



SUPPLIER GUIDEBOOK



CONTENTS

INTRODUCTION	5
Beckman Coulter Quality Policy	5
DanaHER Corporation	5
Beckman Coulter	5
Preferred Supplier Program	5
Purpose and Scope.....	5
Supplier Management Process Overview	6
SUPPLIER EXPECTATIONS AND REQUIREMENTS	6
Quality Management System Expectations	6
Supplier Code of Conduct	7
Integrity and Compliance.....	7
Contractual Requirements	7
Proprietary/Confidential Information	7
Communication.....	7
Business Continuity Plan	7
Change Control/Notification	8
Sub-Tier Supplier Management.....	8
Finished Medical Device Suppliers (Original Equipment Manufacturer).....	9
Beckman Coulter Owned Property	9
Regulated Products.....	9
Counterfeit Product and Material Policy	9
Component Obsolescence.....	9
SUPPLIER EVALUATION AND SELECTION PROCESS	10
Process Overview	10
Approved Supplier List/Approved Service Provider List.....	10
Suppliers Audit Requirements – On-Site and/or Self-Assessment.....	10
Supplier Status	11
PROCUREMENT AND DELIVERY	12
Purchase Orders	12
Delivery.....	12
Inventory Management	13

SUPPLIER PERFORMANCE MONITORING.....	13
Annual Supplier Re-Evaluation	13
Product Qualification	13
Product Documentation	15
Incoming Inspection	15
Nonconforming Product.....	16
Immediate Notification of Quality Issues.....	16
Customer Complaints	16
Corrective Action	17
Supplier Corrective Action Request (SCAR).....	18
SUPPLIER DEVELOPMENT	18
Continuous Improvement.....	18
Cost Management	18
Total Cost of Quality.....	18
Supplier Scorecards.....	18
Supplier Business Reviews.....	18
FURTHER GUIDANCE	19
APPENDIX A, QUALITY AUDITS	20
APPENDIX B, SUPPLIER SCORECARD CALCULATIONS	21



SIMPLIFYING, AUTOMATING
AND INNOVATING COMPLEX
BIOMEDICAL TESTING



INTRODUCTION

Beckman Coulter Quality Policy

Quality is the single most important function of every Beckman Coulter employee.

Quality means: Always striving for excellence

- > Meeting or exceeding our customers' expectations
- > Complying with regulatory requirements
- > Maintaining an effective quality management system
- > Continuously improving

Quality leadership is essential to industry leadership.



Danaher Corporation

Danaher is a global science and technology innovator committed to helping customers solve complex challenges and improving quality of life around the world. Beckman Coulter is a Danaher Operating Company.

www.danaher.com

Beckman Coulter

Beckman Coulter is a global provider of biomedical testing systems and related products that simplify and automate laboratory processes. The company's instruments and chemistries are used in all areas of the biomedical testing continuum: patient care, translational solutions, and research and development. From complex DNA sequencing to simple one-use diagnostic screening kits, Beckman Coulter's products are utilized in every phase of the battle against disease.

Beckman Coulter develops, manufactures and markets products that simplify, automate and innovate complex biomedical testing. Our diagnostic systems are found in hospitals and other critical care settings around the world and produce information used by physicians to diagnose disease, make treatment decisions and monitor patients. Scientists use our life science research instruments to study complex biological problems including causes of disease and potential new therapies or drugs. Hospital laboratories are our core clinical diagnostic customers. Our life science customers include pharmaceutical and biotechnology companies, universities, medical schools and research institutions. For more than 75 years, our products have been making a difference in peoples' lives by improving the productivity of medical professionals and supplying critical information for improving patient health and reducing the cost of care. Beckman Coulter employs approximately 10,000 people throughout the world and has an installed base of more than 275,000 clinical and research systems operating in laboratories around the world.

www.beckmancoulter.com

Preferred Supplier Program

Beckman Coulter offers a preferred supplier program whereby companies that meet quality, delivery and cost performance requirements, align with the strategic needs of the business and support competitive commercial terms are selected as a targeted partner for Beckman Coulter's global supply base consolidation efforts and product development initiatives. Preferred suppliers gain access to Beckman Coulter business units and introduction to other Danaher businesses as a result of their performance. Preferred suppliers are also targeted for participation in training and development opportunities offered by Beckman Coulter and Danaher across multiple technical & operational disciplines.

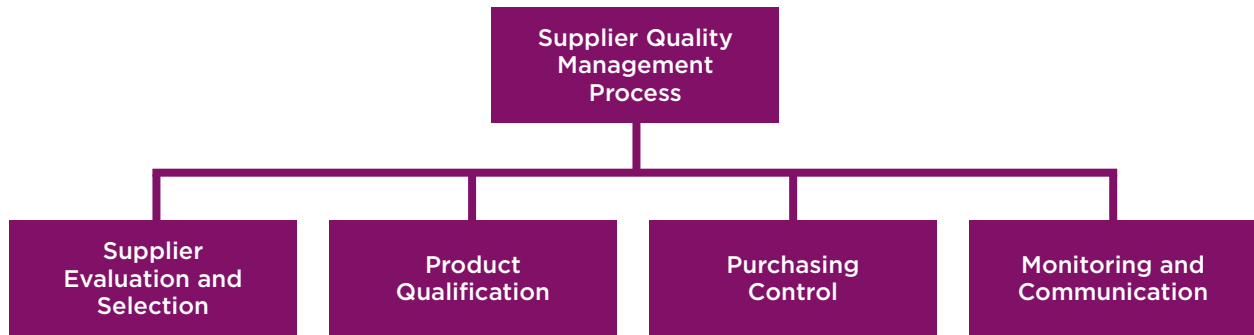
Purpose and Scope

The Supplier Guidebook has been developed as a reference document for our material and service supply base to provide an overview of Beckman Coulter's Global approach to Supplier Quality Management. The approach outlined in this document is not only best practices but expectations of our suppliers that we choose to align with in long term, mutually beneficial partnerships. We encourage our suppliers to share this with their team members and refer to it often

Supplier Management Process Overview

The Global Supplier Quality Management organization at Beckman Coulter strives for excellence throughout our material and service supply base. For our organization, this means choosing to partner with the right suppliers by performing rigorous qualification and subsequent monitoring of supplier performance. Our goal is to collaborate with suppliers, to develop processes that deliver outstanding quality and performance. To help us obtain these goals, the organization has put significant effort into the development of our Supplier Quality Management process which provides a structured framework for the control of supplier’s products. This process will help to ensure:

- > Products sourced by Beckman Coulter are compliant with applicable business and regulatory requirements. Product is defined as service, software, direct materials (items on the Bill of Materials and processed materials), in-direct materials (non-BOM materials that can impact the finished device performance).
- > Consistency across Beckman Coulter supply base regarding quality and business expectations
- > Pursuit of continuous improvement



SUPPLIER EXPECTATIONS AND REQUIREMENTS

Quality Management System Expectations

Beckman Coulter expects its supplier partners to have an effective and documented quality management system, to ensure that customer needs and expectations are met. We expect Current Good Manufacturing Practice (cGMP) as stated in Title 21 of the Code of Federal Regulations, Part 820, to be followed and practiced where applicable. Formal registration is highly preferred, for example ISO 9001, ISO 13485, or equivalent.

Expectation:	Suppliers will have a documented Quality Management System per cGMP.
Best Practice:	Suppliers should maintain a relevant industry certificate, for example, ISO 9001 or ISO 13485.

Beckman Coulter expects our supply chain partners to embrace a sound quality management system and to work with us in a spirit of trust, cooperation, and teamwork. Individual Beckman Coulter plants may establish additional quality system expectations while recognizing that each Beckman Coulter plant has unique customer requirements. At a minimum, the supplier will establish, document, implement, and maintain a quality management system and continually improve its effectiveness. You are encouraged to discuss this guidebook and any additional site expectations with your site specific Beckman Coulter procurement and quality representative.

Expectation:	Suppliers will have an active continuous improvement process.
Best Practice:	Suppliers should deploy an industry recognized continuous improvement program (e.g. Six-Sigma DMAIC, Lean Six-Sigma).

Suppliers are expected to perform a self-evaluation to identify and resolve gaps to the guidelines in this guidebook. An evaluation of the guidelines with your supply chain should also be completed. Your Beckman Coulter Supplier Quality representative may assist with any questions or guidance you may have in completing this evaluation.

Supplier Code of Conduct

The Danaher Supplier Code of Conduct is located on the Danaher website, www.danaher.com/suppliers. Suppliers are to comply with the code of conduct, and are to register on the Danaher website.

Integrity and Compliance

Refer to www.danaher.com/how-we-work/integrity-and-compliance.

Contractual Requirements

As included in the terms and conditions of Beckman Coulter Purchase Orders, acceptance of a Beckman Coulter purchase order constitutes acceptance of the requirements of the purchase order terms and conditions. In addition to the requirements contained in the purchase order terms and conditions, Beckman Coulter will execute a Supply Agreement or Quality Agreement with key suppliers. A Supply Agreement is a specific type of contract which defines terms and conditions under which Beckman Coulter will conduct business with a supplier, including responsibilities for quality. A Quality Agreement is a legal binding agreement which defines the supplier's quality responsibilities under which Beckman Coulter will conduct business with a supplier. Suppliers are expected to discuss and understand the specific applicability of these requirements with the Beckman Coulter representatives in order to make effective business decisions. Refer to the Beckman Coulter Purchase Order for the Beckman Coulter Standard Terms and Conditions of Purchase.

Proprietary/Confidential Information

Suppliers shall consider all Beckman Coulter engineering drawings / specifications related to purchase order and requests for quotations as proprietary information. These include, but are not limited to sample parts, sketches, drawings, software and specifications. All such items shall remain the property of Beckman Coulter. The supplier shall treat all such information and property as confidential unless otherwise agreed in writing from the Beckman Coulter representative. Suppliers may be required to sign Non-Disclosure Agreements (NDA) depending on the level of engagement required.

Communication

Open communication between Beckman Coulter and suppliers is integral to a successful relationship. Both sides must be willing to collaborate at all levels. While the discussions around new product or service development, continuous improvement, business strategies, technical roadmaps, quality data and other business points will include cross-functional representation from both sides. It is an expectation that any communication regarding Beckman Coulter products will include either a Supplier Quality or Procurement representative from Beckman Coulter.

While many discussions are expected to take place throughout the supplier-customer relationship, suppliers shall not make changes to specifications or processes without prior written approval from Beckman Coulter.

Business Continuity Plan

Suppliers are highly recommended to have a disaster recovery plan that identifies the actions supplier will take to assure its ability to deliver an uninterrupted supply of products, material, and/or services in the event a disaster occurs. If requested by Beckman Coulter, supplier will submit a copy of its plan to Beckman Coulter for Beckman Coulter's review and comments.

Change Control / Notification

A supplier shall not make any changes to a specification, requirement, or process for supplied products without notifying the applicable Beckman Coulter representative in advance. No changes to products shall be made without obtaining written approval from the applicable Beckman Coulter representative. The Beckman Coulter representative shall be considered, at a minimum, to be the purchasing agent noted on the affected purchase order unless otherwise prescribed by the individual Beckman Coulter plant. The Beckman Coulter Supplier Quality representative should also be included in change communications.

Proposed supplier changes shall adhere to the terms and conditions applicable to every purchase order. Notice is to be made at least 180 days before implementing the changes. The notification shall include, at minimum, the affected Beckman Coulter products, the change information, date when change is expected to be implemented, Beckman Coulter purchase order number(s) affected, and impact upon any pending deliveries. Examples of information to be included in the change notification are; equipment/process and/or product validations, first article reports, cost impact evaluation, revised certificate of analysis/conformance, etc. BEC Supplier Change Notification Form GLB-QS-TMP-0172 is used to communicate a Supplier Change Notification and is available from the applicable Beckman Coulter representative.

Expectation:	Suppliers will not make any unapproved changes, and will notify Beckman Coulter of proposed changes at least 180 days before making the changes.
Best Practice:	Suppliers should use the Supplier Change Notification form GLB-QS-TMP-0172 or similar format.

Changes requiring notification include those that impact:

- > Form, fit or function
- > Material or specified supplier
- > Manufacturing location, equipment, processes, test or inspection requirements
- > Beckman Coulter (BEC) branded finished goods and OEM products
- > Quality System registration, certificate of analysis or conformance

Sub-Tier Supplier Management

Suppliers are expected to maintain qualifications for sub-tier suppliers and the products purchased through them. It is the Supplier's responsibility to ensure and control the quality of all materials that are purchased to manufacture products for Beckman Coulter. Suppliers will manage sub-tier suppliers with controls commensurate with those Beckman Coulter applies to direct suppliers. Suppliers are responsible to ensure that product manufactured utilize only authentic, conforming and specified material requirements as stipulated in the bill of materials. Prior to implementing changes, including changes requested by sub-tier suppliers, Suppliers must notify Beckman Coulter (see Change Control / Notification section of this guidebook).



Finished Medical Device Suppliers (Original Equipment Manufacturer)

In addition to expectations stated throughout this guidebook, suppliers of finished medical devices suppliers may 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.

Beckman Coulter Owned Property

Suppliers shall exercise care with all Beckman Coulter supplied property including tooling, materials, intellectual property, reusable containers and other items purchased, furnished, charged to, or paid for by Beckman Coulter, while it is under the supplier's control or being used by the supplier or its supply chain. The supplier shall assure such items are identified, protected, verified, and maintained to ensure expected operating performance. The supplier is to provide equipment maintenance and calibration information when requested. Where any such item becomes lost, damaged, or otherwise found to be unsuitable for the intended use, the supplier shall record and report the information to Beckman Coulter. The supplier will not dispose any of Beckman Coulter's property without prior written approval.

Regulated Products

Products supplied to Beckman Coulter will meet the requirements of country, federal, state and local environmental regulations. Regulations that restrict the use of certain products include, but are not limited to, the RoHS Directive, the REACH Regulation, Conflict Minerals (Dodd-Frank Act), Waste Electrical and Electronic Equipment (WEEE), and Global Harmonization System (GHS). Therefore, suppliers shall have knowledge of, and inform Beckman Coulter of, restricted and regulated products that are used to manufacture, process, or package products. Additional information is to be provided by the supplier when requested by Beckman Coulter, to ensure compliance to these requirements.

Counterfeit Product and Material Policy

Beckman Coulter prohibits the use of counterfeit product. A counterfeit part is a suspect part that is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by a supplier in the supply chain. The supplier have processes in place to ensure that all materials and products are not counterfeit and adhere to Beckman Coulter specifications and requirements. If supplier becomes aware of suspected counterfeit product, Beckman Coulter will be immediately notified.

Expectation:

Suppliers are to ensure that all materials and products are not counterfeit and adhere to Beckman Coulter specifications and requirements.

Suppliers are to notify Beckman Coulter immediately if they become aware of suspected counterfeit product

Component Obsolescence

Beckman Coulter expects suppliers to have an effective component obsolescence program to avoid shipment disruptions. In the event that product or material used in Beckman Coulter product is identified as becoming obsolete, the supplier is to communicate immediately with Beckman Coulter with written notification. The supplier and Beckman Coulter will work together to identify acceptable alternatives for the discontinued item.

Expectation:

Suppliers will have an effective component obsolescence program.

Suppliers will communicate immediately with written notification if product or material used in Beckman Coulter product is identified as becoming obsolete.

SUPPLIER EVALUATION AND SELECTION PROCESS

Process Overview

Beckman Coulter Suppliers are selected after a thorough review and evaluation of

- > Overall business health (for example, Dun and Bradstreet report)
- > Quality Management System, using ISO 9001 and 13485 as the preferred standards
- > Approach to customer service which includes provision of 100% conforming product and on time delivery
- > Ability to provide products that meet Beckman Coulter's requirements
- > Continuous improvement capabilities which result in improved quality and supplier productivity
- > Total cost including the cost of quality
- > Strategic alignment, partnering with suppliers on development projects
- > Planning method and inventory policy



We are committed to partnering with suppliers whose core values, industry expertise and business interests align with those of Beckman Coulter. While we are committed to long-term strategic relationships, past business does not always guarantee future business. The method utilized at Beckman Coulter to select suppliers involves a tollgate phased approach to drive full evaluation, risk identification and risk mitigation. Upon completion of the supplier selection, the chosen supplier is added to the Approved Supplier List (ASL) or Approved Service Provider List (ASPL).

Beckman Coulter may request supplier to submit to a 3rd party financial assessment. If contacted by a 3rd party for financial information without a direct request prior from Beckman Coulter, supplier should contact their Beckman Coulter procurement representative to verify the 3rd party requestor prior to submitting any company information. Failure to comply with Beckman Coulter's request for financial assessment will impact supplier standing with Beckman Coulter.

Approved Supplier List/Approved Service Provider List

All suppliers of Beckman Coulter must be assessed and approved by Supplier Quality before being added to the ASL or ASPL. Each Beckman Coulter supplier is required to maintain an effective quality system. The quality assessment process at Beckman Coulter has been developed based on the ISO-9001 standard and may include a Self-Assessment and/or On-site Audit.

Once Supplier Quality has determined the supplier meets the necessary requirements, they will add the Supplier to the ASL or ASPL and include the supplier's name, manufacturing location and other relevant information. It should be noted that if a supplier has multiple locations, Beckman Coulter may require a quality assessment of each location that will be supplying Beckman Coulter sites with products and that each location will have a separate entry on the ASL or ASPL.

Suppliers Audit Requirements – On-Site and/or Self-Assessment

The supplier planning process includes evaluations of the supplier's capabilities to determine if the supplier can achieve procurement, technical, and quality requirements.

- > Procurement: Verification that the supplier has adequate financial resources and sound business integrity and ethics. Suppliers may be evaluated for financial resources, capacity for growth, ability to meet schedules, experience in the area being evaluated, and cost. Refer to the Danaher Supplier Code of Conduct and Danaher Integrity and Compliance sections of this guidebook for additional details on these requirements.
- > Technical: Evaluation of the supplier's technical expertise and capability to produce the requested material. Criteria may include assessment of manufacturing environment, measurement capability, manufacturing equipment, engineering staff, experience with manufacture of similar products, ability to obtain raw materials, and specific licensure requirements.

- > Quality Audit: Evaluation of the material supplier’s quality system through a Supplier Self-Assessment and/or an On-site Audit. The self-assessment serves as an initial document to provide supplier quality system information while an on-site audit allows Beckman Coulter to more completely assess the supplier’s quality system. Service providers are assessed based on pre-defined criteria which may include a requirement for an On-site Audit. Quality Audits are scored according to the severity of the finding. Refer to Appendix A for definitions of severity of findings and for audit scoring details.

As part of the supplier management process, the supplier must allow Beckman Coulter to audit their facility annually and in situations which may require a “for cause” audit. Suppliers are expected to be available upon 30 days’ notice for a routine audit and within 24 hours for a “for cause” audit. Refer to the Supplier Performance Monitoring section of this guidebook for details. Additionally, Beckman Coulter may request to audit supplier’s sub-tier suppliers.

With changes in regulation, some of our suppliers and their sub-tier suppliers may be subject to unannounced audits as required by regulating agencies. These would include suppliers who provide critical or crucial material for use in Beckman Coulter products or processes.

Expectation:	Suppliers must allow Beckman Coulter to audit their facility annually, upon 30 days’ notice. Suppliers must allow Beckman Coulter to audit their facility within 24 hours for a “for cause” audit.
---------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Audit findings are documented on a Supplier Corrective Action Request (SCAR). All audit findings must be addressed by the supplier within the timeframe specified by the auditor. Failure to respond on time may negatively impact the supplier’s approval status. Refer to the SCAR section of this guidebook for details.

Expectation:	Suppliers will respond to audit finding SCARs: > SCAR response to be provided within 30 days of SCAR issue date. > SCAR corrective/preventive action to be provided within 90 days of SCAR issue date.
Best Practice:	Suppliers will respond to audit finding SCARs: > SCAR response to be provided within 21 days of SCAR issue date. > SCAR corrective/preventive action to be provided within 75 days of SCAR issue date.

Supplier Status

Beckman Coulter suppliers will be assigned a qualification status based on the results of the initial Quality Assessment and subsequent re-evaluation process. This status may also be affected by supplier performance throughout the year. The qualification status is as follows:

- > Approved: suppliers who meet Beckman Coulter evaluation and/or selection criteria.
- > Conditionally Approved: suppliers approved with limitations or conditions. Restrictions and/or special monitoring and/or temporary controls may be put in place for a period of time until requirements are met for approved status. An improvement and re-evaluation plan may be created to move the supplier status from Conditionally Approved to Approved.
- > Not Approved: suppliers who do not meet BEC evaluation and/or selection criteria.
- > Inactive: a supplier that is no longer supplying products to Beckman Coulter or that has not supplied products for the most recent 24 months. This supplier will need to be re-qualified and approved by the Supplier Quality function before Beckman Coulter can purchase products from this supplier.



PROCUREMENT AND DELIVERY

Purchase Orders

Purchase orders are Buyer-generated documents that authorize purchase transactions. When accepted by the supplier, it becomes a contract binding on both parties. Purchase Orders from Beckman Coulter sites will include the following information:

- > Item Number, Revision and Description
- > Purchase Order Type (Blanket or Discrete)
- > Supplier Name and Address
- > Quantity, Unit of Measure and Unit Price (include currency type)
- > Delivery date and date order was placed
- > Taxable (Y or N)
- > Payment terms and Freight terms
- > Bill to Address and Ship to Address (including warehouse or organization to receive into)
- > Buyer Identification
- > URL for Terms and Conditions

The PO may include:

- > Routing and transportation service provider instructions
- > Specification or drawing attached
- > Other necessary information, as needed

Refer to the Purchase Order for payment terms. Beckman Coulter Supplier Management operates under a standard of Net 90 Payment Terms or credit card, but terms may vary in different regions. Evaluation of payment terms are part of the overall business evaluation of our supply base.

Delivery

The delivery date specified in the purchase order or subsequently mutually agreed upon will be the date on which the products must be delivered to Beckman Coulter's facility. On Time Delivery (OTD), the measure of material availability when expected, is defined as zero days late and no more than three days early. If items are received by Beckman Coulter more than three (3) days before the date due to be received, Beckman Coulter may return them at the supplier's expense. In the event that the supplier is late in delivering to the agreed upon date, the supplier would be responsible for expedite costs to remedy the past due deliveries. Refer to the Terms and Conditions applicable to the purchase order. For instructions on submitting invoices, contact your Beckman Coulter procurement representative.

Service suppliers are required to provide their services per the agreed upon date specified in the purchase order.

Expectation:

Suppliers are expected to deliver materials on time; zero days late, and no more than three days early.
Suppliers are expected to provide services per the agreed upon date specified in the purchase order.

For Suppliers of inbound material for U.S. Domestic manufacturing or warehousing, refer to the Beckman Coulter Inbound Routing Guide for direction and support for the safe and efficient transport of inbound material to our sites. This logistics and transportation routing guide is available through your Beckman Coulter Procurement representative.

Inventory Management

Beckman Coulter aims to partner with suppliers that have strong inventory management programs in place and who are continuously improving lead times and cycle times. Beckman Coulter has developed an approach to inventory management that is focused on cost and volume. Beckman Coulter understands that different types of product may require different inventory management programs and we strive to collaborate with our suppliers to identify the right approach to inventory management for each product type.

Best Practice:

Beckman Coulter will partner with suppliers that have strong inventory management programs in place, for example, vendor managed inventory, stocking agreements, kanban, etc.

SUPPLIER PERFORMANCE MONITORING

Annual Supplier Re-Evaluation

Annual Supplier Re-Evaluation is an integral part of our Supplier Management process related to Supplier Monitoring. The annual process allows each site to review supplier performance and complete a supplier re-evaluation. The results of this review may drive additional actions at both Beckman Coulter and the supplier, and in some cases may require re-assessment activities. The annual process is standardized across all of the Beckman Coulter sites however; site to site data and experiences with individual suppliers may differ and drive varying results.

The re-evaluation process includes a review of the following:

- > Beckman Coulter Product Risk which is based on an internal Beckman Coulter supplier categorization
- > Supplier Quality Risk which takes into account Supplier status (approved, conditionally approved, not approved), number of quality escapes related to supplier quality, and the number of SCAR's issued to the supplier
- > Supplier Business Risk potential impact to Beckman Coulter business and supply continuity
- > Supplier Audit Interval which reflects the last time that Beckman Coulter evaluated the Supplier's systems through either a Quality Self-Assessment or an On-site Quality or Process Audit

Once the annual re-evaluation is completed, each supplier will have an internal Beckman Coulter Audit Prioritization (APN) score. Based on that score, there may be actions necessary to evaluate and mitigate any risks identified through the annual review. These actions may include any of the following:

- > On-site quality system audit in the coming year
- > On-site product or process audit in the coming year
- > Supplier self-assessment audit/review in the coming year
- > Increased incoming inspection requirements at Beckman Coulter
- > Focused quality improvement activities to mitigate risk

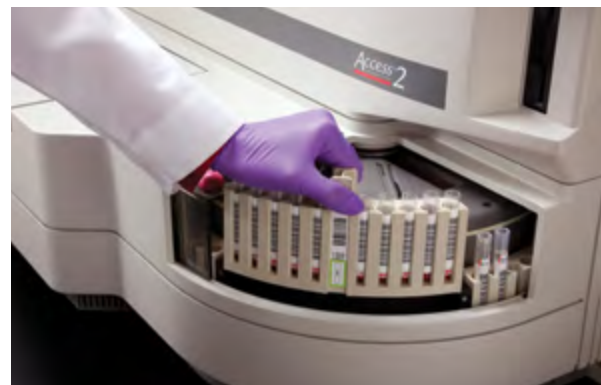
After completion of the evaluation and subsequent activities, it is possible that the supplier status may be changed as a result of this process. Your Beckman Coulter site Supplier Quality representative will work closely with you through any post evaluation activities to help ensure that proper follow-up activities are fully understood and completed.

Product Qualification

The qualification process at Beckman Coulter for new designs, changes to a design, supplier transfers of existing designs, or supplier manufacturing changes, is a multi-step process. Reliability is instrumental to our business and the qualification process is designed to not only show that products meet design requirements but that they will continue to meet these requirements over time, with the correct process monitoring steps in place. The product qualification may consist of the following items as based upon the component risk category as defined by Beckman Coulter:

First Articles: Product purchased from a supplier may require a First Article submission. First Article requirements are as follows:

- > Must consist of the requested quantity of the product produced using the finalized production process.
- > Must be manufactured to a revision controlled Beckman Coulter drawing. NOTE: Product manufactured to uncontrolled or red lined drawings are not considered First Articles.
- > Must be clearly identified on the outside of the package as First Article products.
- > Supplier must provide First Article inspection data for all drawing/specification requirements, unless otherwise specified, accompanied by a copy of the drawing/specification suitably marked for direct correlation between the data and the drawing features notes, etc.
 - i. The data should be submitted on a Beckman Coulter provided First Article Inspection Report (FAIR) form when provided, in both hard copy and electronic versions.
 - ii. Electronic Data should be sent to Beckman Coulter prior to the product shipments for evaluation to avoid unnecessary delays in return shipping or remanufacturing of the product.



Fit and/or Functional Tests: If required per the qualification plan, products for fit and/or functional testing will be included in the request for First Article product. Fit and/or functional test products will be evaluated and may include evaluation of the individual product, evaluation with sub-assemblies or evaluation with fully functional units based on product complexity and overall risk.

Process Performance Index (Ppk): The supplier may be required to provide initial process performance data during the product qualification process. This requirement will be communicated to the supplier in advance and will outline the critical to quality specifications to be evaluated as well as minimum sample size requirements. A minimum Ppk requirement will be specified prior to the qualification process. Failure to meet the minimum Ppk requirements may result in not achieving qualification status, require process changes and requalification or increased process controls which may include 100% inspection at the supplier.

Expectation:	Suppliers will provide process capability data during product qualification.
Best Practice:	Suppliers should meet a Ppk of 1.33 for critical to quality characteristics and 1.00 for other control characteristics.

Measurement System Analysis (MSA): Beckman Coulter expects suppliers to have a program in place to assess the accuracy, repeatability and reproducibility of measurement systems used to monitor and control the manufacturing of Beckman Coulter products. The P/T ratio is the ratio of the precision of a measurement system to the (total) tolerance of the feature being measured. The P/T ratio is computed as: $(6 \times \text{measurement system standard deviation}) / (\text{total tolerance of the feature being measured})$. Measurement systems should have a P/T ratio <10% for major critical to quality features and <30% for any remaining control features. Beckman Coulter's Supplier Quality representative may request copies of MSA studies for measurement systems used for in-process or final inspection of Beckman Coulter products.

Reference ASTM E2782, Standard Guide for Measurement Systems Analysis (MSA) or contact a Beckman Coulter Supplier Quality representative for further guidance on evaluating measurement systems accuracy, repeatability and reproducibility.

Expectation:	Suppliers will use Measurement System Analysis to assess the accuracy, repeatability and reproducibility of measurement systems.
Best Practice:	Suppliers should use an industry recognized MSA standard, for example, ASTM E2782. Measurement systems should have a P/T ratio <10% for major critical to quality features and <30% for any remaining control features.

Supplier Process Controls

The supplier is required to have a documented plan identifying their controls for all Critical To Quality (CTQ) features. The plan shall include the followings at a minimum:

- > Supplier name
- > Beckman Coulter part number
- > Specification including tolerance
- > Sample Size and measurement frequency of all CTQs
- > Inspection equipment used
- > Identify data and/or quality certificates to be sent with each shipment, if required

Expectation:	Suppliers will provide process capability data during product qualification.
Best Practice:	Suppliers should meet a Ppk of 1.33 for critical to quality characteristics and 1.00 for other control characteristics.

Additional Supplier Testing

The supplier may be required to provide test results for any testing requirements stated in the component qualification plan. Examples of performance testing are:

- > XRF Testing for RoHS compliance
- > Automated Optical Inspection (AOI) inspection of PCB
- > Takaya (Flying Probe Tester: In-circuit and functional testing)
- > Cable scan test: Continuity checkers and resistance measurements
- > HP 3070 Test: voltage, resistance, capacitance and inductance measurements

Supplier IQ/OQ/PQ

An IQ/OQ/PQ may be required when the supplier is building or installing equipment or molds to manufacture the component being qualified. High volume injection molded consumable equipment is an example.

Product Documentation

Supplier documentation should follow Good Documentation Practices. Suppliers may be requested to provide inspection data, product certifications, certificates of conformity, certificates of analysis, etc., for each manufactured lot of product shipped or for each service provided to Beckman Coulter. It is the expectation that suppliers maintain this data and have it readily available.

Control of Documents:

Suppliers must establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. The Supplier must have current revisions of documents available at all appropriate locations. Suppliers must have a documented procedure for the control and distribution of drawings and/or standards. Obsolete drawings must be destroyed or appropriately identified as such for limited distribution.

Control of Records:

Suppliers are expected to maintain production and quality records and any test results required as part of the specifications for each manufactured lot of a product for at least six (6) years from the date of delivery of the product, and will provide Beckman Coulter with copies of such records upon request. Records must be stored in an environment that will prevent deterioration, damage, or loss. Electronic record approvals and storage should comply with 21 CFR Part 11 requirements.

Incoming Inspection

Suppliers should exercise good manufacturing lot control methods. Product manufactured for Beckman Coulter should be clearly identified and tracked by lot. A lot is defined as one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. Data collected for process controls and final inspection should be collected, maintained and provided on a lot basis, if requested by Beckman Coulter.

Suppliers are expected to maintain adequate quality systems and processes for the provision of 100% conforming product so that incoming inspection by Beckman Coulter is not required. At the discretion of each Beckman Coulter site, incoming inspection may be implemented for ongoing verification of purchased product.

Expectation:	Suppliers will provide 100% conforming material.
Best Practice:	Suppliers should maintain adequate quality systems and processes for the provision of 100% conforming product so that incoming inspection by Beckman Coulter is not required.

Selected products that meet the requirements may be identified as potential candidates for a Dock to Stock (DTS) program at Beckman Coulter. After proven quality history and controls at the supplier, products may bypass incoming inspection at Beckman Coulter. The supplier would continue to maintain their process controls and final inspection at their own facility and maintain inspection data on all lots sent to Beckman Coulter for possible future reference. Product placement into this category is at the discretion of the supplier quality

representative and products may be removed from this program and re-enter incoming inspection status at any time. Each Beckman Coulter site will have specific requirements around which products may be considered for a DTS status.



Nonconforming Product

Beckman Coulter expects the supplier to maintain adequate quality systems and processes for the provision of 100% conforming product. Suppliers are expected to have active and effective internal processes to detect and prevent shipment of nonconforming product to Beckman Coulter.

Expectation:

Suppliers are expected to maintain adequate quality systems for the provision of 100% conforming product.

Suppliers are expected to have active and effective internal processes to detect and prevent shipment of nonconforming product.

Product known by the supplier to be nonconforming to specifications will not be shipped to Beckman Coulter without prior written approval. The supplier will submit a request for deviation to the appropriate contact within Beckman Coulter. This request will include a complete description of the nonconformance, the cause of the nonconformance, and the corrective action the supplier will implement to permanently resolve the root cause. A sample of the nonconforming product may be requested by Beckman Coulter for evaluation. Unless otherwise instructed, the supplier will hold the nonconforming product until receipt of Beckman Coulter approved deviation of authorization to ship.

Discrepancy reports will be generated for each instance of nonconforming purchased product found at Beckman Coulter. The supplier will receive notification of nonconformities that are clearly or potentially caused by the supplier through the site specific nonconforming product process.

Nonconforming product data is used to monitor and measure supplier's quality performance and to identify negative quality trends and specific areas for improvement.

Immediate Notification of Quality Issues

Suppliers are to verbally notify Beckman Coulter immediately of potential product quality escapes, and then follow up in writing, if the supplier becomes aware of any quality control or other information that suggests an adverse impact on products that have been provided to Beckman Coulter or on the ability of products to meet or to continue to meet specifications. Suppliers are to notify Beckman Coulter if product supplied to Beckman Coulter is under regulatory inspection or, in the course of a regulatory inspection, negative findings are made related to quality issues.

Expectation:

Suppliers are to notify Beckman Coulter immediately if they become aware of any adverse impact on the products provided to Beckman Coulter or on the ability of products to meet specifications.

Suppliers are to notify Beckman Coulter if product supplied is under regulatory inspection or, in the course of regulatory inspection, negative findings are made related to quality issues.

Customer Complaints

As needed, Beckman Coulter may require suppliers to assist with complaint investigations to investigate the cause of complaints initiated by Beckman Coulter customers. Corrective actions will be required if the product is deemed to be out of compliance with the specifications or attributed to a supplier related cause. Suppliers are expected to provide thorough and timely support to complaint investigations and resolution.

Expectation:

Suppliers are expected to provide thorough and timely support to complaint investigations and resolution.

Corrective Action

Suppliers are expected to have a robust system for corrective action. A robust corrective action process eliminates the cause(s) of the nonconformities in order to prevent reoccurrence. Suppliers shall investigate resolution to nonconformities using a process of their choosing. Some examples of widely used processes are 5 Whys, 8D, and DMAIC. Suppliers needing help in establishing such as system shall contact the applicable Supplier Quality representative for assistance.

Expectation:	Suppliers will have a robust system for corrective action.
Best Practice:	Suppliers should use a standard process for investigation of nonconformities, for example, 5 Whys, 8D, DMAIC.

Supplier Corrective Action Request (SCAR)

A formal request for corrective action will be issued to suppliers for high impact or repeat quality issues per the Beckman Coulter guidelines for escalation of quality or delivery issues.

The supplier is expected to identify the root cause for the problem, take containment action and countermeasures, and determine and implement appropriate and preventive corrective actions to eliminate the root cause.

The supplier's corrective action plan shall address at minimum the immediate correction (what was done to prevent further shipment of the defective product), the root cause (identifying the procedural or process element that fundamentally allowed the defect to happen), and the root cause corrective action (what action(s) are to be taken against the root cause, by when, and by whom). It is Beckman Coulter's expectation that the supplier will complete the SCAR process according these timelines:

- > Supplier SCAR response is to be completed within 30 days of the SCAR issue date with the results of the investigation, identification of root cause and corrective/preventive action plan.
- > Supplier SCAR corrective and preventive actions are to be completed within 90 days of the SCAR issue date. The supplier is expected to provide objective evidence of the actions taken.

Note: The supplier is to contact the Beckman Coulter Supplier Quality representative in advance of these dates if they are not able to meet this timeframe.

Expectation:	SCAR response to be provided within 30 days of SCAR issue date. SCAR corrective/preventive action to be completed within 90 days of SCAR issue date.
Best Practice:	SCAR response to be provided within 21 days of SCAR issue date. SCAR corrective/preventive action to be completed within 75 days of SCAR issue date.

Beckman Coulter requires follow-up on each corrective action submitted. Follow-up shall be performed in a timely manner by the applicable Beckman Coulter supplier quality designee to assure that the actions were taken as noted in the corrective action submission and were effective in addressing the root cause, thus preventing reoccurrence.

Beckman Coulter will provide the supplier with formal acceptance and closure of the SCAR.

Recurrence of the same nonconformity in product produced after implementation of a corrective action will result in issuance of another SCAR and may result in a change of supplier qualification status or an on-site audit until the issue is fully resolved.



SUPPLIER DEVELOPMENT

Continuous Improvement

Beckman Coulter follows the Danaher Business System (DBS) model. This is a systematic approach to driving improvement across all functions of the business. Beckman Coulter is willing to use DBS tools and processes with key suppliers to improve supplier performance.

The supplier is to establish ongoing programs intended to improve the quality of the products and the supplier's productivity. Beckman Coulter and the supplier will partner in discussing quality improvement activities, issues and opportunities. Both parties will agree to make themselves available to drive improvement that will benefit the applicable product, process, and/or service provided.

Cost Management

The supplier will work to drive product and process efficiencies in the manufacturing of the products or in the provision of services to target cost reductions of 5% annually on Beckman Coulter's total purchases. Reductions may be associated with, without limitation, productivity, contract product pricing, logistics costs, quality improvement, inventory, manufacturing efficiencies and new business opportunities.

Total Cost of Quality

Beckman Coulter looks at the overall cost of doing business with its suppliers, including the cost of poor quality. There are costs associated with processing, handling, and managing poor quality. Suppliers are expected to provide products which meet our requirements. The supplier is to utilize its best efforts to achieve a "zero-defect" objective and to deliver defect-free products to Beckman Coulter at the lowest possible cost as defined and measured by Beckman Coulter's system for measuring supplier performance.

Supplier Scorecards

Beckman Coulter uses Supplier Scorecards to assess the performance of selected suppliers by using Key Performance Indicators (KPIs) for Quality, On-Time Delivery, Cost Performance and Payment Terms. Innovation points are awarded to suppliers who are engaged with Beckman Coulter in significant projects.

Scores are assigned to each KPI, and a Total Score and the percentile rank is calculated. Follow up actions may be required as a result of this process. Refer to Appendix B for details of the Supplier Scorecard calculations.

Supplier Business Reviews

Selected suppliers may go through a review process as deemed fit by the applicable Beckman Coulter business unit. The purpose is to review supplier performance regarding quality, delivery, cost and innovation. It can include topics such as strategic sourcing and new product development. Both Beckman Coulter and the supplier provide overviews and any gaps are discussed.



FURTHER GUIDANCE

The Supplier Guidebook has been developed as a reference document for our supply base to provide an overview of Beckman Coulter's Global approach to Supplier Management. For additional guidance and site-specific requirements, contact your Beckman Coulter Procurement and/or Quality representative.



APPENDIX A, QUALITY AUDITS

A supplier nonconformity is defined as the non-fulfillment of specified requirements. It is a failure to comply with a provision of an approved policy, specification, procedure, regulation or standard, substantiated by observation, logical conclusion or objective evidence, singly or in combination.

Classifications of Nonconformities:

High Severity	<p>A nonconformity that indicates</p> <ul style="list-style-type: none"> > The absence of quality management system elements or processes required > An identified failure to meet product or service claims > An identified safety risk to user or patient > The identification of adulterated or mislabeled product > Repeat medium severity nonconformities during the audit
Medium Severity	<p>A nonconformity that indicates</p> <ul style="list-style-type: none"> > The incomplete and inadequate implementation of quality management system elements or processes or highly ineffective operation of one or more required quality management system processes or subsystems > Conditions with the potential for adverse effects on: product and user/patient safety, proper labeling and branding, adulteration and service quality > Repeat low severity nonconformities during the audit
Low Severity	<p>A nonconformity that indicates</p> <ul style="list-style-type: none"> > A weakness in or failure to fully implement a required quality management system element or process. Low severity nonconformities > May be isolated incidents of non-fulfillment of requirements > Typically do not indicate systemic failures of the quality management system > Are unlikely to result in product adulteration, misbranding, or in adverse safety effects for users/patients

Audit Scoring and Supplier Qualification Status

Note: Material Suppliers only. Service Provider approval is based on whether or not they can meet the predefined selection criteria.

All Audit / Self-Assessments start with a score of 100 pts. and deductions are made based on the audit results.

	DEDUCTIONS
High Severity Items unaddressed or missing	-41
Medium Severity Items unaddressed or missing	-8
Low Severity Item unaddressed or missing	-4

New / Prospective Supplier Status is determined as follows:

- Audit score of 100 - 75 = Approved
- Audit score of 74 - 60 = Conditionally Approved
- Audit score below 60 = Not Approved

Active Supplier Re-evaluation

- Audit score of 100 - 75 = Approved
- Audit score below 75 = Conditionally Approved

APPENDIX B, SUPPLIER SCORECARD CALCULATIONS

The Supplier Scorecard evaluates selected suppliers on the following Key Performance Indicators (KPI):

- > Total Score: The number of Points Earned divided by the Points Possible.
- > Quality Score: The Summation of Quality KPI's (Field Action Score, Non-Conformance Score, and SCAR Score).
- > Non-Conformance Rate: The number of supplier caused non-conformances divided by a logarithmic function of the lots received. Note: Development material is excluded.
- > SCAR: Count of Supplier Corrective Action Requests Issued failing to meet requirements including Part Quality, Labeling / Packaging, Delivery, Responsiveness, or Documentation. Note: Audit finding SCARs are excluded.
- > SCAR Rate: The number of SCARs divided by a logarithmic function of the lots received.
- > On Time Delivery: A measure of material availability when expected. This metric is calculated by the number of shipments without issues divided by the total number of shipments expressed as a percentage.
- > PPV: Purchase Price Variance is the difference in the Standard Cost (set annually) and the purchase price on the invoice and/or purchase order expressed as a percentage reduction of the spend. A positive number is favorable. The metric is capped at 4% savings for all suppliers.
- > Delivery Escapes: Events when material or finished goods have left Beckman Coulter control prior to discovery of a supplier caused defect. These events require external containment actions, for example, Stop Ship, Part Corrective Actions or Recall.
- > Innovation Points: awarded to suppliers who are engaged with Beckman Coulter in significant projects.



Diagnostics Division Headquarters
250 South Kraemer Boulevard
Brea CA 92821-6232
Phone: (714) 993-5321 or (800) 526-3821
Fax: (800) 232-3828

Life Science Division Headquarters
5350 Lakeview Parkway S Drive
Indianapolis IN 46268
Phone: (317) 808-4200 or
(800) 742-2345