JOB TITLE

Biocompatibility Engineer

DEPARTMENT

R&D

REPORTS TO

Chief Scientific Officer

POSITION SUMMARY Main Job Functions

Note: In addition to these functions, employees are required to carry out such other duties as may reasonably be required.

Biocompatibility Engineer focused on Respiratory and Airway Management products. You will be a part of the R&D team that is responsible for implementing technical strategies, evaluating and developing products, and providing a superior level of technical support that benefits the organization

JOB LOCATION

(Head Office) Flexicare Medical Ltd, Cwm Cynon Business Park, Mountain Ash, CF45 4ER

SUPERVISORY RESPONSIBILITIES/POSITION IN STRUCTURE Attach outline organisation chart, as appropriate.

No supervisory duties

MAIN DUTIES Duties/responsibilities (in order of priority)

The position collaborates closely with Mechanical Engineers, Clinical, Marketing, Quality & Regulatory in the Respiratory and Airway management business to develop and commercialize Class 1 & 2 medical devices. This position shall provide strategic direction related to the development of systems and programs for the following areas: Microbiology, Cleaning and Biocompatibility testing.

Essential Functions:

• The main responsibilities involve the biological safety risk assessment, by chemical analysis and characterisation, of medical devices in development.

• You develop protocols, reports, and regulatory summaries in collaboration with cross-functional teams, laboratories and suppliers.

• Management of external test laboratories and ensure compliance with global regulatory requirements and standards related to biological safety such as ISO 10993.

• You are also entrusted with defining testing strategies for materials, design and process that satisfy cost and technical requirements as well as analyzing biocompatibility testing (extractable and leachable, chemical characterization and biological evaluations).

• Review and approves external chemical analysis reports

• Keep GOP and associated templates updates with current state of the art

• Additional responsibilities may be assigned, as required, by management.

SKILLS, QUALIFICATIONS, COMPETENCE LEVEL Qualifications/education/Specialist Training required

ESSENTIAL

• Bachelors Degree or higher in Biochemistry, Chemistry, Chemical Engineering, (Bio)Medical Engineering or Physics.

DESIRABLE

• In-depth knowledge of quality assurance techniques, practices, ISO and Regulatory (FDA) compliance.

• In-depth knowledge of medical device regulations and standards – example 18562 and 10993 standards.

• Understanding of respiratory physiology and mechanical ventilation.

EXPERIENCE REQUIRED

ESSENTIAL

• work experience in a technical role

DESIRABLE

• General understanding of directives, regulations and standards.

• Strong knowledge in international standards and regulations including ISO9001, ISO13485, EN62366, ISO10993,

 ISO14971 and the Medical Devices Directive (93/42/EEC). Understanding of FDA Regulations

PARTICULAR APTITUDE/SKILL REQUIRED

ESSENTIAL

• Knowledge of analytical/physical/organic chemistry and ability to translate this knowledge into a consistent work programme to analyse the properties of devices and materials

• Ability to work with a Team in accordance with company objectives.

• Ability to define problems, collect and analyze data, establish facts, and draw valid conclusions.

• Ability to verbally communicate ideas and issues effectively to other team members and management.

• Actively network with the internal and external scientific, technical and regulatory community to maintain state of the art knowledge.

• Partner with Quality to support the development, maintenance and adherence to quality systems and continuous process improvement.

• Partner with product development and regulatory functions to ensure new and sustaining products meet all necessary requirements.

Soft Skills:

• Leadership: The ability to make things happen by encouraging and channeling the contributions of others; recognizing and addressing important issues in a timely manner, and acting as an agent for change and continual improvement when required to achieve results.

• Accountability/Ownership: Work closely with team members and take ownership – educate and communicate to the team

• Influence: The demonstrated ability to gain acceptance and commitment from other to one’s own beliefs and ideas.

• Negotiating: The ability to construct and maintain a strong bargaining position so as to insure positive response and agreement: striving for win-win situations.

• Adaptability: Must possess the ability to understand new concepts quickly and apply them accurately throughout an evolving environment and organize work assignments to meet established timetables.

• Data-Driven Decision Making: ability to move teams through vague and complex situations. Present complex ideas in a simple manner to resolve issues.

DESIRABLE

AGREED       DATE 04.12.2023

AUTHORISED       REVIEWED ON

PRODUCT COMPLAINTS / EVENTS

- When an employee is made aware of a Product Complaint a Product Complaint report shall be completed fully and

 submitted immediately to Flexicare UK QA, but no later than 2 working days from date of awareness.

- Date of awareness, or day zero (0) is the day the first Flexicare employee is informed of an event.

- In addition, in case of public holidays or weekends, the elapsed time between awareness date and the submission of a

 complaint shall not be more than 4 calendar days.

This ensures all new complaints/Events can be reviewed in a timely manner to ensure the Company meets its Legal obligations in reporting adverse events to the relevant Regulatory Agencies within tight deadlines. The above is a mandatory Flexicare policy. Please refer to SOP 12 in our Quality Management System.

BACK UP

Indicate another position that can take over the main tasks and responsibilities during the employee’s absence:

JOB LIMITATIONS

At no time should you work outside your level of competence. If you have concerns regarding this, you have a responsibility to inform your Department Manager immediately.

PERFORMANCE APPRAISALS

You will be expected to participate in a performance/appraisal system in operation or introduced at Flexicare (Group) Limited.

CONFIDENTIALITY

You are required to comply with Flexicare’s Confidentiality and Data Protection rules and Policies.