which includes:

- Corrections, Corrective Actions, and/or Preventive Actions defined, including responsible owners and estimated date of completion for each action
- Proposed effectiveness criteria for Corrective and Preventive Actions

Further supplier responses may be required:

- Objective evidence demonstrating implementation of corrective and preventive actions as defined in the action plan
- Objective evidence demonstrating effectiveness of corrective and preventive actions

Supplier Change Impact Assessment (SCIA)

Boston Scientific must approve any change that: a) has the potential to impact form, fit, function, performance, life, reliability, sterility, safety, environmental compatibility or chemical characteristics or is a change resulting from the implementation of CAPA and b) occurs after the production equivalency form is signed (if required) or the first article/qualification units are received.

For more impactful changes, more time may be required for review and approval. For facility moves, Boston Scientific requires notification 24 months prior to the move and for all other changes, suppliers are expected to request the proposed change 180 days in advance of implementing the change.

Please be sure to notify Boston Scientific as early as possible in the change process to avoid delays to production schedules. Supporting data and a description of the change's benefit to Boston Scientific may be requested of the supplier to facilitate acceptance of the proposed change.

The SCIA process is initiated by answering five questions:

1. What is changing? (i.e. Changing _____ from _____ to _____)
2. What is the potential impact on product?
3. What is the proposed timing of the change?
4. What is the impact if the change is rejected?
5. What supporting data is available? If no data is required, what is the justification?

Supplier Reviews, Scorecard and Award Program

Structured supplier reviews with strategic suppliers will be held on a recurring basis. These reviews will address current activities, performance metrics, upcoming events, and action items. It is also an opportunity for suppliers to present changes, new initiatives, or other key information.

Boston Scientific may provide a Supplier Scorecard to communicate performance to key metrics in the areas of Quality, Technology, Service, and Value.

Boston Scientific's Supplier Award program recognizes its highest-performing suppliers. The award will be given to suppliers which demonstrate a sustained level of exceptional performance and a superior commitment to the Boston Scientific relationship. Boston Scientific awards include:

- Rhythm Award – For superior performance in Rhythm Management
- Indirect Supplier Award – For superior performance in providing services or non-product materials
- Sustainability Supplier Award – For world class environmental sustainability performance
- Galway Supplier Achievement Award – For superior performance in supporting the Boston Scientific Galway factory

Rhythm Award





Glossary of Terms

AA

Acceptance Activity - the inspection/test of incoming product, in-process product or finished devices for conformance to specifications

CAPA

Corrective and Preventive Action – a record used to document and resolve product risks or risk to the overall quality management system

CofA/CofC

Certificate of Analysis/Certificate of Conformance – test data and information demonstrating that materials meet specifications, including the following:

- Manufacturer's name
- Boston Scientific material number
- Manufacturer's catalog number (if applicable)
- Manufacturer's batch number
- Manufacturer's super lot number (if applicable)
- Material revision number
- Expiration Date (if applicable)
- Quantity
- Approver's name and signature

eCMA Form (Electronic Component Material Assessment Form)

A Form used to gather required compliance information for medical device, environmental and other regulations

Finished Medical Device

Finished devices that are manufactured for or distributed by Boston Scientific

Group 1 Parts

Materials/components that have increased patient safety risk, are implantable, or may come into contact with the patient

Group 2 Parts

Finished medical devices or materials/components that have reduced patient safety risk

LAR

Lot Acceptance Rate

Lot Tolerance Percent Defective (LTPD)

A level of defectiveness that is unsatisfactory and therefore should be rejected by the sampling plan

Non-Conforming Events and Prevention (NCEP)

A record used to document and resolve a nonconformity or potential nonconformity that does not meet the CAPA criteria, but warrants an investigation and some level of action

Process Capability

Often referred to as P_{pk} or C_{pk} , this is a measure which compares the process variation to the specification limits

Production Equivalency

The initiation of supplier change control; required prior to qualification for Group 1 materials – Production Equivalency includes confirmation of process validations, equipment validations, AA implementation, revision control, training implementation, and approval of sub-components

Quality Record

Quality records include, but are not limited to: Design Master Records (DMR), Design History File (DHF), travelers, Acceptance Activity verification reports, change control documents, traceability data, inspection and test records, documents detailing materials/processes used for production, and plant location information

RBIA

Risk Based Incoming Acceptance

SCAR

Supplier Corrective Action Request – a record used to document and resolve a supplier nonconformity or potential nonconformity that does not meet the CAPA criteria, but warrants an investigation and some level of supplier action

SCIA

Supplier Change Impact Assessment

SQA

Supplier Quality Agreement – an agreement executed between Boston Scientific and a supplier defining the quality responsibilities and expectations for supplier performance

Tier 1 Supplier

A supplier that provides materials, components, assemblies, services or finished goods directly to Boston Scientific

Tier 2 Supplier

A supplier that provides materials, components, assemblies, services or finished goods to a Tier 1 Supplier



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