# Quality Manual Contents

This manual describes the Quality System at BiosPacific and is considered the top tier of our documentation system. The organizational structure, responsibilities, procedures, processes and resources for implementing quality management are described. Related Standard Operating Procedures (SOPs) are referenced where applicable.

**BiosPacific Quality Policy**

BiosPacific, Inc. is committed to the highest level of quality in the distribution, sales and support of the products we sell and will maintain and continually improve the effectiveness of our Quality Management System. Product quality, compliance to all applicable regulatory requirements and standards, continuous improvement and customer satisfaction shall underlie all of our efforts in the distribution, advertising, sales, shipping and technical support of our products.

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**Company Profile**

BiosPacific, Inc. (BiosPacific) distributes proteins and antibodies for several manufacturers. The staff is primarily sales and sales support, and works closely with customers and product vendors to assure that the customer's requirements are met. The office is located in Emeryville, California.

In July 2005, BiosPacific was purchased by R&D Systems, Inc. (R&D Systems) and became a wholly owned subsidiary. R&D Systems was founded in 1976 in Minneapolis, MN. It is a wholly owned subsidiary of TECHNE Corporation (a holding company with no employees). In July 2014, TECHNE was renamed as Bio-Techne. The stock is traded publicly on NASDAQ's National Market System under the "TECH" symbol.

Regulatory oversight is provided by R&D Systems based on customer and product information supplied by BiosPacific. Areas where regulatory support is available are audits, training, ISO certification, labeling, import/export regulations, reporting hazardous materials, and other applicable regulations as necessary.

Applicable Standards: EC No 1069/2009 and EU 142/2011

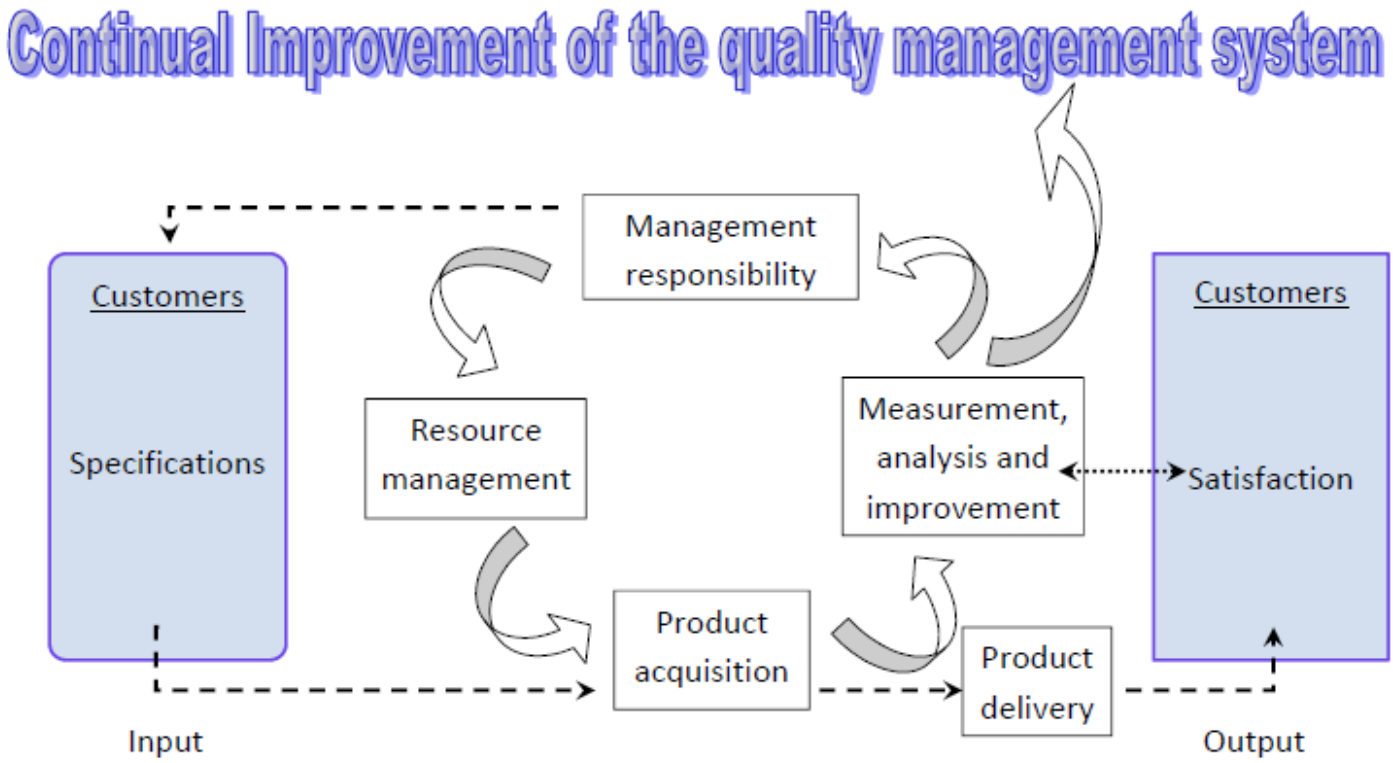
BiosPacific has been ISO certified since 8/26/2011. Our Certificate of Registration is ISO 9001:2008 # FM 574663.

Sections of the ISO 9001 Standard which do not apply are as follows:

Section 7.3 Product Design and Development (BiosPacific does not perform design and development activities)

Section 7.5.2 Process Validation (BiosPacific does not perform any process validation activities

**Quality Systems Flow Chart**




**Management Responsibilities**

The Managing Director serves as the Quality Management Representative. In this role, she/he:

- works with Quality Assurance and Regulatory Affairs at R&D Systems to assure that the quality system at BiosPacific is adequately established and sustained to meet applicable regulatory requirements
- reviews the effectiveness of the quality system in an annual Management Review to assess effectiveness and adequacy (including resources) and to identify improvement opportunities
- provides input regarding the performance of the quality system at BiosPacific to R&D Systems, to be included in their annual Management Review
- promotes awareness of customer requirements

Related Procedure: SOP 209 Management Review of the Quality System

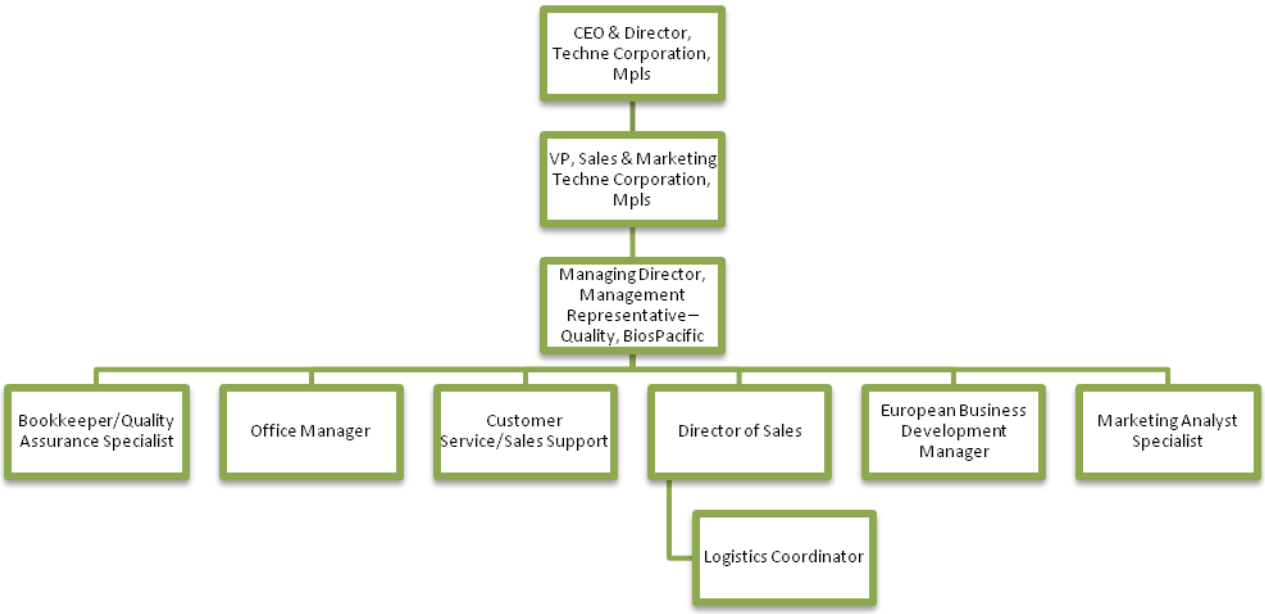
## Personnel

It is our policy to hire only qualified personnel and to assure that they are trained in all aspects of their jobs.

- Copies of job descriptions, job applications, resumes and annual performance reviews are kept on file at BiosPacific.
- BiosPacific maintains training records for its employees and reviews the effectiveness of the training on an annual basis.
- All employees are required to complete the Quality training provided by Quality Assurance (QA) at R&D Systems. This training includes the applicable regulations and is done at a minimum of every three years.
- A file of pertinent Standards is maintained and is available to BiosPacific employees for training as needed.

Related Procedure: SOP 201 Personnel Training Procedure

## Organizational Chart



## Document Controls

To assure consistent quality, written, approved procedures are used for the processes performed at BiosPacific. The Quality Assurance Specialist (QAS) at BiosPacific is responsible for maintaining the Document Control system and is therefore responsible for controlling the issue, distribution, revision and archiving of documents. A formal Document Change Request (DCR) is routed with each new and revised document to record the revision history. Each document is reviewed by, at a minimum, the Managing Director and QAS. A Document Control Index is maintained to provide an overview of the current, approved documents.
The release of literature, including promotional materials, posters, and datasheets posted on the website, is controlled by a written procedure.

In addition to Standard Operating Procedures (SOPs) the documents that must be controlled include:

- Checklists, forms and logs related to SOPs
- Contracts and supply agreements
- Data sheets and Certificates of Analysis
- Customer specifications

Related Procedures:
SOP 200 Document Control
SOP 210 Control of Customer Property
SOP 205 Recordkeeping
SOP 307 Literature Control
SOP 211 Control of Records

## Purchasing Controls

Purchasing controls are in place to assure that the quality of supplies, service and product is consistent and meets specifications where applicable. Vendors are qualified and their performance is monitored. Numbered Purchase Orders (PO) are used, linking the customer and the specific vendor supplying the product. Contracts and supply agreements are written if necessary.

Related Procedures:
SOP 207 Vendor Qualification
SOP 300 Contracts and Supply Agreements
SOP 301 Order Processing
SOP 308 Supply Specifications and Order Form
SOP 540000 Vendor Qualification & Monitoring (R&D Systems)

## Identification and Traceability

The ability to trace a lot of product from the customer back to the manufacturer is essential. Vendor lot numbers are recorded in the appropriate log (Product Lot Book) and/or on the PO to facilitate traceability. In addition, a BiosPacific lot number is assigned and logged into the Product Lot Book along side the vendor lot number. The lot number is also documented on the vial label and the lot specific product specification sheet.

Related Procedures:
SOP 302 Receiving
SOP 303 Generating Data Sheets and Certificate(s) of Analysis
SOP 304 Bottling and Labeling
SOP 308 Supply Specifications and Order Form

## Production and Process Control

Process control is accomplished by using written procedures, calibrating equipment, performing product inspections and training. Deviations from the written procedures are recorded and monitored. Typically, product is ordered on an "as needed" basis when customers place orders. Product inventory is stored in temperature controlled and monitored refrigerators and freezers. Line clearance is performed prior to aliquoting and packing activities to assure that no labels or other materials are left in the area from previous activities.

Related Procedures:
SOP 204 Process Deviation
SOP 304 Bottling and Labeling
SOP 400 Equipment Maintenance and Calibration

## Acceptance Activities

- Incoming materials are inspected against the PO for transit damage, product description, quantity, lot number, and meeting the specification, if applicable. In addition, product for resale will be inspected for source lot and concentration using the vendor's data sheet or the lot specific Certificate of Analysis.
- Invoices are reviewed to assure that the customer's order has been placed accurately in-house.
- Final inspection is done to assure product has been packed and labeled for shipping as required by the PO and the related SOP.
- Acceptance activities are supported by completed records that are retained.

Related Procedures:
SOP 302 Receiving
SOP 305 Shipping Procedures
SOP 306 Invoice Entry
SOP 308 Supply Specifications and Order Form
SOP 309 Control of Non-conforming Product

**Corrective and Preventive Action (CAPA)**

We are committed to customer satisfaction and to assure that, procedures are in place to remedy any customer dissatisfaction or non-conformity that is identified.

Complaints are logged and monitored until the issue is resolved with the customer. When appropriate, a root cause analysis is done to determine the most effective action to correct the dissatisfaction and/or non-conformity and also to prevent repeat occurrences. Procedures are in place to monitor the effectiveness of CAPA.

Customers are contacted about field notifications, recalls, discontinuations and product change information.

Customer surveys are used to monitor and trend indicators of satisfaction and to identify areas where improvements can be made.

Related Procedures:
SOP 202 Complaint Handling
SOP 203 Corrective and Preventive Action
SOP 206 Field Notification
SOP 208 Customer Satisfaction
SOP 501 Disaster Plan

**Quality Audits**

Periodic audits assure adherence to our established quality systems.

Internal audits may be initiated by the Managing Director at BiosPacific or by Quality Assurance (QA) at R&D Systems either to audit a process or to audit compliance with a particular SOP. A comprehensive quality system audit is performed annually by R&D Systems QA. Audit results are reported to management and are used as a basis for improvement if indicated.

BiosPacific is audited by regulators and customers as requested.

Vendor audits are performed as needed.

Related Procedures:
SOP 207 Vendor Qualification
SOP 540291 Internal Audit Procedure (R&D Systems)

**Records**

Quality records are maintained to support the requirements of the quality system and to aid management in reviewing the system's effectiveness. Also, records are maintained to demonstrate that products were ordered, bottled, labeled, stored and shipped according to the applicable regulations.

Records are stored in conditions to facilitate their preservation. They are accessible to authorized personnel and may be reviewed for customer history and to support customer inquiries. Quality system records are retained for at least three years, or as specified in individual SOPs or customer contracts.

The quality records that are maintained include:

- Quality System documentation
- Document Change Requests
- Calibration and maintenance records
- Audit reports
- Management review minutes
- Customer complaints
- Vendor qualifications
- Purchase orders
- Contracts and supply agreements
- Personnel records/training records
- Field notifications and recalls

Computers are connected to surge protectors to prevent interruption and loss of data and, in addition, are routinely backed-up on site and to the cloud through our IT service provider.

Related Procedure: SOP 211 Control of Records
SOP 401 Computer Maintenance