JOB DESCRIPTION

(*may be completed electronically)*

Job Title:	QA/RA Engineer
Line Manger:	Head of Quality and Regulatory Affairs
Role Summary:	Support operational quality and regulatory compliance at Tissue Regenix Ltd and its UK subsidiaries.

Role deliverables

Summarise the main functions to be performed or main requirements to deliver in order to successfully fulfil this role.

Support head of QA/RA with quality activities associated with the supply (production and distribution) of medical devices at Tissue Regenix UK facility, including:

- Administration of the quality management system in line with system requirements including, but not limited to, CAPA, nonconforming products, document control, feedback & complaints, supplier control, validation, equipment maintenance & calibration, and control of quality records and regulatory standards.
- Lead or support (as applicable) the investigation and resolution of quality issues (corrective and preventive actions, nonconformances, nonconforming products etc.).
- Lead or support (as applicable) the effective implementation of changes (process changes, improvements etc).
- Support outsourced production activities, e.g. product packing, irradiation and testing, including liaising with sub-contractors and testing laboratories as required.
- Assist with verifying the implementation and efficacy of actions.
- Assist with the review and routine monitoring of records and data.
- Assist with the implementation and maintenance of quality controls within the operation.
- Lead or support (as applicable) internal and supplier audits.
- Lead or support (as applicable) PMS activities as required.
- Administration and management of product technical files, such as design dossiers, design history files, regulatory standards, and risk management files
- Perform all activities in compliance with health & safety, external (e.g. ISO 13485) quality standards and internal policies and procedures.

Knowledge

Summarise the requirements for experience / qualifications / existing competencies as appropriate.

- Must have a minimum of 2 years' industry experience in a role of a similar level within the medical device or other regulated industry.
- Must have a minimum of Batchelor's degree level in biological sciences (or related subject) or a minimum of 5-years relevant experience.
- Must have experience working within an ISO 13485 quality management system or equivalent.
- Must have excellent oral and written communication skills.
- Must have good working computer skills including MS Word and Excel.
- Must have strong record of problem solving and a solution-oriented approach.
- Must be organised and self-motivated.
- Must be able to plan & prioritise their own workload.
- Must have a flexible and hands-on attitude to all aspects of work.
- Must have a high level of accuracy, diligence & attention to detail.
- Must be able to work well as part of a team as well as individually.
- A good understanding of manufacturing practices (GMP), ideally for biologics would be beneficial.
- Experience in auditing would be beneficial.
- Experience conducting root cause investigations would be beneficial.
- Experience of design control for biological medical device development and associated quality standards would be an advantage.
- Experience of project management would be beneficial.
- Working knowledge of regulatory requirements for medical devices would be beneficial.

Employee: *Sign / Date*		**Line Manager:** *Sign / Date*	