Quality Assurance Manager

Buckinghamshire

Ref: PSL4045

Attractive Salary Package
Commensurate with experience

Join a leading global specialist in the provision of technology based solutions, products and services to the global clinical research market. You will be responsible for maintaining and enforcing quality standards for clinical research operational activities and facilitating the QA function.

As QA Manager, your remit will include conducting internal audits, line managing staff and working to Good Clinical Practice in relation to the 2001/20/EC Directive for trial activities and the company's ISO 9002 standards and Investor in People Principles.

Key responsibilities will include, but not be limited to:

- Facilitating, planning and co-ordinating the preparation and approval of SOPs and QPs in line with the company's Quality Management System.
- Managing and leading the maintenance and timely revision of SOPs, QMS and Quality Manual and the dissemination of SOPs to appropriate staff, along with provision of effective training.
- Implementing and maintaining a master schedule of quality observations to verify operational activities.
- Facilitating external client audits and following up on results. An integral element of the role is to host and provide support in the preparation and co-ordination of inspections by regulatory authorities and clients.
- Mentoring and training staff in the audit process, reviewing results of audits and recommending strategies for improvement.
- Liaising with staff to ensure that there is significant and relevant QA involvement in all operational activities.
- Supporting the Head of Training to ensure that relevant formal QA training programmes are provided. You will need to be enrolled as a member of BARQA and disseminate information and updates as appropriate.

To fulfill this role you will need to be a proactive, experienced Clinical Research QA professional, preferably with global experience and possess expertise in GCP and clinical trial regulations.

Ideally you will have a life sciences background with experience in writing and developing SOPs and quality documents. Validation/GAMP/21CFRpart11/SDLC knowledge is desirable. You will have experience with managing and mentoring others and help to ensure that QA is a consideration in all company activities.

Strong communication skills will be important in building both internal and external relationships with customers and operational groups.

This is a great opportunity to join a highly successful business, where you will report directly to the Managing Director on initiatives and actions and where the long term career prospects are excellent.

For further information or a discussion in complete confidence, please contact Dr Grant Coren, Pharma-Search Ltd - grant@pharma-search.co.uk, telephone: + 44 (0) 1442 345 340.

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