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1. GENERAL

1.1 Introduction / Purpose

This manual provides an overview of the Quality Management System (QMS) at Waters Corporation, Milford, Massachusetts, USA and the Global Distribution Center.

The quality system scope defined pertains to the Waters Milford site and the Global Distribution Center. The QMS is based on the requirements of ISO 9001, ISO 13485, Canadian Medical Device Regulations and 21 CFR 820 in addition to meeting all applicable regulatory and customer requirements.

1.2 Applicable Milford Quality Management System Standards for Certification

ISO 9001:2015 Quality Management Systems - Requirements

ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for regulatory purposes

1.3 Milford Quality Management System Scope

Waters Milford has determined the quality management system scope appropriate to the Waters Milford site. ISO 13485 is applicable to all products, processes and services in the medical device sector while ISO 9001 is applicable to all products, processes and services in other industry sectors. In determining the quality management system scope for ISO 9001 and ISO 13485, consideration was given to the context of organization, external & internal issues, relevant interested parties and their requirements, and products and services of the Waters Milford site.

For ISO 9001:2015, the quality management system scope is:

> The Design, Development, Manufacture, Installation, Servicing, and Technical Support of High/Ultra Performance Liquid Chromatography (HPLC/UPLC) Instruments and Supplies, Mass Spectrometry (MS) Instruments and Supplies, and Applications Software for General Research use. The Design, Development, and Manufacture of Test Kits, Kit Reagents, Certified Reference Material, Calibrators, Controls, and Accessories for General Research use.

For ISO 13485:2016, the quality management system scope is:

> The Design, Development, Manufacture, Installation, Servicing, and Technical Support of High/Ultra Performance Liquid Chromatography (HPLC/UPLC) Instruments and Supplies, Mass Spectrometry (MS) Instruments and Supplies, and Applications Software for use in the In Vitro Diagnostic Medical Device Industry. The Design, Development, and Manufacture of In Vitro Diagnostic Test Kits, Kit Reagents, Calibrators, Controls, and Accessories.

1.4 Milford Quality Management System Non-Applicability of Requirements

Where any requirement of ISO 9001 or ISO 13485 is determined to be not applicable, Waters Milford will ensure that it does not affect Waters Milford ability or responsibility to ensure product conformity and enhance customer satisfaction.

ISO 9001:2015 Non-Applicability and Justification
None - All requirements are applicable.

ISO 13485:2016 Non-Applicability and Justification
7.5.5 Particular requirements for sterile medical devices Clause 7.5.5 is not applicable as Waters Milford products are not subject to sterilization. **7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems** Clause 7.5.7 is not applicable as Waters Milford products are not subject to sterilization and so not require sterile barrier systems. **7.5.9.2 Particular requirements for implantable medical devices** Clause 7.5.9.2 is not applicable as Waters Milford products are not implantable medical devices. **8.2.6 Monitoring and Measurement of Product** The monitoring and measurement requirement for implantable medical devices is not applicable as Waters Milford products are not implantable medical devices.

1.5 Quality Policy

Quality Policy
We provide 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.

The Quality Policy supports our Corporate strategic vision, provides a framework for setting quality objectives, and establishes our commitment to meet requirements/regulations. It also identifies our commitment to continually improve our products, processes and customer satisfaction. The Quality Policy is communicated, understood, and applied throughout Waters Milford through the Learning Management System, Town Halls, and site management reviews. As appropriate, it is made available on the Corporate Waters website to all relevant interested parties. The Quality Policy is reviewed annually for continuing suitability.

1.6 DEFINITIONS & ABBREVIATIONS Not Applicable

1.7 ROLES & RESPONSIBILITIES

Roles	Responsibilities
Waters Management	It is the responsibility of Waters Management to ensure implementation of this Quality Manual.

1.8 REFERENCES & RELEATED DOCUMENTS

Refer to Appendix II

2. COMPANY INFORMATION

Waters Corporation, headquartered in Milford, Massachusetts: develops, manufactures, services, and markets instruments, software, accessories, and supplies for analytical and preparative liquid chromatography (Ultra Performance Liquid Chromatography (UPLC), High Performance Liquid Chromatography (HPLC) and Mass

Spectrometry (MS) Systems. Waters' markets include In-Vitro Diagnostic medical device and non-medical device industries.
In addition, Waters Corporation has maintained a commitment to leading edge programs in the area of service, support, customer education, and compliance.

Customers
Our customers work from the early stages of discovery and development through final quality control and assurance. Our major market segments are: Pharmaceutical, biotechnology, semiconductor, chemical, environmental testing, and food and beverage companies; university laboratories, government and private analytical and research laboratories; defense and regulatory agencies; clinical laboratories, hospitals, dialysis centers, medical schools, and medical research institutes.

Research and Development

Waters' Milford Massachusetts, USA, product development includes the design of new liquid chromatography instruments, software for instrument control, applications, and accessories.

Since these instruments are characterized by a rapid rate of technological change. Waters makes significant investments in research, development and product improvements to meet/exceed customers' needs/expectations.

Manufacturing

Waters' manufacturing activities are conducted at the facilities in Milford Massachusetts. For some products, Waters uses contract manufacturer organizations (CMO) and original equipment manufacturers (OEM). Manufacturing activities include the production of parts and assemblies used in its products. Some of the parts are built by outside qualified suppliers. Products incorporate mechanical, electronic, chemical, and optical components. Prior to shipment to the customer: completed instruments and component products are extensively tested and evaluated to meet specified requirements.

The following is a breakdown of IVD products and Waters Milford operational responsibilities:

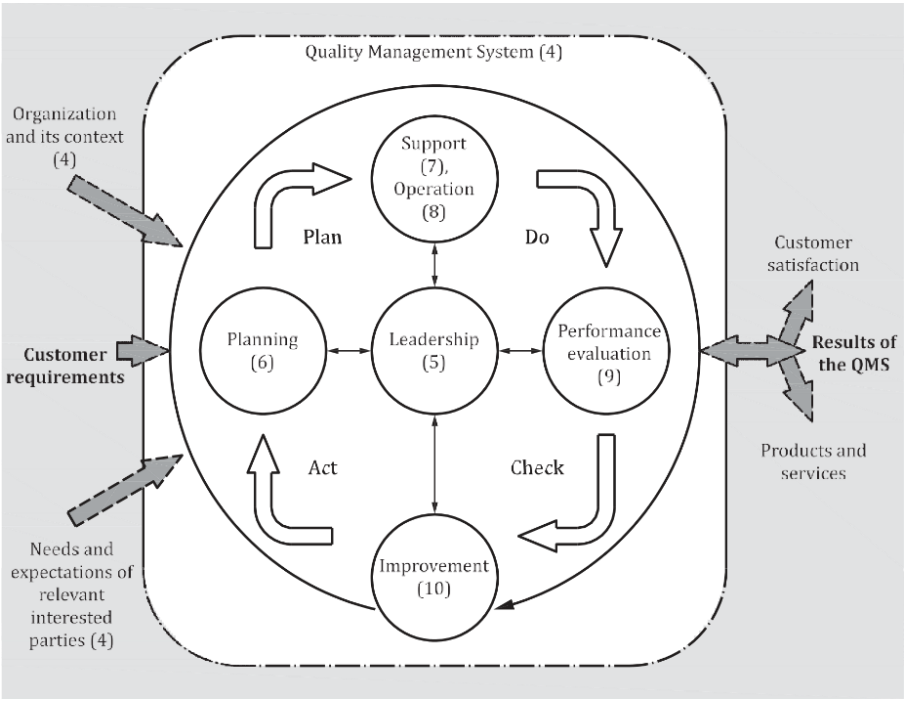
Product Family	Waters Milford Operational Responsibilities
Reagent Kits	Complaint Handling & Reporting
Chemistry Consumables	Design & Development, Complaint Handling & Reporting
Mass Spectrometers	Installation & Servicing, Complaint Handling & Reporting
Liquid Chromatography	Design & Development; Manufacturing; Installation & Servicing; Complaint Handling & Reporting
Software	Design & Development; Manufacturing; Installation & Servicing; Complaint Handling & Reporting

3. MILFORD QUALITY MANAGEMENT SYSTEM OVERVIEW

3.1 Process Approach

The QMS is based on the PDCA (plan-do-check-act) cycle, as depicted below:

- **PLAN**: Plan the processes, resources, goals, objectives, etc. to meet requirements and achieve intended outcomes.
- **DO**: Implement processes according to planned requirements.
- **CHECK**: Evaluate, Monitor, Measure processes and their results.
- **ACT**: Determine and implement improvements.



Extract from Figure 2: ISO 9001: 2015 - Representation of the structure of this International Standard in the PDCA cycle

3.2 Milford Quality Management System Processes

The QMS addresses all applicable requirements of ISO 9001& 13485 statutory and regulatory requirements. Waters Milford uses a risk based approach to determining the extent of the QMS documentation to achieve compliance and intended outcomes.

QMS processes are determined and implemented. The QMS process requirements will be defined in the specific policy and/or procedure documentation which will be supported as applicable by additional process specific documentation.

Waters Milford Business Operations Process Map (Appendix I) provides a high level overview of the interaction of essential Operation/Product Realization processes, Management processes, and Support processes, including alignment with planning and risk activities across all processes. Appendix II provides references to the QMS process policies and procedures.

4. CONTEXT OF WATERS MILFORD ORGANIZATION

Waters Milford Management evaluates and determines the organizational context of Waters Milford site, interested parties and their requirements, internal and external issues that are relevant to our business purpose, strategy, and QMS. The output from context of organization evaluation provides Waters Milford Management with an understanding of key factors that influence the business and QMS. The information is used as an input in determining quality management system processes, objectives, improvements, risk mitigations, etc. Waters Milford Management monitors and reviews information regarding interested parties and their requirements, and internal and external issues that are relevant. The context of organization information is subject to change as business and factors affecting our business and quality management system changes. This information is reviewed, at least annually, as part of the site management review process.

5. LEADERSHIP

5.1 Leadership Commitment

Waters Milford Senior Management demonstrates leadership and commitment to the Quality Management System. This is accomplished by:

- Being accountable for the QMS effectiveness.
- Maintaining & improving customer satisfaction.
- Establishing a quality policy and quality objectives compatible with the organization context and strategy.
- Ensuring the integration of the QMS into relevant business processes.
- Ensuring that QMS conforms to applicable requirements (standards/regulations) and meeting desired outcomes.
- Promoting the use of the process approach, risk-based thinking, and improvement.
- Providing the needed QMS resources.
- Communicating the importance of conformance with QMS requirements and effective quality management.
- Engaging, directing, and supporting people, as applicable to contribute to the effectiveness of the QMS.
- Supporting relevant management to demonstrate leadership in their area.
- Being customer focused ensuring customer and applicable statutory requirements are determined, understood, and met.
- That risks/opportunities affecting conformity and customer satisfaction are addressed.
- Ensuring that responsibilities and authorities for relevant roles are assigned, defined, documented communicated, and understood:
    - Including the interrelation of personnel managing, performing, and verifying work affecting quality
    - Including appropriate independence and authority
- Ensuring that planned changes are controlled and do not adversely affect the QMS integrity.
- Assigning a Management Representative with specific responsibility and authority for oversight of the QMS.

5.2 Management Representative

Management has appointed the Site Quality Director as the Quality Management Representative. The Management Representative is a member of Waters Milford management and will have responsibility and authority for the oversight of the QMS including:

- Ensuring the quality management system processes are documented.
- Reporting to Executive Management on the performance/effectiveness of the QMS and the need for any improvements.
- Ensuring the promotion of awareness of applicable regulatory requirements and QMS requirements.

6. PLANNING

Waters Milford manages the risks and opportunities relevant to the business, QMS, product, and service. This includes consideration of internal and external issues, the needs and expectations of interested parties, as well as business and quality management system processes. When actions are determined necessary to address risks / opportunities: They are planned and implemented to ensure the QMS achieves intended results. Additionally, Waters Milford verifies the effectiveness of any actions taken.

Quality Objectives are established at relevant functions, levels, and processes, as needed. Waters Milford Management ensures that appropriate planning is determined and implemented to achieve the specific objectives.

When changes are required to the QMS, Waters Milford Management ensures that the changes are implemented in a planned manner ensuring that the change does not adversely affect the integrity of the QMS.

7. SUPPORT

7.1 Resources

Waters Milford Management (hereafter identified as WMM) determines and provides appropriate resources to establish, implement, maintain, and improve the QMS. This improvement includes the operation and control of processes. In determining the required resources, consideration is given to the capabilities of, and constraints on, existing internal resources. This includes what can be obtained from external providers. Resources include provision of people, infrastructure, work environment, monitoring & measurement, and organizational knowledge. These resources are needed for the operation and control of processes in order to achieve conformity of products and services.

7.2 Competence, Awareness & Communication

WMM:

- Determines the competency of personnel performing work for Waters Milford that affects the performance and effectiveness of the QMS and ensures that personnel are competent.
- Ensures that personnel performing work for Waters Milford that affects the performance and effectiveness of the QMS are aware of the Quality Policy, relevant Quality Objectives and applicable QMS information.
- Establishes internal and external communications processes to ensure that appropriate communication takes place regarding the QMS; including its effectiveness.

7.3 Documented Information

WMM ensures that QMS documentation is established, implemented, and maintained using a risk based approach for QMS effectiveness. This will ensure conformity to applicable standards and regulations. The Waters Milford QMS documentation as outlined in Appendix III is controlled and consists of:

- Policy - provides an interpretation of a regulation or standard via guiding principles and defines minimum core requirements with the intentions and direction of an organization as formally expressed by its top management.
- Procedure - defines the process from input to output and describe “what happens” within the organization resulting in products (services) and show how we will fulfil the policy.
- Work Instruction - defines the execution to the requirements and describes who, what, how and when to execute a specific task.
- Form – a document to be completed to record data / results, to show that polices, procedure and work instructions have been followed.

- Template - a document that contains guidelines for the type of information required for each section, which is specific for each document family. Standard information is included. A template is a pre-formatted document that serves as a starting point for a new document.
- Records - documented information containing results achieved or demonstrating objective evidence of activities performed, events occurred, or statements made. Evidence of recorded data / results.

Data Integrity includes the following:

- Review by authorized personnel for suitability and adequacy
- Controlled distribution, access, retrieval and use
- Available and suitable for use, where and when it is needed
- Adequately protected, stored and preserved
- Control of change process
- Retention and disposal control
- Records retained shall be protected from unintended alterations
- Protecting any confidential health information to support any regulatory requirements
- ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate)

8. OPERATION

8.1 Operational Planning & Control

Waters Milford plans, implements, and controls processes to meet product and service conformity requirements, including any actions to address risks or opportunities. The planning and control includes:

- Determining requirements and quality objectives for the products and services.
- Determining and establishing criteria for processes and the acceptance of products/services.
- Including as applicable required verification, validation, monitoring, measurement, inspection & test, handling, storage, distribution, and traceability activities specific to the product.
- Determining and providing required resources.
- Implementing applicable controls for the processes.
- Determining, establishing, and maintaining required documentation to provide evidence of process conformity and the resulting product/service meets requirements.
- Determining products and services to be obtained from external providers and ensuring that outsourced processes are controlled.
- Controlling planned changes and reviewing the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
- Determining and establishing a process for risk management for product realization and maintaining records of risk management.

8.2 Requirements for Products & Services

Waters Milford primary focus is to be an active partner with our customers, understanding their environment and identifying solutions suitable to their needs and applications, which will both meet, and exceed, their expectations. Customer communication also includes but is not limited to:

- Providing information relating to products and services
- Handling enquiries, contracts or orders, including changes,
- Obtaining customer feedback and complaints, advisory notices, recalls,

- Handling or controlling customer property,
- Establishing specific requirements for contingency actions, when applicable.
- Product and/or service requirements including changes are determined and reviewed prior to acceptance.

8.3 Design & Development

Waters Milford plans and controls product design and development activities to ensure requirements are met. Design and Development projects are scaled based on the requirements and product complexity. Each design and development project includes planning, determining inputs, generating design outputs, applying appropriate design and development controls including review, verification, validation, transfer, change control, risk management activities, creation, and maintenance of design history files.

8.4 Control of Externally Provided Products, Processes and Services

Waters Milford defines, reviews, and communicates purchasing requirements to suppliers and ensures that externally provided products, processes, and services conform to requirements. Waters Milford is responsible for external provider conformity by determining controls to be applied and identifying/managing external provider risks. Waters Milford evaluates, approves, and re-evaluates suppliers to defined criteria and monitors their performance. Waters Milford determines and implements appropriate verification of externally provided products/processes/ services and addresses any supplier issues proportionate to the risk associated with the purchased product/service in compliance with applicable regulatory requirements.

8.5 Production & Service Provision

Waters Milford production and service processes are planned, documented, carried out, monitored and controlled to ensure product conforms to specification. Controlled production and service provision includes, but is not limited to:

- Standard Operating Procedures/Instructions/Plans/Specifications/Drawings - defining production methods, process/product characteristics, and acceptance criteria
- Qualification and use of suitable Infrastructure and Environment
- Measurement and monitoring of process parameters and product characteristics at appropriate stages
- Availability and use of suitable monitoring and measurement equipment
- Provision of competent personnel
- Implementation of defined operations for labeling and packaging
- Implementation of any required cleaning, install, and service activities
- Implementation of appropriate product preservation
- Implementation of any required validation and re-validation activities for processes, equipment, & software
- Implementation of any applicable actions to prevent human error
- Implementation of product release, delivery and post-delivery activities
- Maintaining appropriate identification and traceability
- Managing any customer property
- Establishing and retaining verified and approved records providing appropriate traceability
- Control of production process and document changes

8.6 Production & Service Release

Waters Milford conducts monitoring and measurements at appropriate stages to ensure that product and service requirements have been met. Products or services are not released until planned arrangements have been

completed or released under an authorized concession by relevant authority and/or customer where resulting product/service is accepted.

8.7 Control of Nonconforming Outputs

Waters Milford controls nonconforming product to prevent its unintended use or delivery including nonconformances detected after delivery and takes appropriate action based on the risk of the nonconformance.

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

Waters Milford determines and implements suitable methods for monitoring, measuring, analysis and evaluation to assess the performance and effectiveness of the QMS. Waters Milford ensures timely complaint handling and, as applicable, regulatory reporting in accordance with applicable regulatory requirements.

Customer satisfaction is evaluated to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

Data Analysis of the QMS process output will provide information regarding the processes, process performance results and their effectiveness.

9.2 Internal Audit

Waters Milford conducts internal audits at planned intervals to determine if the quality management system conforms to requirements (QMS, Contract, ISO 9001/ ISO 13485, statutory, regulatory, etc.). The Internal Audit process determines whether it is effectively implemented and maintained. Internal audit results are reported to applicable Management. Based on audit findings, correction or corrective action is determined and implemented.

9.3 Management Review

WMM reviews the performance of quality system periodically to assess the effectiveness, alignment with strategic direction, adequacy, and continuing suitability of the quality management system to identify any improvements needed. Relevant QMS input information/data will be reviewed/discussed and relevant output decisions will be documented relating to improvement opportunities, changes including new or revised regulatory requirements, resources, and risks.

10. IMPROVEMENT

Waters Milford will maintain and ensure the continued suitability, adequacy, and effectiveness of the QMS. Waters Milford determines opportunities for improvement and selects applicable improvement actions for implementation. Improvement actions may include product/service/process/QMS improvements including corrections, changes, corrective actions, preventive actions, risk actions, continual improvements, etc. Corrective actions or Preventive actions required to eliminate the cause/potential cause of nonconformities will be determined and implemented using a risk based approach proportionate to the effects of the nonconformities or potential nonconformities.

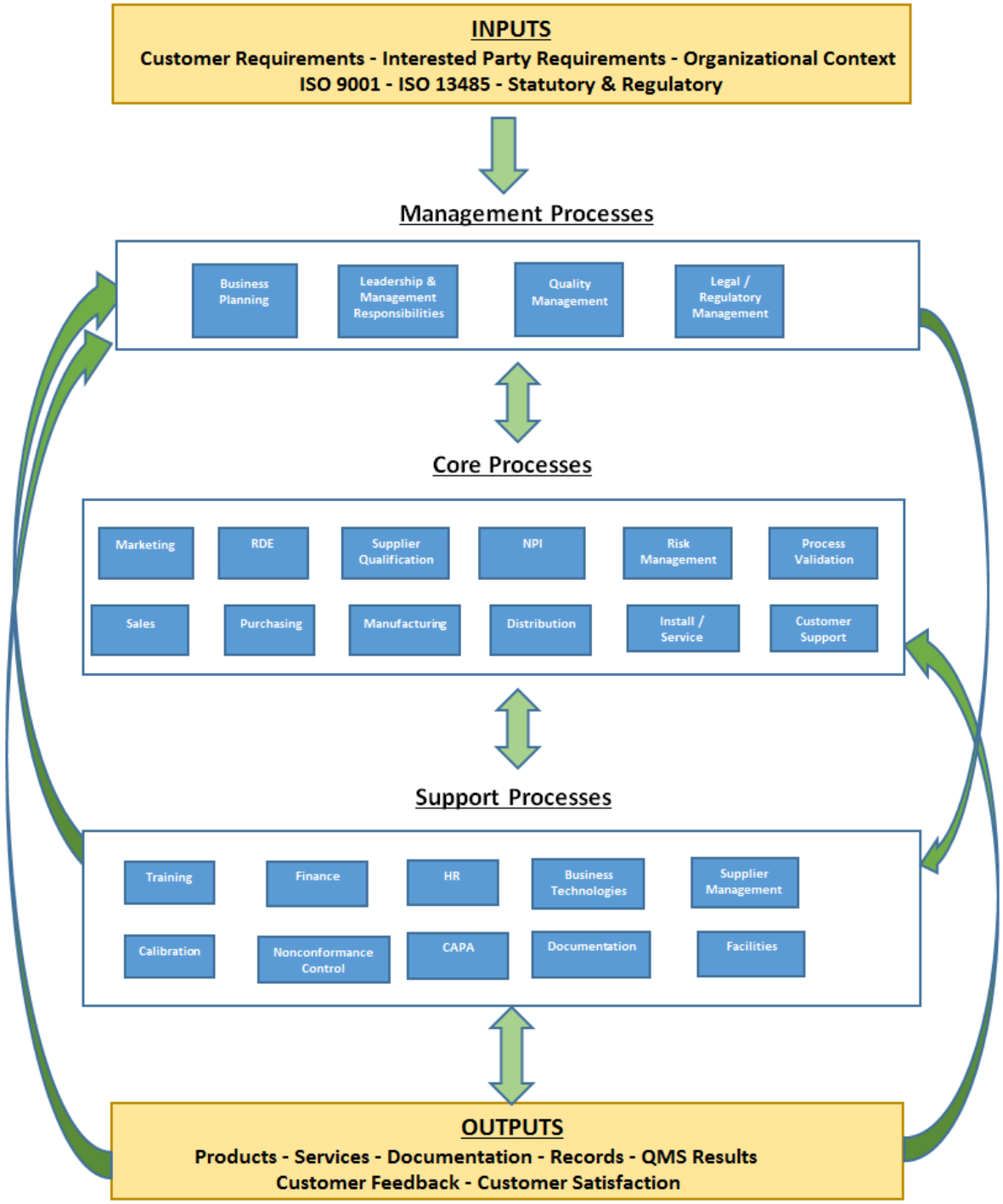
11. APPENDICES / ATTACHMENTS

Appendix I: Waters Milford QMS Processes & Interactions

Appendix II: Quality Documentation System Cross Reference

Appendix III: Quality Management System Document Hierarchy

APPENDIX I: WATERS MILFORD QMS PROCESSES & INTERACTIONS



∆ APPENDIX II: QUALITY DOCUMENTATION SYSTEM CROSS REFERENCE

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
4 Context of the Organization	4 Quality Management System	21CFR820.5	Sections 2, 3, 5, 6, 7; 28 – 31; 32 – 34; 43	Management Core	WAT000001QM Waters Business Operations Quality Manual 730001504 Outsourced Process List 730001930 Milford Management Review (MMR)
4.4 Quality Management System and its Processes 7.5 Documented Information	4.2 Documentation Requirements	21CFR820.20e, 40 21CFR820.180, 181, 184, 186 21 CFR Part 11	Sections 10-20, 32, 55, 56 No specific requirement	Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730002900 Global Document Management Policy 730001877 External Standards and Regulations Log WAT000050MP Waters Record Retention Corporate Policy 730002947 Milford Quality Record Retention Schedule
5 Leadership 5.1 Leadership and Commitment 5.2 Policy	5 Management Responsibility 5.3 Quality Policy	21CFR820.20a	No specific requirement	Management Core Support	730000639 Quality Policy WAT000103MP Executive Management Review Procedure 730001930 Milford Management Review (MMR) 730000945 Global Training Policy
6 Planning	5.4 Planning	21CFR820.20a,d	No specific requirement	Management Core Support	WAT000004MP Production Planning 730001296 Quality Planning 730000945 Global Training Policy
5.3 Organization Roles, Responsibilities and Authorities	5.5 Responsibility, Authority and Communication	21CFR820.20b1,b3	No specific requirement	Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730001296 Quality Planning 730000945 Global Training Policy
9.3 Management Review	5.6 Management Review	21CFR820.20c	No specific requirement	Management Core Support	WAT000103MP Executive Management Review Procedure 730001930 Milford Management Review (MMR) 730000945 Global Training Policy
7 Support 7.2 Competence	6 Resource Management	21CFR820.25, 70	No specific requirement	Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730000945 Global Training Policy
7 Support	6.3 Infrastructure 6.4 Work Environment & Contamination Control	21CFR820.70a,c-h, 21CFR820.75, 21CFR820.170	Section 14 No specific requirement	Management Core Support	730000169MP Corporate BT Disaster Recovery Process 730001503 Facilities Preventive Maintenance Procedure

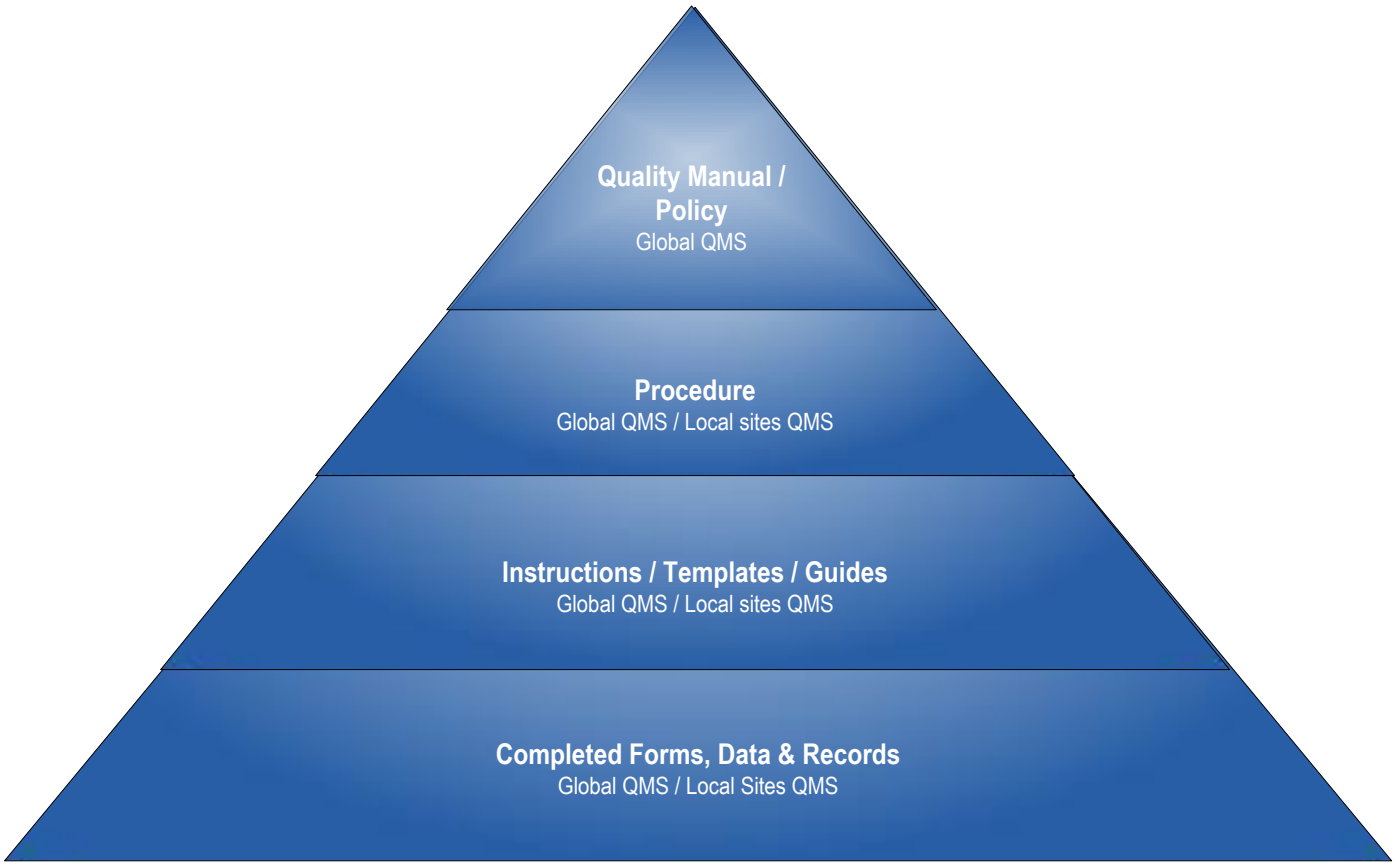
ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8 Operation	7 Product Realization	21CFR820.20d, 21CFR820.30h, 21CFR820.80a	Sections 9, 10, 32	Management Core Support	730000370MP Global Policy – Product Risk Management 730000945 Global Training Policy
8 Operation	7.2 Customer Related Processes	21CFR820.30c	Sections 2 – 5; 6, 7, 8, 9; 10 – 20; 21 – 23; 28 – 31; 32, 34, 43; 52 – 56; 57, 58; 59 – 62; 63, 64; Schedule 1 No specific requirement	Management Core Support	730001236 WPDP Market Requirements Document Procedure 730000301SO Service Plan Support 730000945 Global Training Policy
8.3 Design and Development of Products and Services 8.3.5 Design and Development Outputs 8.3.6 Design and Development Changes	7.3 Design and Development 7.3.4 Design and Development Outputs 7.3.5 Design and Development Review	21CFR820.30a-j	No specific requirement	Management Core Support	WAT000104MP DPG Software Development Process 730000355MP SDMS Software Development Life Cycle (SDLC) 730001095 Global Design Control Policy 730000985 Waters Product Development Process 730000454MP Corporate Instrument Development Process 730002180 Global Services Product Development Procedure 730000339MP Worldwide Software Development Procedure 730000945 Global Training Policy
8.3.3 Design and Development Inputs	7.3.3 Design and Development Inputs	21CFR820.30c,h 21CFR820.30c	Sections 10, 11, 13; 14 – 16; 18, 19, 32	Management Core Support	730001236 WPDP Market Requirements Document Procedure 730000945 Global Training Policy
8.3.4 Design and Development Controls	7.3.6 Design and Development Verification	21CFR820.30f,g,j	No specific requirement	Management Core Support	WAT000215MP Validation & Verification Policy WAT000216MP Design Verification Process 730000945 Global Training Policy
8.3.4 Design and Development Controls	7.3.7 Design and Development Validation	21CFR20.30g 21 CFR820.70i	Sections 12, 20, 32	Management Core Support	WAT000215MP Validation & Verification Policy WAT000217MP Design Validation Process 730000945 Global Training Policy

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8.3.6 Design and Development Changes	7.3.8 Design and Development Transfer 7.3.9 Control of Design and Development Changes 7.3.10 Design and Development Files	21CFR820.30h,i,j 21CFR820.70b	Section 1: MDR definition of a "significant change"; Sections 34, 43	Management Core Support	WAT077822SO Production Engineering Change WAT077824SO Development Engineering Change 730002069 Design History File, Index (CIDP Only) 730000945 Global Training Policy
8.4 Control of Externally Provided Processes, Products and Services	7.4 Purchasing	21CFR820.50a,b	No specific requirement	Management Core Support	WAT000016MP Global Supply Chain Management WAT077817SO Managing the Qualified Suppliers List WAT078475SO Auditing of Suppliers 730002112 Supplier Quality Planning Procedure WAT077814SO Supplier Score Card (SSC) WAT077940SO Incoming Inspection Procedure 730000945 Global Training Policy
8.4 Control of Externally Provided Processes, Products and Services	7.5 Product and Service Provision	21CFR820.70a,c-h, 21CFR820.75, 21CFR820.170, 21CFR820.200	No specific requirement	Management Core Support	WAT000018MP Returned Goods Process WAT000340MP GSS Service Support Process WAT000342MP Service Support Activities for New or Revised Products 730000945 Global Training Policy
8.4 Control of Externally Provided Processes, Products and Services	7.5.6 Validation of Processes	21CFR820.75	Section 17	Management Core Support	730000617 CSV: Global Software Tool Validation Policy 730000838 Process V: Process Validation Procedure 730001835 Process Validation Procedure for Milford 730000945 Global Training Policy
8.5.2 Identification and Traceability	7.5.8 Identification 7.5.9 Traceability	21CFR820.60, 21CFR820.65 21CFR820.80e	Sections 21, 52 – 56	Management Core Support	WAT000020MP Data Products Serial Number Procedure WAT079006MP Instrument Serial Number Procedure 730000504 Finished Product Labeling Requirements 730000945 Global Training Policy
8.5.3 Property Belonging to Customers or External Providers	7.5.10 Customer Property	None	No specific requirement	Management Core Support	WAT000018MP Returned Goods Process 730000945 Global Training Policy

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8.5.4 Preservation	7.5.11 Preservation of Product	21CFR820.120 21CFR820.130, 21CFR820.140, 21CFR820.150, 21CFR820.160	Section 14	Management Core Support	WAT000046MP Stockroom Material Handling & Storage Practices 730003902 Packaging Procedure 730003893 Receiving Procedure
8.5 Production and Service Provision	7.6 Control of Monitoring and Measuring Equipment	21CFR820.72	No specific requirement	Management Core Support	730001799 Operating Procedure, Calibration and Preventive Maintenance
8.5 Production and Service Provision	8 Measurement, Analysis and Improvement	21CFR820.250	No specific requirement	Management Core Support	730000859 Statistical Methods and Techniques 730000861 Analysis of Data Procedure
7.1.5 Monitoring and Measuring Resources	8.2 Monitoring and Measurement 8.2.1 Feedback 8.2.2 Complaint Handling	21CFR820.198	Section 57	Management Core Support	730001385 Global Escalation Procedure WAT000103MP Executive Management Review Procedure 730001930 Milford Management Review (MMR) 730000394MP Global Policy – Complaint Handling 730000680 Device Master Record
9.2 Internal Audit	8.2.4 Internal Audit	21CFR820.22	No specific requirement	Management Core Support	WAT078440SO Quality System Internal Audit Procedure
8.6 Release of Products and Services	8.2.5 Monitoring and Measurement of Processes	21CFR820.22, 21CFR820.250	No specific requirement	Management Core Support	730000859 Statistical Methods and Techniques 730000861 Analysis of Data Procedure
8.5.1 Control of Production and Service Provision	8.2.6 Monitoring and Measurement of Product	21CFR820.80b-e, 21CFR820.250 21CFR820.86	No specific requirement	Management Core Support	WAT078433SO Receiving Incoming Material WAT000036MP Machining Inspection WAT000235MP Reliability Engineering Management Procedure
8.7 Control of Nonconforming Outputs	8.3 Control of Nonconforming Product	21CFR820.90a,b	No specific requirement	Management Core Support	730000970 Global Nonconformance Policy 730001028 Nonconforming Product Process – Milford WAT000506SO Corporate Procedure Product Recall WAT000074MP Stop Ship Procedure 730000634 Global Product Improvement Procedure

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
9.1.3 Analysis and Evaluation	8.4 Analysis of Data	21 CFR 820.250	No specific requirement	Management Core Support	730000861 Analysis of Data Procedure
10 Improvement 10.2 Nonconformity and Corrective Action 10.3 Continual Improvement	8.5 Improvement 8.5.2 Corrective Action 8.5.3 Preventive Action	21CFR820.20c, 21CFR820.100, 21CFR820.198	Sections 57, 58, 59 – 62; 64, 65	Management Core Support	730001930 Milford Management Review (MMR) WAT000103MP Executive Management Review Procedure 730000394MP Global Policy – Complaint Handling 730000548 Policy: Global Corrective Action & Preventive Action (CAPA) System 730000622 Corrective and Preventative Action

APPENDIX III: QUALITY MANAGEMENT SYSTEM DOCUMENT HIERARCHY



DOCUMENT HISTORY

(Note: Complete Document History may be obtained via the Document Management System.)

VERSION:	32	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
SUMMARY OF CHANGE: UPDATED TO CURRENT GLOBAL POLICY TEMPLATE TO INCLUDE SECTIONS 1.6, 1.7, 1.8. SECTION 1 TO INCLUDE GDC. SECTION 5.2 REVISED FROM SITE QUALITY MANAGER TO SITE QUALITY DIRECTOR. SECTION 7.3 TO ALIGN WITH GLOBAL DOCUMENT MANAGEMENT PROCESS. APPENDIX II UPDATED TO INCLUDE APPLICABLE DOCUMENT # / DESCRIPTION; APPENDIX III UPDATED TO ALIGN WITH GLOBAL DOCUMENT MANAGEMENT PROCESS.					
VERSION:	31	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
SUMMARY OF CHANGE: Document title to 730000680 corrected. Multiple changes to Appendix II in order to align with Appendix I.					