Statement of Quality Policy

1.0 STATEMENT OF QUALITY POLICY

The Source BioScience Group, hereafter referred to as 'The Company', is committed to developing a culture of excellence with the intent that the services it provides:

a) are of the highest quality
b) do not compromise patient safety
c) do not compromise the confidentiality, integrity and availability of patient information
d) meet the expectations of interested parties, customers, the respective Regulatory Authorities and staff
e) meets the needs of the users and patients, and are committed to ensuring the rights, well-being and safety of patients
f) comply with the requirements of, and continually improve through the application of, the Quality Management System
g) are carried out with due care and respect for treatment of patients, samples, or remains

The Company is fully committed to this policy in order that the quality of the products and services it provides are of the highest standard.

To ensure this the Company will:

a) Operate a Quality Management System to integrate the organisation, procedures, processes and resources
b) Set Quality Objectives and implement this Quality Policy
c) Ensure that where relevant, risk-based thinking is applied to planning and decision-making
d) Ensure that all personnel are familiar with the Quality Manual and all procedures relevant to their work by providing an email notification from the Q-Pulse Quality Management System (QMS) which must be acknowledged as read and understood by each member of staff relevant to that procedure
e) Commit to the health, safety and welfare of all staff
f) Ensure that visitors to the Company will be treated with respect and due consideration will be given to their safety when on site
g) Uphold professional values and be committed to good professional practice and conduct
h) Commit to comply with all relevant environmental legislation as appropriate
i) Ensure that personal information is always protected, regardless of how it is formed, shared, communicated or stored
j) Commit to confidentiality in accordance with the General Data Protection Regulation and Caldicott Principles
k) Commit to follow ALCOA (Attributable, Legible, Contemporaneous, Original and Accurate) data recording principles to ensure data integrity and validity

To achieve this, the Company will establish, implement and maintain procedures for all aspects of its operations that will ensure its compliance with the requirements of; ISO 9001 (Quality Management Systems – Requirements). In addition, various aspects of the laboratory work are undertaken to individual scopes of accreditation / approval.

All employees of The Company must be aware of the importance of protecting patients' safety, statutory and regulatory requirements as well as meeting customer needs. They will be conversant with this policy and with the reasons for it, and with the detailed procedures that apply to his/her work. Responsibilities and authority within The Company are documented below.

A key feature of this policy is the prevention of problems, by ensuring that well trained employees follow the correct procedures.

All employees of The Company share the responsibility for the quality of service it provides, and the quality objectives established to assist this process.

The Scope of the work undertaken is as follows;

The company operates under ISO 9001 for the design, manufacture and provision of laboratory products and services. The specific accreditations per service are as follows:

Clinical Trial Services

Provider of Laboratory and Clinical Trial management services that are conducted according to the appropriate standards and/or such specifications as are agreed between the Customer and the Company. These services are compliant with Good Clinical Practice (GCP) – EU Clinical Trials Directive 2001/20/EC (The Medicines for Human Use (Clinical Trials) Regulations 2004, Statutory Instrument 2004 No.1031 as amended in 2006 no. 1928 and 2984). These services also operate under a Human Tissue Authority licence (Licence no. 12344).

Healthcare Diagnostics Services

Provider of histopathology, molecular diagnostic tests and cytology services to the NHS and Private sector. This is accredited to ISO 15189 Medical laboratories - Requirements for quality and competence (customer no. 9571). Services that are accredited to ISO 15189 standards are listed on our UKAS Schedule of Accreditation. These are non-Hospital Pathology Services, Histopathology, Molecular Genetics and Molecular Diagnostics.

The Healthcare Diagnostics Services process a variety of patient data and through their IT systems. This service operates in accordance with Cyber Essentials Plus.

Life Science Products and Life Science (Contract Research)

Making innovative functional genomics products and contract research available to academic and commercial research communities worldwide. This service operates in accordance with, and is certified to, ISO 9001.

1.1 REQUIREMENTS REGARDING PATIENTS

The needs and requirements of the users is at the heart of the service we provide, and the management system has been designed to ensure the well-being, safety and rights of patients. This is embedded throughout the management system and approach we take, with the following processes in place:

- There are opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results – we have a user feedback policy (QA-POL-1) with methods of recording complaints, suggestions and feedback, and compliments. We provide contact information on our website and actively seek feedback from website visitor. We have frequent scheduled client meetings to discuss the service provided and send out user surveys which are reviewed in the management review to inform quality objectives.
- We provide information on our services on the Source BioScience website and provide guide to services for all new clients, with information on what we provide, specimen requirements, and information on transport and reporting.
- Review of services and examinations offered carried out as part of the management review and governance structure processes, to ensure the services we provide are clinically appropriate and meet needs of users and patients.
- There is an incident reporting and investigation procedure in place which includes duty of candour, with a requirement to inform users and patients where there is a potential for harm and what we have done to mitigate this.
- We have processes in place for the retention and storage of specimens and records to ensure the integrity of these where they may be required in the future.
- We provide care that is free from discrimination, with this built into the company culture through training and policy.

Signed by:

Jay LeCoque
CEO