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QUALITY PROCEDURE

QP 8-3

Delivery & Quality Requirements for Supplier's

Rev	Description	Date	C.R.No.	Orig.	Chkd.	Apprd.
1	First release	Nov 18	-	JR	TR	RCK

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1. Scope

The purpose of this document is to formally communicate Bioquell UK Ltd (now known as Bioquell) delivery and quality requirements to the supply chain.

2. Normative References

ISO9001:2015 clause 8.4 Control of externally provided processes, products and services refers.

3. Terms & Definitions

In this Quality Procedure (QP), the terms "shall" and "must" mean that the described action is mandatory; "should" means that the described action is necessary and expected with some flexibility allowed in the method of compliance; and "may" means that the described action is permissible or discretionary.

The term "Supplier" means vendor, supplier of goods, service provider, sub-contractor and distributor.

Questions concerning this procedure should be directed to your respective Bioquell Buyer or Quality Manager.

4. Supply of Goods & Services

Goods and services provided by our Suppliers have a key impact on the quality of the products, solutions and services we offer our customers. To maintain a high level of quality, we are determined to establish and maintain close and long-lasting relationships with our Suppliers.

Bioquell Terms and Conditions of trade shall apply to all contracts unless otherwise agreed.

5. Quality Management System Requirements (QMS)

5.1 Minimum Quality Requirement

The minimum quality requirement for suppliers of goods and services to Bioquell shall be QMS certification to ISO9001 by a UKAS (or equivalent) accredited certification body that is a member or signatory of the International Accreditation Forum (IAF).

Self-certification or non-accredited certification shall not qualify.

This minimum requirement guarantees the Supplier has put in place a consistent QMS able to satisfy our basic needs.

5.2 Exceptions

Where the above criteria detailed in 5.1 cannot be met, depending on the product, its application, value and criticality, special authorisation may be granted where evidence of compliance can be provided.

This may include a site visit and/or an audit by the relevant Bioquell personnel.

5.3 Specifications and Standards

It shall be the responsibility of suppliers to obtain, review, work to and maintain current issues of specifications and standards from appropriate sources.

As part of the supplier's contract review, the supplier must make sure that they are working to the latest Bioquell drawings as detailed on the Bioquell Purchase Orders.

5.4 Record Retention Requirement

Suppliers should retain records relating to processing, testing, calibration, manufacture, supply, traceability and certification.

This will be governed by the suppliers' internal processes unless otherwise stated by Bioquell as part of any contractual agreement with the Bioquell Customer.

6. Control of Sub-Tier Suppliers

The Supplier, as the recipient of the contract, shall be responsible for meeting all requirements, including work performed by the Supplier's subcontract Suppliers.

Bioquell personnel, Customers and/or End Users shall be allowed access to the Sub Supplier's plant and facilities for the purpose of surveillance and inspection if, and when required.

7. Identification & Traceability

Suppliers' shall provide the following delivery documentation:

Delivery Note must reference:

- Bioquell part number;
- Supplier part number (if applicable);
- Drawing issue level
- Quantity;
- Bioquell Purchase Order number;
- Serial/batch numbers (if applicable), lot/date codes (if applicable);
- Shelf-Life information (if applicable).

Delivered goods must clearly show externally via a label the Supplier name, Bioquell part number, revision level, quantity and if appropriate, box 1 of X.

Where possible the supplier should endeavour to individually label parts.

7.1 Hazardous/ Dangerous Products

The following additional information is required if hazardous/ dangerous products/ materials are supplied;

- Hazardous / Dangerous Labels on outer packaging;
- Paperwork on outer packaging identifying full content;
- MSDS Data Sheet – Outer Packaging;
- If the product is a liquid or a cream, then it MUST be bagged before it is final packaged.

8. Certification

Certification refers to any document that states the goods or services meet or conform to specification or PO requirements.

These include, but are not limited to; Certificates of Conformance, Certificates of Analysis, Material/ Mill Certificates, Certificates of Attestation and Certificates of Calibration. The certifying document shall be deemed as an authorised contractual guarantee that the goods and services referenced on the certificate meet drawing, specifications, technical data and PO requirements.

Bioquell mandatory requirement is that a Certificate of Conformity (C of C) must be supplied with every delivery. Minimum information required on a C of C is as follows:

- Supplier Name & Address;
- Drawing number and / or part number and revision;
- PO number;
- Quantity;
- Batch unique identifier (Batch number / Lot number / Date code);
- Statement that goods and / or services conform to the specified requirements;
- Printed name/ date/signature of authorised certifying quality representative or company official.

In addition, calibration and test certification shall include:

- Calibration / test specification including tolerances and criteria;
- Calibrated test apparatus / instrument / standard used traceable to NIST or equivalent;
- Test results;
- Pass or fail or equivalent statement of conformance / non-conformance.

Any documentation requested by Bioquell forms an integral part of the purchase order and must be completed as requested and provided with all deliveries to avoid any processing delays.

9. First Article Inspection Report (FAIR)

The purpose of carrying out a FAI is to give objective evidence that all engineering, design and specification requirements are correctly understood, accounted for, verified and recorded.

Bioquell will communicate all FAIR requirements via a PO. The FAIR will be provided at the time of delivery of the purchase order and this will be a non-chargeable service unless otherwise agreed.

9.1 FAIR submission

Shall be communicated to the supplier via the Bioquell Purchase Order (PO) and performed by the supplier when:

- The part being ordered is a new part for Bioquell and/or the supplier;
- Part drawing has been up-issued as a result of a change in design, affecting fit, form or function of the product. The FAIR is required for the design change only.
- A change of manufacturing source, process, inspection method, location of manufacture, tooling or materials that can affect fit, form or function;
- A lapse in production for a period of 2 years or as specified by the customer.

When FAIR is required, the report shall accompany the parts into Bioquell.

9.2 FAIR Documentation

QF 8-6-001, First Article Inspection Report (FAIR) shall be used by all suppliers when submitting into Bioquell a FAIR. The form comes in 3 parts as defined below and it also has instructions on how to complete the form in readiness for submission into Bioquell:

- Form 1 - Part Number Accountability' shall be used to summarise associated part numbers and associated FAIs for Assemblies.

- Form 2: 'Product Accountability' shall be used for raw materials, specifications, processes and functional tests.

- Form 3: 'Characteristic Accountability' shall be used to summarise actual specific design characteristics. Each characteristic shall have its own unique characteristic number and this number shall be marked on the relevant drawing/specification document. Characteristics not measurable in the final product shall be verified in the manufacturing process.

9.3 FAIR Level 2

Part numbers that are bespoke to Bioquell and have a technical drawing (Part numbers that start with but not limited to TD, TS, T) assigned will require a FAIR Level 2.

The minimum documentation required for FAIR Level 2:

- Forms 1, 2 & 3 as above to head each stage of the FAIR documentation pack;
- Certificate of Analysis/ Material certificate (if required);
- Any subcontractor FAI reports (if applicable) including their Certificate of Conformity;
- Source Inspection Report (if applicable);
- Applicable concessions;
- Dimensional report;
- Balloon print, if Bioquell have requested one (this supports any dimensional report);
- Test Results, where applicable;

9.4 FAIR Level 1

If the part number refers to a label or Printed Circuit Board Assembly (PCBA) then they are subject to a FAIR Level 1.

Note: FAIR Level 1 may also be required for all TD parts if a part is up-issued due to a minor change as detailed on the technical drawing revision control table. The FAIR will be required on the change only.

The minimum documentation required for FAIR Level 1:

- Form 1 only;
- Certificate of Conformity;
- Signed off artwork (Labels only);
- Certificate of Conformity for UL/CSA parts (PCBA only);
- Test certificates, if applicable (PCBA only).

9.5 FAIR Level 0

Parts that do not require a FAIR are:

- Proprietary parts/ Consumable of The Shelf (COTS).

9.6 FAIR Review & Verification

Upon receipt of the parts with the completed FAIR, Bioquell QA shall allocate a unique Bioquell FAIR number from the FAIR index and then verify the part(s) for compliance to the latest Bioquell drawing, using calibrated equipment.

Any deviations detected shall be notified to the supplier and the Bioquell Purchasing Dept. Remedial action or FAIR resubmission will follow.

If the FAIR is fully compliant then Bioquell QA will sign and date Form 1 of the FAIR and send copy back to the supplier for their records. This approval allows the supplier to supply into Bioquell.

10. Shelf Life

Products with finite shelf life shall have the expiry date identified on the product and the delivery documentation.

The remaining shelf life must be a minimum of 90% of the total shelf life for the material at time of delivery.

11. Packaging

The Supplier shall adequately plan for packaging designed to prevent product contamination, deterioration, damage or loss.

Suppliers should provide expendable packaging or returnable containers, where appropriate, of sufficient density and protection from likely damage that may occur.

Mechanical and electromechanical parts should be packaged with anti-static material where possible. The use of approved industry standard labelling and bar-coding shall be in accordance with any contractually agreed packaging specification.

12. Concessions

It is the policy of Bioquell not to accept a product that fails to meet the required specifications. All concessions shall be considered as non-conforming product.

12.1 Approval

Concessions must be approved by Bioquell and approval received by the supplier prior to delivery of parts to Bioquell.

The concession must state the deviation requested, the relevant Bioquell PO, part number and description, quantity affected and any recovery action for future deliveries.

The supplier concession number must be annotated on to the suppliers' delivery paperwork and a copy of the concession supplied together with the parts in question.

The supplier can use the Bioquell concession form or their own internal concession document.

13. Non-Conforming Products

When non-conformances occur, the supplier must perform an investigation, identify the root cause and implement Corrective Action Preventive Action (CAPA) in order to prevent recurrence of the problem.

For non-conforming product, the Supplier shall:

- Within 48 hours of notification of the non-conformity, generate and submit into Bioquell a CAPA Report detailing the containment actions taken.
- Within 10 working days update and submit the CAPA Report detailing the investigation, root cause analysis and CAPA's implemented.
- Within 20 working days, submit into Bioquell a completed CAPA Report.
- Close out the CAPA in conjunction with the Bioquell Quality Department.

Important Note: there is no default CAPA Report format and therefore the supplier can use their own format as along as it covers the requirements of the above bullet points. This includes 5Y.

13.1 Returning of Rejected Parts.

Parts being rejected back to the supplier should be clearly identified by Bioquell personnel and a copy of the relevant Return to Supplier (RTS)/ NCR should accompany said parts.

The more information Bioquell can give the supplier the better, for example photographs, marking physical components in defect areas, dimensional and test results.

Once the supplier is made aware of the rejection, it is the responsibility of the supplier to arrange collection of the rejected parts unless otherwise agreed with Bioquell.

13.2 Returning of Reworked Parts.

Parts that are reworked by the supplier should be clearly identified both at a part level and at a delivery level. This identification should meet the following minimum requirements:

- Delivery paperwork references the Bioquell RTS/ NCR number.
- Parts to be identified with the RTS/NCR number, nature of rework and inspection method.

13.3 Replacement Parts

Any replacement parts should be in accordance with the relevant drawings and specifications.

13.4 Credit Notes

If parts cannot be reworked and replacement parts are not available, then Bioquell Purchasing Department will request that the supplier issues a credit note

13.5 Reworked Parts, liability Bioquell

If Bioquell sanction rework of parts by a supplier, where liability for the rework is not the result of any action taken by the supplier, then the supplier, upon returning the parts should ensure that parts are correctly labelled as described in this QP plus place a copy of the rework PO with the parts. This will enable Bioquell to inspect the rework in accordance with the instruction on the rework PO. This also allows Bioquell to manage off site stock for rework accurately.

14. Obsolescence Management

The suppliers shall notify Bioquell of any pending obsolescence, the relevant last time buy date and last time ship date at least 6 months prior to the last time buy date.

15. Purchase order acknowledgement

The supplier shall acknowledge receipt of any purchase order from Bioquell and confirm a delivery date and price for each item purchased, within 3 working days. This will be communicated to the Bioquell buyer indicated on the purchase order and sent to their e mail address. The supplier shall advise Biqouell if there will be any delay in providing acknowledgement.

16. On Time Delivery (OTD)

Suppliers shall supply conforming goods and services On Time In Full (OTIF) to the Bioquell purchase order due date or the agreed, confirmed delivery date. An on-time delivery is defined as a purchase order line item being delivered zero days late and a maximum of 5 days early against the purchase order due date. Purchase order delivery must include all required, correct completed documentation and certification where applicable. Any requested documentation forms part of the purchase order agreement. Delays in supply of requested documentation can cause line or operation interruption.

16.1 Late Deliveries

If non-delivery or late deliveries are anticipated, suppliers shall immediately notify the buyer indicated on the PO and confirm a revised, anticipated delivery date. Delays can cause line or operation interruption.

16.2 Short Orders

If short orders are anticipated, suppliers shall immediately notify the buyer indicated on the PO. Short orders can cause line or operation interruption.

17. Legislation

Conformity to RoHS, WEEE Directives and REACH regulations form part of the supplier selection process. Suppliers will be responsible for ensuring that all parts are compliant.

18. Non-Disclosure Agreements

Bioquell reserve the right to withhold sensitive programmatic information from a Supplier until such time as an agreed NDA is established between all concerned parties.

19. Counterfeit Product Prevention

The Supplier shall ensure that counterfeit parts are not used in the manufacturing of Bioquell parts.

The control and verification of this aspect should be considered as part of the verification of purchased product and is therefore the responsibility and liability of the Sub Contractor.

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20. Customer Furnished Assets (CFA)

If the supplier has on-site test equipment and/or tooling that belongs to Bioquell then the supplier shall ensure that the equipment is identified accordingly and stored when not in use to ensure no unneccessary damage or deterioration occurrs.

The supplier shall notify Bioquell immediately if the CFA has encountered damage so that an assessment can be made at the earliest opportunity.

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