

Waters values, quality policy, and expectations, as they apply to potential and existing suppliers



Expectations to Foster and Enable Strong Relationships

# Deliver Benefit™



“Deliver Benefit comes in a whole lot of different ways. You deliver benefit to your customers; you deliver benefit to your employees; you deliver benefit to your stockholders; you deliver benefit to the world. The secondary benefit, if the customer is having success, is that benefit is being delivered to somebody else. So, in effect, you change the world.”

James L. Waters, Founder

# Quality Policy

Waters™ provides innovative technological solutions that enable customer success, by consistently delivering safe, effective, and reliable products and services.

We maintain the effectiveness of our quality management system and foster an environment of continual improvement while meeting statutory and regulatory requirements.

We are dedicated to customer experience excellence through our core values, the engagement of our people, and our strategic vision.

# Foreword

Waters instrumentation, and the components, assemblies, software, and services our suppliers provide, are some of the most innovative and precise in the industry, allowing us to provide high-tech, high quality products to the world. Our customers expect the best and we expect the best from ourselves and our suppliers.

As a result, we are working to build strong partnerships with our suppliers. Waters views our suppliers as an extension of our own business. Communicating our values, expectations, and needs builds the foundation of a successful supplier-customer relationship.

The Global Supplier Quality Manual drives an overview of our expectations to further support strong relationships. Our goal is to grow through innovation, exceeding our customers' expectations, and providing the highest quality product in our industry. To meet that goal, strong customer-supplier relationships are a critical prerequisite, and as we grow, our suppliers grow, and everyone wins.



# Purpose and Scope

The purpose of the Supplier Quality Manual is to clearly communicate Water's values, quality policy, and expectations, as they apply to potential and existing suppliers.

Suppliers have direct impact to the quality of the product that is delivered to our customers. It is important to understand these expectations, identify gaps, and continuously improve to drive best-in-class practices. Waters is committed to establishing long-term partnerships with our suppliers, ensuring success by meeting or exceeding product and quality requirements.

If conflicting information of standards, specifications, or documentation from Waters Corporations arises, the following order of precedence applies unless otherwise noted contractually:

- Specification Requirements (Engineering Drawings, Product Requirements, etc.)
- Agreements (Quality, Purchase Orders, Supply, Etc.)
- Additional Contracts (OEM Requirements, other as needed)
- Waters Supplier Quality Manual



## Supplier Ethics

Waters values fair, reliable business relationships with suppliers and partners, and encourage those with whom we do business to share in our vision of responsible and ethical business practices. Waters expects their suppliers to adhere to all applicable laws, rules and regulations of the countries in which they operate. It is critical that our suppliers uphold the human rights of workers and treat them with dignity and respect while ensure a safe and healthy working environment.

The foundation of Waters values resounds in the practice of social and environmental responsibility. The expectations of the supply base are to demonstrate the highest standards of business ethics. As a responsible organization, Waters reserves the right to discontinue business relationships with suppliers that fail to conduct business in a legal, responsible, and ethical manner.



## Human Rights and Labor Standards Policy

Waters strives to have a positive social impact on the communities where we do business. We will work with our suppliers to ensure that local laws are followed with regards to wages, over time and that child or forced labor is not associated with the manufacture of our products or parts. Waters adheres to the UK Modern Slavery Act.





## Supplier Diversity

Diversity in the supply base is the foundation for Waters success in delivering benefit to our key stakeholders. A high-quality supply chain with a wide range of diversity helps Waters support and serve our customer base and the wide range of markets served by our instrumentations. Waters diversity program works with a wide range of businesses included but not limited to minority owned, non-profit, woman-owned, veteran owned, and small business organizations.



## Global Environmental Compliance

Waters adheres to and is certified to ISO 14001:2015. There is included in this certification the requirement and desire to work with suppliers to have and or move towards certification. Our Environmental Policy guides the principles and can be found on our web site at [www.waters.com](http://www.waters.com).

Our expectations for suppliers are to:

- Have health, safety, and the environment be considered in business decisions
- Fulfill all regulatory requirements to minimize the risk of their operations
- Preserve natural resources in operations by reducing pollution and waste reduction
- Set targets that improve performance and enhance environmental impact
- Provide stakeholders with timely information on the impact of their activities and programs related to HSE



All Waters suppliers are expected to support Waters in meeting the following requirements, as they apply:

- RoHS (EU Directives 2011/65/EU and 2015/863) prohibits the use of lead, mercury, cadmium, hexavalent chromium, certain poly-brominated flame retardants, and certain phthalates in electronics sold in the European Union. Certain uses of these materials are “exempt” from the RoHS requirements.
- REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals; EU Directive EC 1907/2006) requires that all companies importing manufactured goods (“articles”) into the European Union take steps to mitigate the use of Substances of Very High Concern (SVHC) in their products and to disclose any SVHCs used. The roster of SVHCs is updated every six months.
- The Dodd-Frank Conflict Minerals Rule requires all publicly-traded US-based companies to conduct due diligence of their supply chain to identify any tin, tungsten, tantalum, or gold (3TG) used in its products, and to take steps to ensure that any 3TG present is not sourced from “conflict regions” in the Democratic Republic of the Congo or the surrounding regions.

Waters suppliers are expected to understand these requirements and to communicate to Waters any challenges they may face in meeting them. Waters evaluates the design, sourcing, and manufacturing processes of every component used in our products against these requirements. Our product designs explicitly mandate RoHS compliance. Suppliers are expected to respond to Waters’ inquiries in a timely manner by providing documentation of each component’s REACH and RoHS status, and by completing a Conflict Minerals Reporting Template (CMRT).



# Global Product Stewardship

All Waters suppliers are expected to support Waters in complying with global transportation, hazard communication, import declarations, and chemical control laws including but not limited to:

- TSCA (The Toxic Substances Control Act)
- GHS (Globally Harmonized System of Classification and Labeling)
- DOT 49CFR
- IATA Dangerous Goods Regulation

To support Waters' efforts, additional information may be required in the form of certifications, full composition disclosures, raw material sourcing, and animal origin information. Suppliers are expected to provide this information in a timely manner upon request.

# Supplier Trade Compliance Expectations

It is the Corporate Policy of Waters Corporation to comply with the import and export regulations governing international business transactions of each country in which it conducts business. Waters' expectation is that all of its business partners:

- Comply with all import and export regulations.
- Provide and support Waters with critical information about the product being furnished such as country of origin, tariff codes, and dual use classification and when requested, information regarding the product to enable Waters to validate the classification.
- As Waters is a member of Supply Chain security initiatives (CTPAT, AEO), Business partners must have and be able to demonstrate business security practices to allow Waters to ensure that its global operations are consistent with the requirements of these programs. Waters may require suppliers to fill out a Supply Chain survey with details of their practices that address various areas of the supply chain security.



# Supplier Expectations

## QUALITY MANAGEMENT SYSTEMS

Waters expects our suppliers to implement and maintain an effective Quality Management System (QMS). Most purchased product suppliers are expected to have a QMS in place that is aligned with or similar to ISO9001, ISO13485, TS-16949, AS-9000, FDA 21 CFR Part 820, or other comparable standard or regulation. Updates to certifications should be communicated to Waters where appropriate.

Suppliers that provide Finished IVD Devices (OEMs) are required to have a QMS in place that complies with the requirements of ISO9001, ISO13485, FDA 21 CFR Part 820, and/or other comparable standard or regulation. OEMs that provide Finished IVD Devices are also expected to complete FDA establishment registration and device listing requirements per FDA 21 CFR Part 807, as applicable. Our OEM suppliers are expected to notify Waters Corporation of any Regulatory inspection. The OEM is expected to also provide timely notification to Waters Corporation if it receives a 483 Warning Letter, or any other finding from a Regulatory Agency.

For existing Suppliers that are not certified to ISO9001 or any other standard, it is preferred that they develop a plan to become certified and can demonstrate progress toward that plan. They are expected to follow Good Manufacturing Practices at a minimum.

## QUALITY AGREEMENTS

Waters Corporation may require that a Quality Agreement be in place with Suppliers whose product is deemed to be critical or high risk. The agreements outline the Supplier specific quality requirements. Once the need for a Quality Agreement is determined, it is expected that the Supplier will work with Waters to put this agreement in place.

### **CHANGE CONTROL AND NOTIFICATIONS**

Knowledge of any changes in product, process, or materials is essential to ensuring Waters maintains the quality of our Products. We recognize that continuous improvement efforts may require changes to manage cost, quality, delivery and technology. Waters requires that Quality and Sourcing are notified of changes to ensure that they do not have unintended effects on our products, our operations and, more importantly, our customers. In the event of significant changes, suppliers and Waters will work together to ensure proper qualification and transition planning.

### **SUB-TIERED SUPPLIER MANAGEMENT**

Waters expects our supplier to disseminate all quality expectations to their sub-tiered suppliers, derived in risk-based processes. Suppliers are responsible to ensure that the product that they provide is in compliance with all requirements as defined in the specifications provided by Waters.

Waters requires that our Suppliers have Purchasing and Supplier control processes in place to manage sub- tiers. These controls are expected to include:

- Nonconforming Product Control
- Corrective Actions Preventative Actions (CAPA)
- Material Traceability
- Product Qualification
- Material Acceptance
- Change Control
- Selection, Evaluation, Approval and Monitoring of Sub-Tiered Suppliers

Suppliers are responsible for ensuring the quality of all components and raw materials utilized in the manufacturing of Waters product. Waters may require a Supplier to engage with a specified sub-tier Supplier. In these cases, relationship management will be established between Waters and the Supplier.

**PRODUCT QUALITY EXPECTATIONS**

Waters Suppliers are responsible for ensuring that the products, processes or services they provide meet established specifications and quality requirements. Audits, approvals or verification by Waters Corporation of the Supplier's facility, quality system, process controls, acceptance activities, or other aspects of the site, does not absolve the Supplier of the responsibility to provide acceptable products or services. The expectation from Suppliers is to provide a high level of customer service, based on mutual trust and collaboration.

**RECORD RETENTION**

Records are expected to be stored in an environment that will prevent deterioration, damage, or loss, and are expected to be readily accessible to Waters, upon request. Suppliers are expected to make available any and all quality Records, in a timely manner, upon request by Waters, or any regulatory body such as the FDA. All quality Records are expected to be retained for a specified period of time equivalent to the design and expected life of Waters Products plus 15 years. Some examples of records include, but are not limited to:

- Device History Records (DHRs)
- Deviations (Process or Product)
- Inspection and Test Records (minimum of 5 Years)
- Complaints
- Nonconforming Product Records

### **PROCESS CONTROLS**

Suppliers are expected to have defined manufacturing processes with appropriate controls in place to ensure all products meet specifications. These controls should include, but are not limited to:

- A documented and qualified manufacturing process
- Monitoring of Process Parameters and Product characteristics
- Trained and Qualified Personnel with robust work instructions
- Criteria for workmanship (Dimensional and/or Functional Specifications)
- Monitoring and Measurement of Incoming, In-Process and Final Acceptance
- Material Lot Traceability and/or Serialization

Robust process controls will ensure the mitigation of quality issues, minimize risk, and reduce the cost of poor quality over time.

### **FIRST ARTICLE INSPECTIONS**

Waters may require a Supplier to provide a First Article Inspection (FAI) in the following activities (not limited to):

- New Product and or/ Process Qualification
- Product, Process, or Manufacturing Site Change
- Corrective Actions Preventative Actions
- Upon request from Waters

### **MEASUREMENT SYSTEMS ANALYSIS**

Waters Corporation suppliers are expected to develop and maintain capable, accurate and stable measurement methods and systems that meet the needs the specifications required by the design of the product they provide. Measurement System Analysis (MSA) is recommended in determining whether measurement or test equipment has sufficient accuracy, precision, or resolution to adequately provide information about process performance, or the effects of variation. One recommended tool is Gage Repeatability and Reproducibility (Gage R&R or GR&R).

**PROCESS CAPABILITY**

Waters expects their suppliers to develop and maintain highly capable processes to produce quality products consistently. Use of Statistical Process Control (SPC) for special part and process characteristics is recommended. Suppliers are recommended to use process capability indexes such as Cp / Cpk / Pp / Ppk.

**CORRECTIVE ACTION PREVENTATIVE ACTION (CAPA)**

Suppliers are expected to establish and maintain a CAPA system. The CAPA system is expected to include the trend analysis of quality data from returned Product or similar Product, to identify existing and potential causes of nonconforming product or other quality problems. It is expected that a formal investigations will be conducted to identify the root causes of the nonconformance. An outcome of the investigations is the defined actions needed to correct and prevent the nonconformance. Verification or validation of corrective and preventative actions for effectiveness need to be conducted to confirm that product is not adversely affected by the action(s) taken. The supplier's management should review all quality problems associated with CAPA activities.

**NONCONFORMING PRODUCT DISPOSITION**

Suppliers should have processes and procedure in place for the disposition of nonconforming product, including review and documentation of decisions. There should be proper segregation and quarantine of nonconforming product to prevent potential escapes to the customer. Procedures for rework, retest and re-evaluation of nonconforming product are expected to be agreed with Waters Corporation to ensure no adverse effects to Waters instrumentation. Suppliers are expected to document rework activities in the Device History Record (DHR) or equivalent (where applicable) and submit results of rework report to Waters, when requested.

### **ESD SENSITIVE PARTS, DEVICES, AND ASSEMBLIES**

Any components, materials, or assemblies that are susceptible to Electrostatic Discharge (ESD) damage should be controlled and processed at the supplier within an acceptable ESD program consistent with ANSI/ESD S20.20. Antistatic or static dissipative packaging material should be used for all ESD sensitive components and assemblies. The packaging must be clearly identified as containing ESD sensitive material.

### **IDENTIFICATION AND TRACEABILITY**

Suppliers are expected to establish and maintain a process for identifying and tracking Product during all stages of receipt, internal processing, test, storage, distribution, and shipment. Traceability to the lot / batch level is expected for any and all materials associated with the manufacture of the product, process information pertaining to the manufacture of the product, and details around the shipment of the product. Where required, suppliers are expected to track all traceability data under serialization of the product with Waters Corporation's direction.

### **PACKAGING, HANDLING, AND LABELING**

Suppliers are expected to have processes in place to ensure that damage, deterioration, contamination, or other adverse effects do not occur during the handling, storage and distribution of their product. Any special packaging and/or labeling requirements will be specified on Waters specification or purchase order. All other product should be shipped to Waters Corporation in a manner that assures proper protection from damage during shipment and proper identification of each shipment container. All packaging should be capable of meeting the test requirements of ISTA 1A or 1B. International shipments may require meeting ISTA 2A or 2B packaging test requirements. Individual containers should be clearly marked/labeled with the appropriate purchase order, Waters part number, serial number (if applicable) and any necessary lifting and/or handling instructions.



### NEW PRODUCT DEVELOPMENT

The expectation is that our suppliers be an active partner in the development of new product solutions and technologies. As an active partner, suppliers should support Waters by properly planning and staffing new product development projects adequately to support activities in the time frame needed. Investing in new technologies to improve product features/performance/capability/cost is fully supported by Waters Corporation and should be developed and qualified collaboratively. Waters is committed to supporting our suppliers by providing clear and regular communication through the development process, engaging suppliers and their expertise, and building long term successes for our supply base.

## Supply Base Management

### NEW SUPPLIERS

Waters Corporation is continually developing and introducing new technologies and solutions. Partnering with innovative, cost effective, high quality suppliers is critical to Waters future successes. New suppliers, dependent on their classification, will go through a qualification process that will include an assessment audit designed to evaluate the supplier's capabilities to meet Waters Corporation needs from a quality and cost perspective. Waters Corporation is committed to providing benefit to our customers and evaluates potential new suppliers based on:

- **Quality:** Capability to repeatedly produce product which meets or exceeds the product specifications and quality expectations
- **Technology:** Technological solutions in support of Waters Corporation Strategies
- **Customer Service:** Demonstrated high level of support and responsiveness, minimizing impact to Waters customers
- **Value:** Competitive pricing, year over year continuous improvement capabilities driving down cost, and active participation in inventory management initiatives
- **Corporate Responsibility:** Ethic and responsible business practices globally

## MONITORING OF PERFORMANCE

Waters Corporation is committed to providing suppliers with regular feedback through scorecards and business reviews concerning quality, delivery performance, service level, strategic goals, projects, and business needs. All Suppliers are objectively monitored and evaluated for quality, customer service and responsiveness, impact, sourcing performance, on-time delivery (OTD) performance, and overall risk. Scorecards are generated on delivery and incoming quality performance that are used to work with selected suppliers to improve their performance.

# Global Sourcing and Procurement

The Waters supplier selection process is structured to be a complimentary process between the Waters Sourcing Groups and Waters Quality with support from our Suppliers. Each organization has responsibilities and obligations to ensure the best suppliers are selected to produce the best quality product, at a competitive price, and to form a long lasting business relationship. For Suppliers, the goal is to support Waters with quality product, fulfill demand, and provide exemplary customer service in regular business interactions. The ultimate end goal is mutual success for all organizations.

Supplier selection by Waters involves a review of the supplier's business model, production capabilities, financial health, and Quality Management System. Waters looks for suppliers that can meet Waters needs over the long term, has a flexible and capable production process, high quality standards, available capacity, and can support multiple Waters manufacturing sites.

# Waters

**THE SCIENCE OF WHAT'S POSSIBLE.™**

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