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1 PURPOSE

The purpose of this procedure is to establish and maintain a procedure for Supplier Control by Quality Management for Waters Pacific Pte Ltd (WPPL).

2 SCOPE

The scope of this procedure is applicable to product supplier such as Contract Manufacturer and Service provider and/or any outsource process / components that affects Waters product conformity.

3 DEFINITIONS AND ABBREVIATIONS

Term / Abbreviation	Definition
3PL	Third Party Logistics
Business Risk	The risk to Waters based on the supplier's inability to produce or deliver quality products as specified by our purchase order.
Clinical Risk	The probability of harm to a patient or Instrument from a defective component or assembly from a supplier.
CMO	Contract Manufacturing Organization. Designated and approved manufacturers of Instrument products under the control of Waters Pacific Pte Ltd with agreement with Waters Corporation.
CAPA	Corrective and Preventive Action
DC	Distribution Centre
ECO	Engineering Change Order
QM	Quality Manager
Qualified Supplier List	The qualified Supplier List (QSL) refers to the approved list of suppliers.
SQE	Supplier Quality Engineer
Supplier Quality Audit	An on-site review by Waters personnel of a supplier's quality systems, management procedures, operations and activities relating to the quality of a product or service. Refer to Quality Auditing SOP.
Supplier Self - Assessment	A self-assessment or audit completed by the suppliers. The Self-Assessment will document the supplier's quality systems, management procedures, operations and activities relating to the quality of a product or service.
Deviation	A non-permanent, planned departure from existing requirements for processes and products. In the context of this document, also known as Temporary Manufacturing Deviation (TMD).
WPPL	Waters Pacific Pte Ltd. Subsidiary of Waters Corporation supporting Waters Corporation in managing contract manufacturers and third-party logistics services in distribution of Waters' products.
Waters Milford	Design authority for Waters' Liquid Chromatography Products based in Milford, MA USA.
Waters Wilmslow	Design authority for Waters' Mass Spectrometry Products based in Manchester UK.
APAC	Asia Pacific
Product	output of an organization that can be produced without any transaction taking place between the organization and the customer
Supplier	organization that provides a product or a service

4 ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Quality	Plan, schedule and lead Supplier Quality Audit. Review and approve Supplier Change Control Plan and Supplier Change Closure Approval.
Procurement	Managing Supplier Change Control request from suppliers Review and approve Supplier Change Control Plan, Supplier Change Closure Approval, and notify the status of Supplier Change Control to supplier
Manufacturing	Review and approve Supplier Change Control Plan
Supply & Distribution	Review and approve Supplier Change Control Plan
Product Planning	Review and approve Supplier Change Control Plan

5 REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
WPPL-SP-02	Control of Documented Information
WPPL-SP-03	Quality Auditing
WPPL-SP-05	Feedback SCAR and CAPA
WPPL-SP-08	Quality Agreement / Plan Procedure
730005499	WPPL Deviation
N/A	ISO 13485 (Medical Devices – Quality Management Systems)
N/A	ISO 9001 (Quality Management System Standard)
730005455	Global Supplier Change Control Procedure
N/A	Qualified Supplier List_APAC

6 FORMS

Doc No:	Document Title
730000443	Risk Assessment
730000442	Supplier profile questionnaire
730006720	Supplier Change Control Form
730007682	Supplier Self-Assessment

6.1 RECORDS

Records shall be retained in accordance with WAT000050MP, Waters Corporate Record Retention Policy and WPPL-SP-02, Control of Documented Information Procedure.

Ref No:	Description of Record
730000443	Risk Assessment

730000442	Supplier Profile Questionnaire
730006720	Supplier Change Control Form
730007682	Supplier Self-Assessment

7 HEALTH & SAFETY

Should anyone following this instruction identify a health and safety hazard which has not been highlighted in this section and/or within the body of the text, they should notify their Manager/ Supervisor immediately.

7.1 Equipment/Materials of Use Required

Not Applicable

8 PROCEDURE

WPPL establish and maintain quality agreement with critical suppliers that requires to be evaluated and control for outsource processes and products that affect Waters product conformity.

8.1 New Supplier Qualification Requirements

Suppliers classified as critical shall be qualified based on requirements below:

- On-site Quality Audit and result shall be satisfactory.
- 730000442 Supplier Profile Questionnaire
- 730000443 Risk Assessment

Suppliers classified as sub-critical shall be qualified based on requirements below:

- On-site Supplier Audit and result shall be satisfactory (optional).
- 730007682 Supplier Self-Assessment (if no on-site audit)
- 730000442 Supplier Profile Questionnaire
- 730000443 Risk Assessment

Suppliers classified as standard shall be qualified based on requirements below:

- On-site Supplier Audit and result shall be satisfactory (optional).
- 730007682 Supplier Self-Assessment (optional)
- 730000442 Supplier Profile Questionnaire
- 730000443 Risk Assessment (optional)

8.2 Supplier Evaluation and Control Criteria

8.2.1 Monitoring Control

For Supplier classified as critical, WPPL shall have following performed

- 1) Onsite Audit / Remote Audit / Supplier Self-Assessment– Minimum every 2 years
- 2) Periodically monitoring using supplier scorecard.
- 3) No monitoring required for special process supplier.

For Supplier classified as sub-critical, WPPL shall have following performed but not limited to

- 1) Onsite Audit / Remote Audit / Supplier Self-Assessment – Minimum every 3 years
- 2) Periodically monitoring using supplier scorecard (optional)

For Supplier classified as standard, WPPL shall have following performed but not limited to

- 1) Onsite Audit / Remote Audit / Supplier Self-Assessment– Minimum every 6 years (optional)
- 2) Periodically monitoring using supplier scorecard (optional)

8.2.2 Onsite Audit

All onsite audits shall be planned and carried out by WPPL quality auditors. Onsite audit shall be carried out in accordance to WPPL Quality Auditing procedures and the audit criteria may include but not limited to the following:

- a) Agreed Quality Plan/ Agreement/ Commercial contract agreed between both parties.
- b) Process/ Product audit based on WPPL QMS requirements of the Product/ Service purchased by WPPL if the supplier is not certified to the required Quality Management System.
- c) Onsite Audit is performed per WPPL-SP-03, Quality Auditing.

8.2.3 Joint Onsite Audit with CMO (where applicable)

All Joint audits shall be planned and lead by CMO quality auditors. Joint audits shall be carried out in accordance to CMO Quality Auditing procedures

8.3 Supplier Classification

Suppliers in Qualified Supplier List_APAC are classified with respect to Business and Clinical Risk. The purpose of classifying suppliers is to determine the supplier qualification requirements and the extent of supplier control that will be implemented.

If the suppliers Risk Classifications are different between Business and Clinical, the more stringent Supplier Classification will be followed. For example: If the supplier has critical business risk and sub-critical clinical risk, the overall risk classification shall be critical.

Suppliers for Business Risk are classified into one of these three possible groups:

CLASSIFICATION	CATEGORY	REASON
Critical	Product Related Strategic	Sole / Custom Source of Supply
Sub-critical	Product Related Strategic / Product Related General / Non-Product Related (Facilities, Service & Consumables) / IT Suppliers	Financial Stability or Technology or Pricing / Cost
Standard	Product Related General	Custom Source of Supply or Financial Stability or Technology or Pricing / Cost

Suppliers for Clinical Risk are classified into one of these three possible groups:

Critical Suppliers

Materials provided by these suppliers are tested/ inspected at the supplier, placed into their manufacturing process. Acceptance is performed at the supplier's site then shipped to Waters. Materials from these suppliers could include but not limited to finished instruments, power supplies, printed circuit boards, lamps, flowcells, engineered seals, etc. Therefore, risk with these suppliers is high. Any supplier providing Waters with parts/assemblies that are intended to meet the Waters Critical Clean™ specification as- received must be designated as a Critical Supplier.

Sub-critical Suppliers

Materials provided by these suppliers are inspected/ tested at the supplier's facility, placed into Waters manufacturing process, verified during in process and final inspection. Some of these materials could be shipped to customers as spares; these materials would be accepted by the field service engineer at customer's sites after the instrument repaired. Materials from these suppliers could include but not limited to valves, vacuum pumps, optics etc. Therefore, risk with these suppliers is medium.

Standard Suppliers

Materials provided by these suppliers are inspected at the supplier's facility, verified at Waters, placed into the Waters manufacturing process. Acceptance is performed at subassembly and instrument level test at Waters. Materials from these suppliers could include but not limited to, sheet metal, machined parts, cabling, plastic parts etc. Therefore, risk with these suppliers is low.

8.4 Deviation

WPPL facilitates the release of Deviation to the respective suppliers.

In the event where the supplier raises a deviation request related to Waters Product, the supplier is to channel it to WPPL so that WPPL will determine its justification. If the deviation request is deemed acceptable, it shall follow procedure WPPL Deviation - 730005499 where Waters will be responsible for reviewing and approving the part/product/process changes to release a Deviation.

8.5 ECO

WPPL facilitates the release of ECO to the respective suppliers. WPPL facilitates to perform part/product/process qualification for changes and new introduction to existing design instruments, parts changes where applicable.

8.6 SUPPLIER CHANGE CONTROL REQUEST

- a) Supplier Change Notification
 - In the event where the supplier raises a change request related to Waters Product, the supplier shall fill up Supplier Change Control form (Document no. 730006720) and channel it to WPPL Procurement.
- b) Supplier Change Control
 - Upon receive the Supplier Change Control form from supplier, WPPL Procurement shall assign the Change Ref No. to individual request base on format PCN YY-MM-NN, YY = Year; MM = Month; NN = Running no. For example: PCN 20-01-01.
- c) Supplier Change Control Plan Approval

- Procurement should initiate a meeting to discuss on the change request together with relevant function which include of Quality, Manufacturing, Supply & Distribution, Test, Product Planning and packaging.
- Supplier change control plan approval shall follow the personnel below or relevant designee

Responsible Person / Designee	Quality Engineer	Manufacturing Engineer	Supply & Distribution Executive	Procurement Engineer	Test Engineer	Product Planner	Packaging Engineer
Supplier							
Contract Manufacturer	✓	✓		✓	✓*	✓**	✓***
Sub-level Supplier	✓	✓****		✓	✓*	✓**	✓***
3PL	✓		✓	✓			✓***
Calibration and services	✓			✓	✓*		

* Require approving when there are changes related to testing

** Require approving when there are changes related to change of Country of Origin

*** Require approving when there are changes related to packaging

**** Require approving when there are changes related to the process

- d) Supplier Change Closure Approval
 - Procurement shall channel change request to Waters Milford or Waters Wilmslow for changes that will manage under Engineering Change Control process.
 - Quality Engineer and Procurement Engineer will review evidences provided by supplier and sign off Supplier Change control form Section 8 Change Closure if there is no further concern.
 - Procurement Engineer will inform the change to the supplier.

8.7 COMMUNICATION OF SUPPLIER QUALITY ISSUES

CMOs are responsible to escalate quality issues that impact shipment to WPPL in timely manner to avoid any business risk. WPPL Quality is responsible for cross-site communication when the quality issue impacting other sites.

9 APPENDICES / ATTACHMENTS

9.1 Supplier Quality Scorecard Rating (For CMO only)

Weightage	30%	20%	30%	20%
Category Rating	SCAR/ Recall/ Stop Ship (%)	SCAR Response Date (Calendar days)	Overall First Pass Yield (%)	Audit/Assessment Results (NC count)
5 Excellent	0	<45	>2%	0
4 Good	<0.01	45 to 60	>1 to 2%	1-3
3 Acceptable	0.01 to 0.02	61 to 75	>-1 to 1%	4
2 Need Improvement	0.021 to 0.035	76 to 90	≥-2 to -1%	5-6
1 Poor	>0.035 / Recall / StopShip / CAPA	>90	<-2%	>6

9.2 Supplier Quality Scorecard Rating

Weightage	30%	25%	40%	5%
Category Rating	SCAR/Recall/Annual Audit Results (Count)	Incoming Inspection (LAR)	Line Reject Rate (DPPM)	On Time Delivery (OTD%)
5 Excellent	0	100	≤3	100
4 Good	-	-	≤233	90 ≤ OTD < 100
3 Acceptable	1-2	80-99	≤1350	75 ≤ OTD < 90
2 Need Improvement	3-5	-	≤6210	50 ≤ OTD < 75
1 Poor	>5 / Recall / Major Audit Finding / CAPA	<80	>6210	< 50 / Impact Waters Shipment

9.3 Supplier Quality Scorecard Rating (For 3PL)

Weightage	15%	20%	15%	15%	20%	15%
Category Rating	Inbound Performance (%)	Order Performance (%)	Inventory Accuracy (%)	Warehouse Performance (PPM)	Outbound Performance (PPM)	CAPA / SCAR / 8D
5 Excellent	100%	100%	100%	0	0	0
4 Good	≥95	≥95	≥99	≤120	≤16	1
3 Acceptable	≥90	≥90	≥98	≤240	≤32	2
2 Need Improvement	≥85	≥85	≥97	≤500	≤48	3
1 Poor	<85%	<85%	<97%	>500	>48	>3

9.4 Supplier Quality Scorecard Rating (For Freight Forwarder Only)

Weightage	20%	20%	20%	20%	20%
Category Rating	Export Transit Time (%)	Import Transit Time (%)	Shipment Quality Control (%)	AED Permit Declaration (Count)	CAPA / SCAR (Count)
5 Excellent	>98%	>98%	≤1%	0	0
4 Good	≥95	≥95	≤3	1	1
3 Acceptable	≥90	≥90	≤5	2	2
2 Need Improvement	≥85	≥85	≤7	3	3
1 Poor	<85%	<85%	>7%	>3	>3

DOCUMENT HISTORY

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

VERSION:	10	ORIGINATOR:	Bethany Lim	Change ID:	N/A
DESCRIPTION OF CHANGE: Use updated template. Section 2: Rephrase to reflect current practice. Section 3 Removed IMTE and add APAC, revised CAR to CAPA Section 4 Removed Designated WPPL Staff and add Supply Chain Section 5 Changed procedure name for WPPL-SP-04 and WPPI-SP-05 to current name. Added ISO 13485 & ISO 9001 Section 6.1 Added Record 730001052, 730000443, 730000442, 730006720 Section 8.1: Moved section 8.5 to 8.1. Update per current practice Section 8.2.1: Changed monitoring control for suppliers. Section 8.2.2: Changed Schenker to Critical supplier. Section 8.2.3: Rephrase to reflect current practice. Section 8.2.4: added Joint Quality Audit with CMO Section 8.6 changed numbering to Section 8.5 Section 8.7: changed numbering to Section 8.6 and added Supplier Change Control process and form into the procedure Section 8.7 Added Communication of Supplier Quality Issues Section 8.8 – 8.11 – Removed Section 9.0 – Removed appendix 1 Figure 1 and Figure 2 and replace with Section 9.1 Key Supplier Quality Scorecard Rating, Section 9.2 Supplier Quality Scorecard Rating, Section 9.3 Key Supplier Quality Scorecard Rating(For 3PL) and Section 9.4 Supplier Quality Score Card Rating (For freight forwarder)					
VERSION:	11	ORIGINATOR:	Soo Chin Pang	CHANGE ID:	N/A
DESCRIPTION OF CHANGE: Section 2 Change the Scope Section 3 Added 3PL, Product and Supplier Section 4 Added Roles & Responsibilities for Quality, Procurement, Manufacturing, Supply & Distribution and Product Planning. Revised WPPL Quality change to Quality and Supply Chain change to Procurement Section 5 Remove WPPL-SP-04, WPPL-SP-06, WPPL-SP-15 and Added 730005455 Section 6 Added 730005456 Section 8 Added 8.1.1, 8.6.1, Remove Manager in Charge in 8.2.2 Section 9 Added Footnote on Category Rating based on Likert scale, 9.5 Supplier Change Control Process Flow, 9.2 to include Recall criteria. Revised 9.1 CM to CMO, 9.3 FOR to For.					
VERSION:	12	ORIGINATOR:	BETHANY LIM	CHANGE ID:	N/A

DESCRIPTION OF CHANGE:

Section 3 Removed Key Supplier

Section 5 Removed WPPL-SP-12 FAIR Qualification Control

Section 6 - removed 730005456 Global Supplier Change Control Form

Section 8 - removed This agreement can be in the form of Quality Plan, contract agreement and/or commercial contract with the respective supplier that clearly describe and reference specification including quality requirements.

section 8.1.1 - removed supplier Quality Audit is performed per WPPL-SP-03, Quality Auditing

section 8.2.1 - Changed from

For Supplier classified as Key Supplier, WPPL shall have following performed.

1) Onsite Audit / Supplier self-appraisal – Once a year

2) Periodically performance review.

3) Periodically monitoring using supplier scorecard

For Supplier classified as critical, WPPL shall have following performed (excluded Key Supplier.)

1) Onsite Audit / Supplier self-appraisal – Minimum every 2 years

2) Periodically monitoring using supplier scorecard based on CMO input.

3) No monitoring required for special process supplier.

For Supplier classified as sub-critical, WPPL shall have following performed but not limited to

1) Onsite Audit / Supplier self-appraisal – Minimum every 3 years

2) Periodically monitoring using supplier scorecard (optional)

For Supplier classified as standard, WPPL shall have following performed but not limited to

1) Onsite Audit / Supplier self-appraisal – Minimum every 6 years (optional)

2) Periodically monitoring using supplier scorecard (optional)

Change to

For Supplier classified as critical, WPPL shall have following performed

1) Onsite Audit / Remote Audit / Supplier self-appraisal – Minimum every 2 years

2) Periodically monitoring using supplier scorecard.

3) No monitoring required for special process supplier.

For Supplier classified as sub-critical, WPPL shall have following performed but not limited to

1) Onsite Audit / Remote Audit / Supplier self-appraisal – Minimum every 3 years

2) Periodically monitoring using supplier scorecard (optional)

For Supplier classified as standard, WPPL shall have following performed but not limited to

1) Onsite Audit / Remote Audit / Supplier self-appraisal – Minimum every 6 years (optional)

2) Periodically monitoring using supplier scorecard (optional)

section 8.2.2 – removed

section 8.2.3 - Added c) Onsite Audit is performed per WPPL-SP-03, Quality Auditing and adjust numbering

section 8.2.3 - Corrected duplicate clause 8.2.3 to 8.2.4

section 8.3 - Removed

section 8.6.1 - correcting the clause from 8.6.1 to 8.7, correcting Running no = XX to NN, updating table by adding in packaging engineer as Responsible Person / Designee, updating table by changing from Calibration to Calibration and services, Adding ***Require approving when there are changes related to packaging

section 9.2 - updating table adding on time delivery weightage as new criteria, changing weightage percentage from 30% to 25% at Incoming Inspection, Adding Major Audit Finding at SCAR/Recall/Annual Audit Results (Count) under Poor category

section 9.1 & section 9.3 - removed key

section 9.5 - removed

VERSION:	13	ORIGINATOR:	Bethany Lim	CHANGE ID:	N/A
Section 3.0 – Change from Supplier Self Appraisal to Supplier Self-Assessment Section 6.0 – Remove 730001052 Supplier Self Appraisal and Add 730007682 Supplier Self-Assessment Section 6.1 – Remove 730001052 Supplier Self Appraisal and Add 730007682 Supplier Self-Assessment Section 8.0 – Change from key Supplier to critical Supplier Section 8.1 – Change from 730001052 Supplier Self Appraisal to 730007682 Supplier Self-Assessment Section 8.2.1 – Change from Supplier Self Appraisal to Supplier Self-Assessment Section 8.4 & 8.5 – Removed Waters Milford and Waters Wilmslow Section 9.1 – Add CAPA into SCAR/Recall/Stop Ship Criteria Section 9.2 – Add CAPA into SCAR/Recall/Annual Audit Results Criteria					