

Quality Policy

GBUK including all subsidiaries, and divisions, is committed to maintaining and continually improving an integrated Quality Management System that ensures the consistent delivery of safe, effective, and high-quality medical devices and related services at competitive prices. This commitment is embedded throughout the organisation and is fundamental to supporting healthcare professionals, enhancing patient outcomes, and ensuring customer satisfaction.

GBUK operates in full compliance with the requirements of ISO 13485 and ISO 9001. The medical devices and IVDs placed on the market by GBUK comply with the following legislation as applicable. The Medical Device Directive (93/42/EEC) as amended, the Medical Device Regulation (EU 2017/745), Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), FDA 21 CFR Part 820, the In-Vitro Diagnostic Directive (EU 98/79/EC), the In-Vitro Diagnostic Regulation (EU 2017/746). Where GBUK distributes unlicensed medicines the rules and guidance for Pharmaceutical Distributors 2022 are followed. Through adherence to these standards and all local legislation and guidance for all territories in which we operate, we ensure that our processes are robust, our products meet all applicable regulatory requirements, and our quality objectives align with the needs of customers, patients, and regulatory bodies.

Customer satisfaction is a core measure of our success. We strive to understand and exceed customer expectations by delivering innovative, reliable, and compliant solutions, supported by responsive service and continual feedback. GBUK recognises that quality is not confined to product performance alone, but extends across every interaction, process, and relationship.

Supplier performance is integral to our ability to meet quality standards. We establish and maintain strong partnerships with our suppliers and service providers, ensuring that their materials, components, and services consistently meet defined requirements. Supplier performance is continuously evaluated as part of our quality system, and we work collaboratively with our supply chain to drive ongoing improvement.

Quality at GBUK is not the responsibility of one function, but a shared commitment across all departments and employees. We promote a company-wide culture of quality and accountability, where every individual understands the importance of their role in maintaining product integrity, compliance, and safety. Integrated quality is at the heart of our operations.

This Quality Policy is prominently displayed across all GBUK sites, communicated to all employees, and made available to relevant stakeholders. It is reviewed at a minimum annually during Management Review, or more frequently as required, to ensure its continuing suitability, alignment with strategic direction, and effectiveness in supporting our mission.

Signed by Mike Geering



I approve this document
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Mike Geering

GBUK Chief Executive Officer