CLINICAL DATA MANAGER

DUNFERMLINE – FIFE – EXCELLENT SALARY AND PACKAGE

Headquartered in Fife Scotland, Edgar Stewart's client is a leading medical device design and manufacturing business with a proud history. Their products are found all over the world, and they are a very well established and growing business. Ongoing new product development, and the need to upgrade and improve legacy equipment means they now need to make the key hire of a Clinical Data Manager.

Reporting to the Clinical Affairs Directors, the Clinical Data Manager will Provide Clinical data management support to the Clinical team and/or study project team and Clinical Data Management team. Other core responsibilities are likely to include:

- Develops Data Management Plan (DMP), maintains DMP throughout lifecycle of study project and ensures DMP is followed according to study design and requirements.
- Participates in the review of Clinical research documents (eg. Protocols, Case Report Forms, Reports).
- Maintenance/tracking of EDC user management and other Clinical databases across allocated Clinical trials, including but not limited to, compiling master user lists and activating/deactivating user accounts.
- Ensure clinical data within EDC is in quality to lock/unlock and freeze/unfreeze as appropriate for statistical review, interim review, and/or final database lock-included but not limited to: data reconciliation and/or coding.
- Assist in defining and/or creating data listings, summary table validation, data specifications and/or process data transfers in preparation for statistical review and/or data management audit.
- Perform close-out audit, as specified, for closing of study trial in EDC or other clinical data management DBs.
- Coordinate and communicate with DB vendors on consistent basis to address Clinical team's requests, project plans, and/or eCRF development activities.
- Collaborate with IT and implementation team(s) to address Clinical application requests and/or changes to Clinical database systems.
- Ensures data system compliance by following the established guidelines of national and international regulatory authorities.
- Perform project specific tasks in compliance with Good Clinical Practices (GCP), regulatory requirements (21CFR Part 11), applicable departmental and companywide SOPs, and project specific protocol

Educated to degree level in Science, Ophthalmology or Allied Healthcare Career along with at least two years data in management and/or related work experience a medical device or pharmaceutical industry/company. Along with having strong communication and presentation skills, the candidate will have Working knowledge of Good Clinical Practices,

Good Manufacturing Practices, Clinical research, Clinical trial process and related regulatory requirements and terminology.

What helps set this business apart from their products and global success, is a can do and people centric culture. We want to hear from people up for a challenge, who enjoy being part of a team and contributing to shared success. People with a highly positive outlook on life, inquisitive and with a good sense of humour tend to do well here.

Apart from getting the chance to work on some leading edge medical device products, you can expect an excellent base salary and comprehensive benefits package. Our client is at the forefront of eye care medical devices, and serious career development alongside personal growth are on offer for the right candidate.

To apply for this role please email your CV to our recruitment partner Alastair Edwards at Edgar Stewart Selection. Alastair@edgarstewart.co.uk