VACANCY: Validation Engineer

TM A021

Location: Harwell, Oxfordshire, UK
Start date: As soon as possible
Position: Full-time, permanent
Salary: £50-55,000 dependent upon experience
Benefits: Pension scheme with 5% employer contribution
Holiday: 25 days per year plus bank holidays
Apply by: 28 February 2021
Apply to: recruitment@electrospinning.co.uk enclosing a copy of your CV and a covering letter, describing how your experience fits with the advertised position.

The Position

A Validation Engineer to join a growing team developing and manufacturing medical device components using novel technology. The successful candidate will manage process validation and manufacturing projects, keeping them on track with respect to project plan and budget, maintaining design history files and communicating with internal team members, clients and collaborators. The Validation Engineer will work as a key member of the product development and manufacturing teams. He/she will be integral in the development of innovative manufacturing processes and strategies for our medical devices technologies in accordance with regulatory requirements and the TECL Quality Management System. This will involve the tasks outlined below while playing a leading role in enhancing the validation capabilities of the company and development of the team.

Main responsibilities

• Provide direction and support on verification and validation strategy and plans.
• Manage the verification and validation programs in compliance with current regulations, with the objective of outputting robust processes with appropriate controls capable of supporting commercial products and international compliance.
• Manage and facilitate process development by co-ordinating and implementing process improvements/optimisation and analysing process stability and capability.
• Develop Master Validation Plans, develop and complete DV/IQ/OQ/PQ protocols, execute validation protocols, root cause deviations and generate validation reports.
• Manage test methods and ensure test method validation requirements (TMV & ATMV) are included in the scope of validation activity.
• Support the development and maintenance of comprehensive PFMEAs to provide input data for validation activities.
• Create and execute protocols and reports and associated documentation for equipment validation.
• Ensure appropriate and required engineering, equipment and project documentation is generated and is maintained in line with the QMS and associated regulatory requirements.
• Manage and deliver assigned development (V and V) and production projects, ensuring they run to time and budget. Actively manage project milestones, communicating with all relevant parties, both internally and externally.
• Ensure the Technical or Design History File for given projects, is kept up to date, and ‘audit ready’.
• Assist in preparation of proposals for both new & existing product development activities.
• Provide continued technical support to any introduced new products / processes.
• Ensure all activities are performed in accordance with ISO 13485 and any other relevant regulations or SOPs.
• Actively support timely closure of CAPAs, Complaints & Audit actions wherever the area of expertise allows.

The experience and skills we are looking for

• At least 5 years in a medical device or related industry including project management experience
• Relevant degree in science or engineering
• Six sigma or similar experience
• Experience in developing and maintaining a Product Life cycle portfolio (Design History File)
• Knowledge/ experience with Medical Devices (CE mark, PMA, 510K)
• Proficient with office software (MS Word, PowerPoint, Excel etc)
• Demonstration of customer facing activities

The behaviours we value

• Teamwork: taking individual responsibility and supporting team members.
• Transparency: communicating openly and highlighting issues promptly.
• Excellence: delivering high quality outputs; aware of priorities and deadlines. Eager to drive continuous improvements.
• Consideration: Considerate with concern for impact on others.
• Learning: embracing personal development and enthusiastic to learn

The Electrospinning Company Ltd

We design, develop and manufacture materials, specifically nanofibre polymer scaffolds, which are used in tissue engineering and regenerative medicine applications. We have a diverse range of R&D and manufacturing projects with an increasing requirement for process verification and validation. We manufacture components of medical devices that are sold in the USA and Japan and are developing others in partnership with a number of global companies. We operate to ISO 13485:2016 medical device quality standards, are located in new facilities on the Harwell Innovation Campus and have a team of 17 people.

We are not able to obtain working visas so you will need the right to work in the United Kingdom.

Data Privacy
Please note that any personal data submitted in the job application for this role will be processed in accordance with the GDPR and related data protection legislation.