DNAe
LIVE DIAGNOSTICS

BioInformatics Software Documentation Specialist

White City, London

The Company

DNAe, the inventors of semiconductor-based next-generation sequencing (NGS) technology, is developing a revolutionary new NGS-based diagnostic platform in an easy-to-use, cartridge-based system designed to generate a clinically actionable result direct from clinical specimen, in a matter of hours.

We currently have a role in our BioInformatics team. The objective of the successful candidate will be to guarantee compliance of DNAe BioInformatics pipelines and processes to the following standards: ISO13845, IEC62304, IEC 62366 standards.

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for industry and FDA Staff, and DNAe requirements. Your skill set includes: IT and Organizational skills, Written communication skills, Attention to detail and Team working.

Responsibilities

- Actively contribute to the Documentation of the bioinformatics pipeline component of DNAe's targeted sequencing solution as well as documentation of procedures and process configurations.
- Guarantee compliance of Bioinformatics processes to Quality standards.
- Train Internal users to Bioinformatics SOPs, from using autonomously the BioInformatics pipeline to data management (From Medical data to Sequence databanks).
- Actively promote interactions within the Bioinformatics team by setting-up compliance reviews.
- Participate in relevant regulatory forums to help ensure our product designs reflect the Bioinformatics challenges of a regulated diagnostic sample-to-answer sequencing tests.
- Partners with the IT, Regulatory and Software teams to document, test and validate new analytical tools and processes.
- Ensures compliance with all relevant standards to guarantee security, and confidentiality of transactions. Actively support IT team to reach highest standards in cybersecurity of BioInformatics data (both in the final diagnostic platform and the DNAe's environment)
- Other duties as assigned.

Required Qualification and Experience

Education:

MS or PhD in Computer Science, Physics, Mathematics, or equivalently technical discipline, or extensive software product development experience.

Skills:

- Confident in windows and Linux environments, Git source code repository, Jenkins
- Clear communication skills and proven ability to train others.
- Demonstrated ability to work autonomously and remotely (online work with daily stand-up meetings and frequent online interactions within the BioInformatics as well as several others DNAe teams such as IT, regulatory and Software).

Experience:

- Demonstrated experience (5+ years) in producing BioInformatics/software documents for regulated environments (ISO13845, IEC62304, IEC 62366 standards, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for industry and FDA Staff, and DNAe requirements, etc.).
- Experience of the process requirements, documentation and traceability needed for regulated development. (Preferably, but not necessarily IEC 62304) (e.g. safety-critical)
- Experience developing medical software validation procedures.

Desirable Experience

- Ideally have worked within a multidisciplinary team with an emphasis on excellent communication skills.
- Experience designing, developing, and validating medical device BioInformatics software (Nucleic Acids Amplification Technologies and/or Next Generation Sequencing)
- Experience in software development flows for medical devices, and familiarity with relevant ISO standards such as 14971, 62304, 61010
- Experience with scientific Python libraries - SciPy, NumPy, Pyplot, Pandas
- Experience as internal auditor in clinical development context especially on topics linked to bioinformatics.
- Other Qualifications: knowledge of statistical and machine learning methods is a plus.

Apply

To apply please email your CV and salary expectations to Careers@dnae.com quoting the job title of this role in the email heading.