United Kingdom Jobs Expertini®

Validation Scientist

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Company: Novacyt Group

Location: Manchester

Category: architecture-and-engineering

At Novacyt Group we pride ourselves on concentrating our expertise on specific market needs. Offering a comprehensive and developing portfolio of quality products, backed by proven supply and delivery services, to ensure the highest possible standards of customer service around the world. Our passion is for customer-centric solutions that advance the science behind diagnostics. This fuels our drive to deliver products that save lives and help in the fight against infectious disease.

We offer an increasing portfolio of in-vitro diagnostic tests, utilising molecular and protein detection technologies – supporting healthcare and disease prevention across the globe in the clinical and life science sectors. Deep strengths in product development, commercialisation, contract design, and manufacturing ensure quality products and robust supply.

Our Group has specialist experience and expertise throughout our business units: Primer Design, Novacyt UK, IT-IS International, and Yourgene Health UK – creating solutions for the diagnostics industry, supplying an extensive range of high-quality assays and reagents worldwide.

Job title: Validation Scientist

Reports to: Manufacturing Manager

Location: Manchester Science Park

Contract Type: Full-time, 6 months FTC

Salary & Benefits: Competitive Salary + Benefits

About Yourgene Health:

Yourgene Health is a leading integrated technologies and services business, enabling the delivery of genomic medicine. Yourgene work in partnership with global leaders in DNA technology to advance diagnostic science.

Yourgene primarily develops, manufactures, and commercialises simple and accurate molecular diagnostic solutions, for reproductive health and precision medicine. Yourgene's flagship *in vitro* diagnostic products include non-invasive prenatal tests (NIPT) for Down's Syndrome and other genetic disorders, Cystic Fibrosis screening tests, invasive rapid aneuploidy tests and DPYD genotyping.

Yourgene has a range of innovative DNA Size Selection instruments, powered by Ranger® Technology, ideal for cell-free DNA applications in NIPT, oncology including liquid biopsy, long fragment recovery and gene synthesis applications.

Yourgene also has a global laboratory service network equipped to be a full life-cycle partner for clinical, research and pharmaceutical organisations to support partners at the preclinical, clinical, and post market stage to develop, manufacture, obtain regulatory approval and commercialise new products and services. In addition, Yourgene offers an NIPT testing service in the Manchester laboratory.

Yourgene Health is headquartered in Manchester, UK with facilities in Taipei, Singapore, the US and Canada.

Our Culture:

Yourgene is a growing, vibrant and exciting place to work, we are looking for committed driven individuals to be part of our next growth journey. Our culture is described by our employee's as collegiate, friendly, professional, innovative, open and fast paced. We have plenty of social and well-being initiatives run by our Nova Social & Charity Huddle that keep our sense of community alive and allow us to be part of charity fundraisers. At Yourgene, we focus on putting values led programmes in place to ensure that we can attract, retain and develop our people. We want our people to have a career with Yourgene and we ensure that they are recognised and rewarded for their achievements and commitment, everyone plays a

critical role in our growth journey.

About the role:

We have a fantastic opportunity for an experienced Validation Scientist to join our team on a 6 months fixed-term contract based at our Manchester HQ located at Manchester Science Park. The Validation Scientist will be responsible for SOP writing and validation under ISO 13485/GMP environment and to drive validation of new processes and improvements in our manufacturing and operations teams.

Key areas of responsibility:

- Validation of changes to Manufacturing & QC standard operating processes
- Document control within a Quality management system to ensure traceable, logical and consistent workflow and procedures.
- Liaise with appropriate departments to contribute to the rapid and effective investigation of process quality and manufacturing problems and for the development of improved QC tests and manufacturing practises.
- Improvement to Inventory management and maintenance.
- Adopt a cross functional approach through regular liaison with Manufacturing, Quality Control and Quality assurance teams to ensure testing is completed in a timely manner
- Contribute to process improvement programs and troubleshooting through the performance of non-routine operations and reporting of data.
- Maintain any relevant proficiency testing, calibration or validation work, that may be appropriate to the QC sphere of activities, as defined in Company Quality System.
- Drafting a validation policy for end users and provide training.
- Ensuing all documentation is completed around validation on the Quality management system.

Validation Scope:

- Automation of process' including dispensing and labelling
- Carrying out equivalency testing on hardware and software

Health & Safety Improvements

Qualifications, Skills and Abilities

HND / Degree in an appropriate Biological Science.

QC experience in GMP / ISO13485 laboratory environment.

Experience of the use of ABI thermal cyclers and genetic analysers.

Good analytical approach to investigating operations & product quality issues.

Experience of DNA extraction and quantitative analysis by spectrophotometry.

Experience of OOS investigations and CAPA resolution.

Strong pipetting skills.

Methodical and organised approach to work.

Computer literate with competence in MS Office and Genemapper.

Closing Date:

Sunday 28th April, 2024

Yourgene Health is committed to encouraging equality, diversity and inclusion among our workforce . The aim is for our workforce to be truly representative of all sections of society and for each employee to feel respected and able to give their best.

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