Validation Engineer – 6 Month FTC

White City, London

The Role

At DNAe we have a fixed contract role for a Validation Engineer, the role is cross functional and works closely with our Engineering, QA and Operations teams.

Primary Responsibilities:

- Create and maintain the Validation Master Plan for process, equipment and cleaning validations at the DNAe UK site
- Take the lead on the site move with respect to validation and related activities. This will involve the creation and execution of appropriate validation documentation as outlined in the Validation Master Plan
- Work with engineers and technicians to draw up a list of testing protocols or re-calibrations that will have to be performed before equipment is used again.
- Generate an Inspection Report Plan consisting of testing protocols performed to ascertain whether any previously required tolerances and quality controls are still intact
- Review results of the Inspection Report Plan including what was found during testing and auditing; document and close out action items.
- Lead the validation processes at DNAe and ensure all processes are documented, implemented and trained on
- Maintain all responsible activities and projects in an inspection ready status ahead of any internal or external audits to ensure successful inspections
- Compliance with the relevant DNAe Quality System processes and procedures
- Lead the validation activities for various non-bespoke R&D software tools and applications used at DNAe
- Guide and participate in software tools validation, risk assessment, requirement development, protocol and validation report writing.
- Validate and release software tools used in device development in FDA regulated medical device business.
- Other duties as assigned by your manager

Required Qualification and Experience

Education:

Bachelor's degree in Engineering (Biomedical, mechanical, chemical or electrical) or Science (biology, chemistry, etc.)

Skills:

- Demonstrates working knowledge of FDA and ISO regulations.
- Knowledge and ability to implement FDA or regulatory requirements as necessary.
- Sound understanding of IQ, OQ, PQ and Software Validation requirements and practices
- Demonstrated ability to communicate effectively both verbally and in writing

Experience:

- Several years of experience as a Quality Engineer in an FDA and/or ISO regulated environment in IVD, medical device, or biotech industry.
- Validation of software tools used in device development in FDA regulated businesses.