Job Title:	Operations Engineer
Line Manger:	Head of Technical & Operations
Role Summary:	Support delivery of the operational plan including associated technical work packages 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.

Lead or support operational activities associated with the supply (production and distribution) of medical devices at Tissue Regenix UK facility, including:

- Lead or support (as applicable) investigation and resolution of operational issues owned by production (corrective and preventive actions, nonconformances, nonconforming products etc.).
- Lead or support (as applicable) effective implementation of operational changes owned by production (process changes, improvements etc).
- Support production activities to facilitate successful delivery of the production schedule. Activities include tissue dissection, pre-treatment, processing, packing, product distribution, incoming inspection of materials, media manufacture and equipment & area cleaning.
- Support outsourced production activities, e.g. product packing, irradiation and testing, including liaising with sub-contractors and testing laboratories as required.
- Perform all activities in compliance with health & safety, external (e.g. ISO 13485) quality standards and internal policies and procedures.
- Lead or support (as applicable) identification and implementation of projects to improve costs and/or efficiencies within the operation.
- Support maintenance of production and health & safety documentation, including procedures, risk assessments and COSHH assessments.

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 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.