INTERNAL VACANCY

Division: GC Aesthetics	**Location:** UK
Job Title: Clinical Affairs Manager	**Department:** Clinical

Responsible to: Chief Marketing Officer

Purpose of Job (Summary)

- To support the overall clinical strategy within all GC Aesthetics markets. To oversee initiation, progress and conduct of all clinical studies, surgeon initiated research support activities and publication efforts to ensure compliance with Good Clinical Practices (GCP), ISO14155, SOPs, and other applicable regulations. Ensure these activities are in line with business, regulatory and customer needs.

- To develop, implement and continuously update all Clinical Evaluation Reports as required for GCA Technical Files in compliance with current and changing regulations.

- To manage and maintain all the QMS documentation, *including PMS*, NCR & CAPA's required in your areas of responsibility. *Ensure these activities are compliant with current and changing regulatory requirements.*

Key Responsibilities

- Manage and execute all GCA's post-market clinical research studies and surveys.

- Responsible for all aspects of clinical project management from study development to final reports (including e.g. patient recruitment, project document development and management, investigator meetings, data analyses and reporting).

- Responsible for developing and implementing all Clinical Evaluation Reports, as per agreed plans, in compliance with current and changing regulations. Ensure all completed CER's are approved (externally) and registered via the recognised systems and processes across both Nagor and Eurosilicone brands (internally).

- Responsible for setting and agreeing GCA clinical budgets across Nagor and Eurosilicone business units in line with corporate objectives.

- Ensure all clinical activities are conducted in a timely manner and within site budgets.

- Monitor and ensure audit readiness of clinical study data and documents at sites to ensure regulatory and protocol compliance.

- Responsible for the development and publication of all relevant clinical study reports and peer reviewed papers.

- Manage external stakeholders such as Contract Research Organization (CRO) or independent clinical service providers' i.e. initial identification of suitable partner, development of scope of work and interactive management to ensure project success.

- Manage external stakeholders such as cosmetic and reconstructive breast surgeons to develop long term

business relationships in order to maximise participation, and ultimately surgeon and patient cooperation for long term patient follow up data across all clinical studies to ensure project success.

- Communicate clinical information to internal stakeholders (e.g. marketing, commercial team) and external stakeholders (e. partners, regulatory authorities)
- Develop and maintain (pre and post- market) clinical strategies to meet current and future business needs (e.g. new products. regulatory and customer)
- Provide clinical input into business processes (e.g. marketing, new products)
- Develop reports for submission to regulatory agencies, as needed
- Support data analyses and publication/presentation generation
- Ensure compliance with legal and regulatory requirements (e.g., GCP, ISO standards, MDD and MDR guidelines)
- Conduct literature searches and obtain electronic versions of articles in support of ongoing bibliography and reviews
- To undertake any other reasonable duties

Supervisory

- Lead and direct clinical study monitors and Principle Investigators to ensure necessary and relevant clinical data is collected and recorded to meet project deadlines in accordance with clinical protocols.
- Monitor the performance of departmental staff, providing coaching and feedback where required, and addressing any performance issues in a timely and professional manner.
- Organise suitable training for staff.

Qualifications / Experience

- Life Sciences Degree, PhD preferable but not essential
- At least 5 years' experience within the Medical Device or Pharma industry