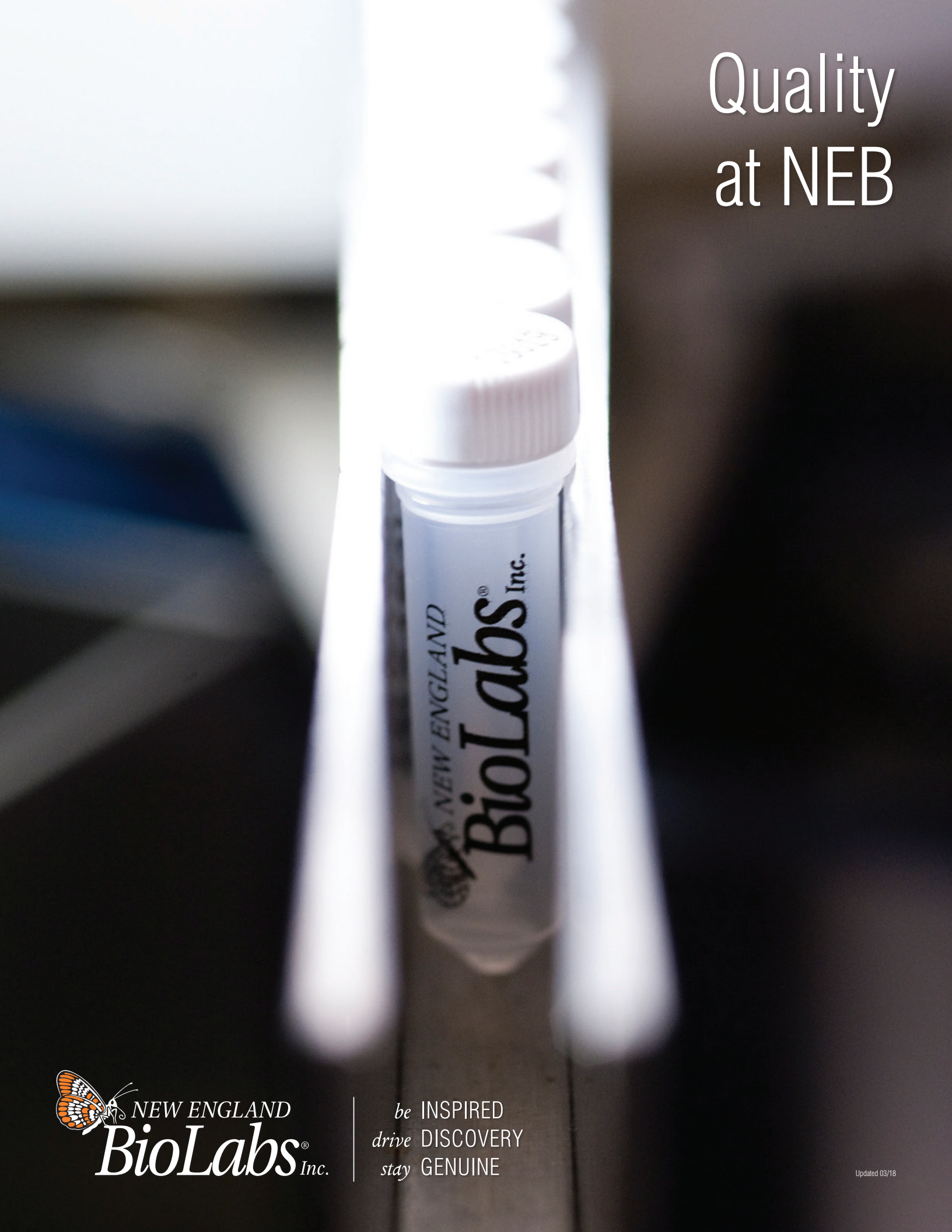


Quality at NEB

NEW ENGLAND BioLabs® Inc.

be INSPIRED
drive DISCOVERY
stay GENUINE

Updated 03/18

New England Biolabs

Established in 1974, New England Biolabs is proud to be recognized as a world leader in the discovery, production and supply of reagents for the life science industry. For over 40 years, we have been committed to meeting the needs of the scientific community. While our product portfolio and distribution network have expanded, our commitment to our customers remains the same:

- Maintain a strong basic research program that contributes to the advancement of science
- Set the standards for product quality and value
- Provide our customers with the highest level of technical support
- Promote and practice sound ecological practices and environmental sustainability

As research in the life sciences continues to accelerate, the demand for high quality, innovative tools continues to grow. At NEB, we strive to understand these needs and develop products that exceed customer's expectations in terms of quality and performance. Most recently, in response to exciting scientific breakthroughs, NEB has expanded its product offerings into areas related to PCR, gene expression, sample preparation for next generation sequencing, synthetic biology, glycobiology, genome editing epigenetics and RNA analysis.

Our state-of-the-art headquarters, which is ISO and LEED certified, includes a modern fermentation center and laboratories for production, quality control, product development and basic research. With a reliance on recombinant technology and expertise in expression and purification techniques, NEB is able to produce the highest quality products with proven lot-to-lot consistency.

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

New England Biolabs, Inc.

240 County Road
Ipswich MA 01938
United States of America

(Central function listed above. See appendix for additional locations)

applicable to:

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

Certificate Number:	11948
EAC Code:	34
Certified Since:	November 3, 2006
Valid Until:	March 4, 2024
Reissued:	March 6, 2021
Cycle Issued:	March 5, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate of Registration

nqa global assurance

Appendix to Certificate Number: 11948

Includes Facilities Located at:

New England Biolabs, Inc.
Certificate Number 11948
240 County Road
Ipswich MA 01938
United States of America

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research.

New England Biolabs, Inc.
Certificate Number 11948
428 Newburyport Turnpike
Rowley Massachusetts 01969
United States of America

The development, production and distribution of molecular biology reagents, and related products, for applications in academic institutions, industry and OEM markets.

New England Biolabs, Inc.
Certificate Number 11948
100 Cummings Center
Beverly MA 01915
United States of America

The development and production of molecular biology reagents, and related products, for applications in academic institutions, industry and OEM markets.

Certified Since: November 3, 2006
Valid Until: March 4, 2024
Reissued: March 6, 2021
Cycle Issued: March 5, 2021

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

New England Biolabs, Inc.

240 County Road
Ipswich MA 01938
United States of America

Central function listed above. See appendix for additional locations

applicable to:

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

Certificate Number:	14124
EAC Code:	34
Certified Since:	August 15, 2012
Valid Until:	March 4, 2024
Reissued:	March 6, 2021
Cycle Issued:	March 5, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate of Registration

nqa global assurance

Appendix to Certificate Number: 14124

Includes Facilities Located at:

New England Biolabs, Inc.
Certificate Number 14124
240 County Road
Ipswich MA 01938
United States of America

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research.

New England Biolabs, Inc.
Certificate Number 14124
428 Newburyport Turnpike
Rowley Massachusetts 01969
United States of America

The development, production and distribution of molecular biology reagents, and related products, for applications in academic institutions, industry and OEM markets.

New England Biolabs, Inc.
Certificate Number 14124
100 Cummings Center
Beverly MA 01915
United States of America

The development and production of molecular biology reagents, and related products, for applications in academic institutions, industry and OEM markets.

Certified Since: August 15, 2012
Valid Until: March 4, 2024
Reissued: March 6, 2021
Cycle Issued: March 5, 2021

Certificate of Registration

nqa global assurance

This is to certify that the Environmental Management System of:

New England Biolabs, Inc.

240 County Road
Ipswich MA 01938
United States of America

applicable to:

The Design, development, production and distribution of molecular biology, reagents, and related products for applications in academic institutions, industry and OEM markets. Exclusions: the Day care facility, Gate house, Beverly and Rowely are currently excluded from the scope of the EMS program

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 14001:2015

For and on behalf of NQA, USA.

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate Number:	EN11948
EAC Code:	34
Certified Since:	June 23, 2009
Valid Until:	May 21, 2021
Reissued:	May 22, 2018
Cycle Issued:	May 22, 2018

General Business Information

Company Name: New England Biolabs, Inc.

Address: 240 County Road

City: Ipswich **State:** MA **Zip Code:** 01938

Telephone: 800-632-7799 **Fax:** 978-921-1350 **Email:** info@neb.com

Type of Business: Manufacturer of reagents for the life science industry

Total Number of Employees: ~500 worldwide No. in QA: 8 No. in QC: 10 No. in Production: 100 No. in Research: 110

Square Footage of Facility: 140,000

Total Years in Business: 42 Years at Present Facility: 10 Years under current ownership: 42

Is NEB privately or publicly held?
Privately held

Will NEB provide financial statements upon request?
No

Does NEB have a Dunn and Bradstreet Number?
Yes, 066605403

What is the NAICS Code?
325414

What is the NEB Tax Identification Number?
04-2631963

Does NEB have any plans for consolidation, moving or operations transfers within the next twelve months?
No, there are no plans for consolidation, moving or operations transfers. However, in 2018 NEB will be building a new facility to manufacture GMP grade select products.

What is the average tenure time of employees at NEB?
14 years

What is the employee turnover rate at NEB?
~2%

Is NEB considered a small business?
Yes, NEB is a Veteran-owned small business

Is NEB ISO 14001 certified?
Yes, see certificate on page 4

Does NEB maintain a written safety program?
Yes, regular safety inspections take place at NEB internally and via regulatory authorities. NEB provides an education/training program for employees to learn good safety/housekeeping practices.

Does NEB monitor quality, on-time delivery and count accuracy?
Yes

What is the % on-time delivery?
99%

New England Biolabs (NEB) Quality Policy

NEB is committed to inspiring and supporting the worldwide scientific research community, as well as our industrial customers' technology platforms, by supplying the highest quality reagents, backed by unmatched product and customer support.

NEB's commitment is guided by the following principles:

Customer Focus and Support

Ensure our customer's requirements are known and provide all customers with:

- Unmatched product expertise and technical support
- Best-in-class responsiveness and service
- Routine measurement and analysis of customer satisfaction

Products

Anchored by our internal research and discovery programs, NEB shall design, develop and manufacture products which are:

- Innovative solutions for leading edge technologies
- Of the highest quality and purity
- Distributed world-wide with same day or overnight delivery
- Offer the highest value to our customers

Compliance and Quality Management System

Develop systems, processes and assure employee training, which enables us to:

- Meet all applicable local, state and federal legal requirements
- Meet the highest standards of compliance for our business
- Monitor and track the performance of our Quality Management System (QMS) via key performance indicators
- Drive improvement of our systems, processes and products
- Partner and communicate with our suppliers to define and manage Quality and/or compliance requirements

This policy statement is approved by NEB, integrated in the Quality Manual, and communicated to all employees and other relevant parties. This policy is used as the basis for setting and reviewing quality objectives in accordance with the ISO 9001:2015 and ISO 13485:2016 Quality Management System Standards per NEB certification #14124.

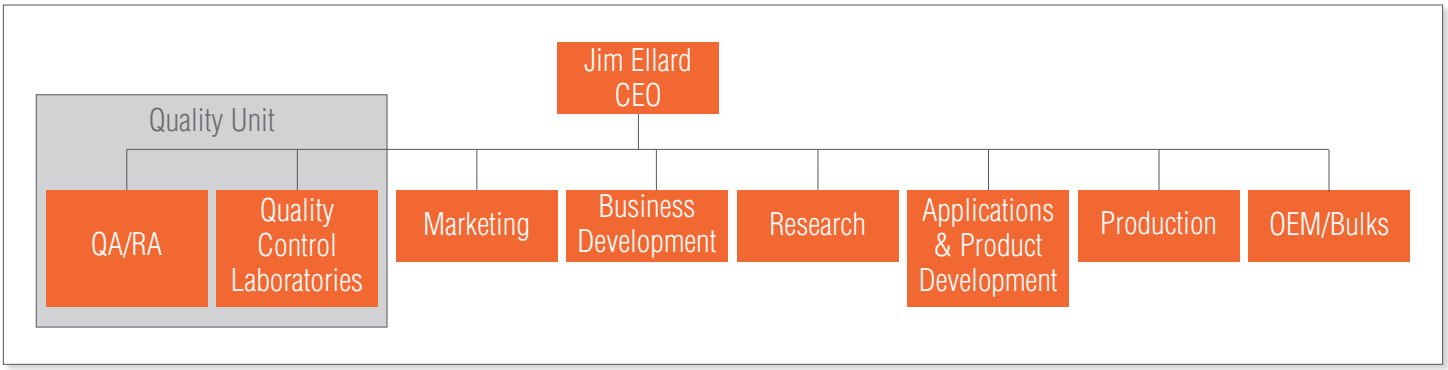
James V. Ellard
Chief Executive Officer
New England Biolabs, Inc.

Lance Goodreau
Director, Quality Assurance and Regulatory Affairs
ISO Management Representative
New England Biolabs, Inc.

nqa ISO 9001 Registered Quality Management
nqa ISO 14001 Registered Environmental Management
nqa ISO 13485 Registered Medical Devices

www.neb.com
NEW ENGLAND BioLabs Inc.
New England Biolabs, Inc., 240 County Road, Ipswich, MA 01938-2723 Telephone: (978) 927-5054
Toll Free: (USA Orders) 1-800-632-5227 (USA Tech) 1-800-632-7799 Fax: (978) 921-1350 e-mail: info@neb.com

Organizational Chart



FAQs

General Quality Information

Does NEB have a formal QA program and are we ISO certified?
Yes, NEB is ISO 13485 (since 2012) and 9001 (since 2006) certified

Is NEB registered with the FDA?
No, not applicable. NEB does not make any finished medical devices or finished IVD products.

Is NEB currently inspected or certified by regulatory agencies other than the FDA?
Yes (OSHA, EPA, NRC)

Does NEB measure and monitor quality improvement? Does management review the Quality System periodically?
Yes, NEB monitors quality via routine Quality review meetings, metrics. Formal Management Reviews are held at least one time per year.

Does NEB have an Electronic Quality Management System?
Yes, NEB uses TrackWise software for complaints, deviations, document control, CAPA, Effectiveness checks, Audit (Internal, External, Supplier), management reviews. The system is 21 CFR Part 11 compliant and validated.

Is there a documented training program for all employees in the appropriate areas?
Yes, POLICY-001, Training Program

Are training records maintained?
Yes, maintained in electronic quality management system TrackWise

Does NEB conduct internal audits?
Yes, in accordance with SOP-091, Internal Audit Procedures and FORM-030, Internal Audit Plan

Does NEB maintain a schedule and records of internal audits?
Yes, schedule is maintained per FORM-030, Internal Audit plan. Actual audit records are kept in electronic quality management system TrackWise.

Does NEB have a Corrective and Preventive Action system in place?
Yes, in accordance with SOP-015, Corrective and Preventative action

Does NEB operate to a documented quality system that includes a quality manual and/or SOP's?
Yes, in accordance with POLICY-006, Quality Manual

CORE Quality Systems and Document Control

Are investigations and subsequent corrective/preventive actions documented?
Yes, in TrackWise system

Does NEB have documented procedures for handling customer complaints?
Yes, in accordance with SOP-018, Management of Customer Complaints

Are customer returns handled through a formal and written procedure?
Yes, in accordance with SOP-018, Management of Customer Complaints

Are customers notified and is corrective action taken if necessary?
Yes, advisory notices to customers are sent per SOP-018, Complaint Management

Are there written procedures for documentation control?
Yes, in accordance with SOP-016, Document Control Procedure

Are production SOP documents controlled by a document management system?
Yes, documents are controlled in TrackWise

Is there a formal document revision review and approval process?
Yes, in accordance with SOP-016, Document Control Procedure

Does NEB have a Change Control system in place?
Yes, per SOP-055 Change Management and Notification Procedure

Will NEB notify customers of changes to form, fit or function of product?
Yes, these provisions are typically defined in a supply agreement

Purchasing/Supplier Information

Does NEB qualify suppliers?
Yes, per SOP-058, Supplier Qualification. Suppliers fill out a Quality survey and critical suppliers are audited.

Does NEB have a Supplier Corrective Action system in place?
Yes, SCARs are documented in TrackWise

Does NEB keep material inspection records?
Yes, in our ERP system

Are incoming materials handled, identified and stored in a manner that will prevent damage, contamination, mix-up and loss?
Yes, incoming materials are kept in secure/segregated areas controlled by Purchasing and chemicals require bar code scans for movement

Does NEB have reliable sources of supply for key components?
Yes, NEB has an approved vendor list and establishes Supply Agreements with critical suppliers and service providers

Does NEB require notification of changes in critical processes or materials from suppliers?
Yes, this is called out in supply agreements with suppliers

Does NEB track supplier performance, on-time delivery and quality?
Yes, suppliers of critical raw materials are evaluated on an ongoing basis and incoming critical materials are QC checked prior to acceptance of inventory.

Product Realization Information

Does NEB have product design capabilities? Are there procedures in place for translating customer requirements into design requirements?
Yes, per SOP-052, Product Design and Development

Does NEB have documented procedures for new product approval and release?
Yes, per SOP-052, Product Design and Development

Product Control, Inspection and Distribution Information

Is there a final product inspection?
Product is tested at the final filling stage and a final packaging inspection is performed per SOP-006, Inspection of Final Product Containers and Closures

Does the QC unit have final authority to accept or reject the finished material?
Yes

Will a C of A be provided for the product?
Yes, C of As can be found on the product page at neb.com or by request at QualityTeam@neb.com

Does NEB collect retains? How long are they kept?
Yes, per SOP-050, Collection, Management, and Storage of Retention and QC/Reference Samples. Samples are kept for the shelf life of the product.

How are lot numbers defined?
Lot numbers include a sequential lot number along with the assay date (month year)

Does NEB have documented procedures for line clearance and cleaning?
Yes, per various hand and machine packaging SOPs

Does NEB have an inventory tracking system used for lot traceability?
Yes, SAP is our ERP system

Is there traceability to all raw materials and component lots that are used in the finished product?
Yes

Does the facility have adequate space to prevent mix-ups and permit material segregation?
Yes

Are eating, drinking and smoking limited to designated areas?
Yes

Is there a procedure in place for handling nonconforming products and materials?
Yes, in accordance with SOP-083, Deviations and Non-Conforming Products

Does this SOP call for clearly identifying and segregating nonconforming products?
Yes

How is the non-conforming material documented?
An investigation would be conducted per SOP-083 and documented in TrackWise. Root cause and CAPAs would be determined, documented and closed in TrackWise.

Is there a system to verify the CAPA is effective?
Yes, an automated Effectiveness Check is initiated in TrackWise at closure of the CAPA

Measurement and Equipment

Are there documented procedures for equipment maintenance?
Yes, SOP-118, Facilities Maintenance Program. Also, our electronic maintenance system eMaintain is used to track equipment maintenance.

Does NEB maintain a production equipment maintenance schedule?
Yes, in eMaintain system

Does NEB have procedures in place to prevent cross-contamination on machinery and equipment?
Yes, various production and packaging SOPS describe controls for line clearance and segregation of products as applicable

Do you have a calibration program?
Yes, SOP-089, Control of Monitoring and Measuring Devices

Is the calibration date and next calibration date recorded and displayed on equipment?
Yes

If equipment is found out of calibration, is its impact on product manufactured since the last calibration assessed?
Yes, if equipment is found OOT, an investigation would be logged into TrackWise so impact and root cause could be determined

Are standards or controls used to perform calibration traceable to NIST standards or other established standards?
Yes, where applicable

Are equipment that have gone beyond calibration cycle or found out of calibration removed until calibration is performed?
Yes, equipment is tagged out of service until calibration can take place

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For additional information, please contact **QualityTeam@neb.com**, or visit **www.neb.com/quality**

Thank you for choosing to partner with New England Biolabs. Please be assured that NEB is committed to maintaining ISO quality certification and quality assurance practices, so that all products are manufactured safely and are of the highest quality. We look forward to working together!

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www.neb.com

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nqa ISO 14001 Registered Environmental Management
nqa ISO 13485 Registered Medical Devices

FSC Mixed Sources
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