NLS-QM-1002-02 Quality Policy Statement

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Quality Policy

New England Biolabs Lyophilization Sciences™ will carry out the contract design, development, and manufacture of molecular diagnostics reagents for in-vitro diagnostic medical devices that consistently satisfy the needs and expectations of its customers and commercial partners.

Quality underpins the company objectives which are delivered by robust processes that demonstrably reflect our competencies and that ensures compliance with UK, EU, and where appropriate US regulatory requirements.

This policy will be achieved via the active involvement of all employees who will be trained and developed to enable them to deliver and to ensure that they continuously review processes to achieve best practice.

The management team are committed to establishing and reviewing all quality objectives and to implementing a process to maintain the effectiveness of and where possible to continually improve the Quality Management System (QMS). Company corporate objectives are set and continually reviewed as part of quality management review meetings. Personal objectives for all employees are set and reviewed at annual appraisals. The requirements and expectations of customers and stakeholders are used as a basis for setting objectives. The Company operates and maintains a documented quality management system structured against the requirements of ISO 13485. Responsibilities are clearly defined, and staff are appropriately trained to ensure personnel have the necessary competence to carry out tasks to the required quality standards and New England Biolabs Lyophilization Sciences ensures via contracts that sub-contractors' staff are similarly competent and are recorded as such.

This policy is endorsed, communicated, understood, and accepted at all levels within the Company. In establishing the quality policy, New England Biolabs Lyophilization Sciences™ will identify the customers and their needs, the needs of other interested parties, resources, and the contributions of suppliers.

This policy is reviewed annually for continuing suitability and relevance to all aspects of the business as part of a Company-wide quality management review. As part of the quality system the policy is a controlled document.

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Quality Manager	Managing Director	Director, Business Operations

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