Job description and person specification

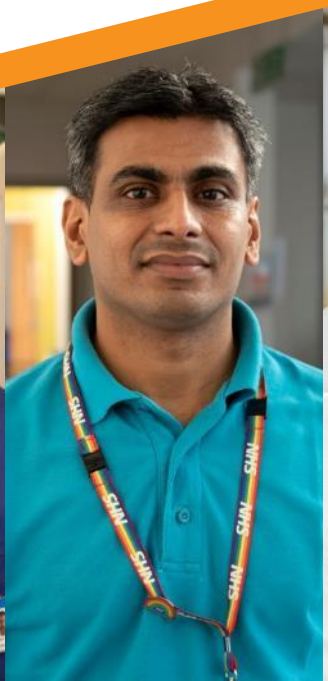
East and North Hertfordshire NHS Trust

Job title: Quality Control Microbiologist

Band: 8a

Department: Quality Control

Division: Planned Care


Contents

Letter from Adam Sewell Jones, Chief Executive

Thank you for expressing an interest in working here at East & North Hertfordshire NHS Trust.

East and North Hertfordshire NHS Trust is a very special organisation. Our teams are amazing, and this has been demonstrated even more so during the unprecedented challenges brought about by the Covid-19 pandemic. Our ability to be flexible and innovative in the way in which we work and deliver our services to our catchment has never been more important than it is now.

We are a large acute Trust which operates across four sites; acute services are offered at the Lister Hospital; specialist cancer services at the Mount Vernon Cancer Centre (MVCC); and non-acute services offered at Queen Elizabeth II and Hertford County hospital. We underwent an extensive £150m reconfiguration some years ago which saw all inpatient and complex services centralised at the Lister.

We are an organisation with a strong culture of positive values and our ambition is to provide high-quality, compassionate care to our community in all that we do, including patient experience, clinical outcomes, patient safety and financial sustainability.

We have many great people working for us doing all sorts of roles, ranging from porters to doctors, from administrators to nurses, and everything in between. But we all share one vision – we put our patients at the heart of everything we do.

We have recently partnered with the world-renowned Virginia Mason Institute in an exciting 3-year programme to create and embed a quality management system – our ENH Production System. Drawing on years of quality improvement and culture change experience, the ENH Production System will equip our teams to identify areas for improvement, make changes and measure impact – all with the patient at the centre.

If you decide to apply, you will be joining us at an incredibly exciting time as we continue on our transformation journey. I hope very much, that after reading this pack, you will want to join us on that journey.

I wish you the best of luck in your application.

Adam Sewell-Jones
Chief Executive

Benefits

As a Trust employee, you can access a range of financial and non-financial benefits to support our staff in all aspects of their life.

Wellbeing:

- Get confidential advice and support on personal, work, family and relationship issues, 24/7, from our Employee Assistance Programme
- Offers and discounts at local gyms
- In-house Health at Work service with advice line and self-referral facility for staff as well as signposting and access to other support, such as weight management clinics and physiotherapy
- On site workplace pharmacy at Lister offering a minor ailment service, flu vaccinations, travel clinic, sexual health, smoking cessation and health check services
- Opportunity to discuss ideas, problems or concerns easily and anonymously with our Speak in Confidence service

Travel:

- Save up to 30% on a new bicycle through our Cycle to Work scheme
- Reduced staff car parking costs through our Car Sharing scheme
- Discounts on local buses and trains
- Competitive rates through our car lease scheme
- Inter-site transport minibus which includes shuttle to Stevenage Railway Station

Work/Life Balance:

- Pursue different interests with the security of employment on your return from your break of 3 months to 5 years with our Career Break scheme
- Generous annual leave with additional days awarded for long service
- A variety of different types of paid and unpaid leave covering emergency and planned leave, such as special leave/ emergency leave/carers leave, through our Special Leave policy
- A Retire and Return scheme, enabling you to draw your pension whilst continuing to work for us after a short break
- Options for flexible working to provide you with a healthy work/life balance such as part time working, term time only, compressed hours (subject to service requirements), and flexible work schedules

Financial:

- Discounts on restaurants, getaways, shopping, motoring, finance through a variety of providers
- Access to the NHS Pension Scheme, providing generous benefits upon retirement, as well as a lump sum and pension for dependants

Learning and Development

- Extensive range of learning and development opportunities, including coaching, for both clinical and non-clinical topics
- Access to our Grow Together scheme, ensuring that you have meaningful, quality conversations with your manager about what matters to you and your development
- We fully encourage our staff to develop to their full potential and are supportive of secondments, acting up opportunities and all learning and development activities.

Other:

- Local and Trust wide staff award schemes where staff are nominated and recognised by their colleagues and peers for their hard work
- Assistance in relocating for some staff with our Relocation Policy

Our vision, mission, and values

Our vision is:

“To be trusted to provide consistently outstanding care and exemplary service”

Our mission is:

Providing high-quality, compassionate care for our communities

Our values are:

We value the diversity and experience of our community, colleagues and partners, creating relationships and climates that provide an opportunity to share, collaborate and grow together

We create a safe environment where we are curious of the lived experience of others, seek out best practice and are open to listening and hearing new ideas and change

We are committed to consistently delivering excellent services and continuously looking to improve through a creative workforce that feels empowered to act in service of our shared purpose

Job description

Job title:	Quality Control Microbiologist
Band:	8A
Department:	Quality Control Department
Base:	Lister hospital, however, you may be required to work on a permanent or temporary basis elsewhere within East and North Hertfordshire NHS Trust and customer sites.
Responsible to:	Principal Pharmacist (Quality Control Services Manager)
Responsible for:	Assisting the Quality Control Services Manager in the provision and delivery of pharmaceutical and scientific Quality Assurance and Quality Control services to all clients including financial and personnel management of the service. Services are provided to NHS Trusts and Independent Sector Hospitals, Commercial Companies and other customers

Job summary:

The Quality Control Microbiologist will be a suitably qualified professional with significant practical experience of pharmaceutical microbiology. They will interpret the current standards and guidance applicable to sterile and non-sterile pharmaceutical facilities and ensure that any microbiology testing and monitoring is undertaken in line with the current industry standards in particular the Guide to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use and the Manufacture of Sterile Medicinal Products.

They will lead the microbiology section of Quality Control Department and develop and deliver pharmaceutical and environmental microbiology and other non-clinical microbiological services. They will train and develop staff and be actively involved in management and implementation of pharmaceutical quality management system and continuous development. They will plan, organise and deliver high quality microbiology service to all internal and external customers of the Quality Control Department.

They will be responsible for managing the Quality Control Department's Information systems.

Key working relationships:

All members of the multidisciplinary team, including pharmacists, scientists, technicians, engineering, nursing and medical staff, allied health care professionals, support workers, administration and clerical staff both within the Trust and customer sites.

Main responsibilities:

1 To interpret the current standards and guidance applicable to sterile and non-sterile pharmaceutical facilities and ensure that microbiology testing and monitoring is undertaken in line with the current industry standards in particular the Guide to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use and the Manufacture of Sterile Medicinal Products.

2 To undertake ongoing CPD to keep abreast with developments and changes in expectations, review, assess impact and implement any such changes where required to ensure that

current regulatory expectations and good practice guidelines are applied and followed in work of the microbiology section.

3 To ensure that all Standard Operating Procedures relevant to microbiology testing are prepared, reviewed and kept up-to-date to reflect the current regulatory expectations and good practice guidelines.

4 To provide leadership and manage staff in the microbiology section including setting agreed objectives, conducting staff annual performance appraisals and regular personal development reviews as well as management of staff performance and absence.

5 To participate in all stages of staff recruitment and retention including preparation of job descriptions and personal specifications for all staff.

6 To organise, plan, deliver, document and monitor staff training in the microbiology section. To act as a mentor to new and junior staff and provide professional guidance to all staff reporting to this post. This includes identifying training needs, preparation of training matrix and training modules for all staff working permanently or on a rotation basis in the microbiology section. Training includes all permanent staff as well as any staff seconded for training such as Laboratory assistants, Pre-registration Pharmacists, Technicians and Student Technicians.

7 To lead microbiology section QMS meetings, discuss, propose, agree with QA staff and implement CAPAs to ensure continuous improvement.

8 To chair laboratory staff meetings and attend external client Quality Assurance meetings where required.

9 To plan, organise and manage testing of microbiology external quality assurance schemes samples by all microbiology staff, evaluate results and trends and take action as necessary. Present trends of results at the QMS review meetings.

10 To actively participate in the laboratory internal audits as well as in any external regulatory or client audits

11 To develop, validate, document and implement new microbiology test methods and techniques for testing of both sterile and non-sterile items; complete method transfers where applicable. To undertake research and development and investigations as required.

12 To ensure all testing is undertaken and the results documented, evaluated and reported in line with the current GMP expectations and applicable standards and within agreed timelines. To ensure that any out of specifications results or deviations are recorded in the laboratory QMS system and investigated as appropriate.

13 To plan, organise and manage microbiological testing of all sterile and non-sterile items and products. This includes microbiological bioburden testing, challenge testing, preservative efficacy and container integrity tests as well as other methods. These are applied to a range of pharmaceutical products, raw materials, ingredients as well as water at different stages of chemical and microbiological purity and intended for a variety of applications including haemodialysis and sterile production.

14 Laboratory tests include *Limulus* Amoebocyte Lysate test by kinetic turbidimetric technique as well as undertaking identification of microbiological isolates using a variety of techniques based on morphology, microscopy, biochemical tests including the API kits.

15 To plan, organise and manage both preparation of in-house microbiology media (where undertaken) and implement suitable schedules for fertility testing of all growth media used by the laboratory or external clients.

16 To manage processing of samples and reporting of results for any testing undertaken by external contract laboratories.

17 To plan, organise and manage the microbiological environmental monitoring (MEM) schedules for client pharmaceutical and healthcare clean rooms as well as subsequent sample incubations, reading and evaluation and reporting of results. To undertake the microbiological environmental monitoring of Pharmacy Clean Rooms and other healthcare clean rooms where necessary.

18 To review MEM data and any changes in trends generated for aseptic and other health care clean rooms and generate the annual microbiological review report where required, To propose appropriate actions as part of the contamination control strategy. Where required, propose and implement on the MRS system appropriate Alert and Action Limits for any testing or monitoring undertaken.

19 To draw up microbiological component of Validation Master Plan for new or upgraded facilities and plan, organize and manage all associated activities.

20 To implement and maintain stock control system for reagents and consumables and ensure effective use of all laboratory resources. To ensure duty of care in relation to the use of all microbiology equipment and consumables and ensure best value for money.

21 To assist with providing information and implementation of a suitable system to enable generation of SORFs and contribute to CIPs and income generation activities.

22 To review and assess all generated data and test results and maintain all aspects of the Quality Management System in relation to the microbiology section. This includes risk and impact management as well as documentation, review and investigation of out of specification results, deviations and errors, application of Change Control system and proposing suitable CAPAs to resolve and prevent any quality issues. To work together both with the laboratory QA team and laboratory clients, where applicable, on implementing suitable CAPAs to ensure continuous improvement.

22 Review and authorise, if appropriate, urgent purchase requisitions for laboratory items where necessary in the absence of service manager or their deputy.

23 To evaluate microbiology section requirements and needs for any required equipment, assist with preparation of a business plan, make recommendations on purchases and co-operate with the supplies department where appropriate. Follow the change control process to prepare and execute an appropriate validation master plan to implement use of any new facility or equipment.

24 To plan, organise and manage implementation, validation, changes or upgrades of laboratory software and any other electronic GxP computer systems in the department. To act as an administrator for the laboratory Databases and undertake DIRA assessments and periodic re-assessments of GxP computer systems.

25 To be aware of the clinical impact of the work being undertaken and the generated results in relation to patient safety and their treatment.

27 To be familiar with appropriate Health & Safety Policies and Procedures. To take reasonable

care of yourself and anybody who may be affected by your actions/non-actions. To be familiar with and protect yourself and any other laboratory staff from microbiological, chemical and other hazards.

This job description is neither exclusive nor exhaustive and the duties and responsibilities may vary from time to time in the lights of changing circumstances and in consultation with the job holder.

Supplementary job description information:

Confidentiality

Each of us have a personal responsibility and liability under the Data Protection Act 2018 around the confidential nature of our jobs. Details of a confidential nature, including information relating to patients or staff, must not under any circumstances be divulged to any unauthorised person. Breaches in confidence will result in disciplinary action, which may result in dismissal. In exceptional circumstances this could result in a prosecution for an offence or action for civil damages under the Data Protection Act 2018.

Health and Safety

You must take reasonable care of your own health and safety and that of other people who may be affected by acts of omission at work and to ensure that statutory regulations, policies, codes or practice and department safety rules are adhered to.

Sustainable Development

We recognise the need for a sustainable development strategy that focuses on reducing carbon emissions. We do this through:

- Reducing environmental impact achieved by greener waste disposal and travel, energy and water consumption
- Being a good community role model and supporter of the local economy
- Providing excellent value for money
- In order to reduce our carbon footprint, every single one of us must play a part in ensuring we are an environmentally-responsible organisation. You recycle at home, we ask that you do the same simple things at work
- When you can, use public or inter-site transport, cycle between sites and claim for mileage
- Recycle all you can: paper, CDs, batteries – there are recycling stations throughout the Trust
- Always switch off lights, PCs and other electrical appliances when not in use
- Don’t waste water

Safeguarding

You must have regard to the need to safeguard and promote the welfare of children in line with the provisions of the Children Act 2004.

You must treat all patients with dignity and respect and ensure that vulnerable adults are safeguarded from abuse and neglect within the provisions of the Hertfordshire Safeguarding Adults from Abuse Procedure.

Infection Control

You are expected to take individual responsibility to ensure working practice is safe.

Equality, Diversity and Inclusion

The organisations which make up Herts and West Essex Integrated Care System believe that fairness for people is fundamental to providing good care. We want to ensure that those who work with us and for us share this core value.

We are committed to equality, diversity and inclusion for all job applicants, staff, patients and the wider community. We are continuing to develop the strength of our inclusive approach, and creating a workforce which represents the diverse communities we serve is an important part of this.

We have agreed to:

- Work together to learn, celebrate and embrace diversity, end unfairness, discrimination and racism, and embed these changes into our everyday work
- Strive towards being an exemplar group of organisations for equality, diversity, inclusion, fairness and belonging
- Commit to value all people and promote a culture of zero tolerance to all kinds of harassment, bullying, discrimination and racism in the workplace
- Pro-actively champion national and local policies and initiatives to address health and workforce inequalities
- Work in partnership with other professional and health and care organisations to embed these principles Work in partnership with other professional, health and social care organisations, trade union and voluntary sector organisations to embed these principles

Each organisation with the Herts and West Essex Integrated Care System has agreed to include this statement on their job descriptions so that staff and job applicants are aware of this commitment. Staff are expected to be supportive of these principles and to demonstrate this in everything they do at work, regardless of their role.

You are required to always demonstrate behaviours which support our commitment to equality, diversity and inclusion, as detailed below, so that our workplaces are free from harassment and/or unlawful discrimination and where diversity is actively valued and celebrated.

Review

These guidelines are provided to assist in the performance of the contract but are not a firm condition of the contract. The job description will be reviewed as necessary to meet the needs of the service, in consultation with the post holder.

Person specification

Requirements	Essential	Desirable
Qualifications / Training		
B.Sc. in a Biological Science or similar subject	Y	
Significant post graduate experience in pharmaceutical microbiology environment.	Y	
Postgraduate Diploma in Pharmaceutical Technology and Quality Assurance or equivalent postgraduate level of knowledge.	Y	
	Y	
Previous Experience		
Experience of working in GLP/GMP environment in QA/QC Department in Hospitals, Pharmaceutical or Biotechnology industry.	Y	
Management/leadership experience as well as demonstrated experience of staff training, development and performance management and assessing staff competencies	Y	
Experience of writing, reviewing and approving standard operating procedures.	Y	
Experience of microbiological environmental monitoring within pharmaceutical manufacturing facilities including of trend analysis of environmental monitoring data and of generating environmental monitoring reports.	Y	
Experience of variety of microbiological laboratory techniques including handling hazardous materials.	Y	
Skills		
Good interpersonal skills and the ability to communicate with all levels of staff and individuals within and outside of the department with confidence, assertiveness and tact. Excellent customer care skills.	Y	
Ability to work with a variety of high precision laboratory and other relevant equipment requiring a high degree of hand-eye co-ordination, manual dexterity and visual & colour acuity.	Y	
Ability to work at speed accurately		
Ability to concentrate and maintain accuracy for long periods of time when analysing data/results and undertaking testing.	Y	
Ability to concentrate and maintain accuracy for long periods of time when analysing data/results and undertaking testing.		

Knowledge Ability to use the technical knowledge, reasoning and professional judgement to critically review and assess highly complex data and information relating to facilities and products in order to evaluate their suitability for their intended use. Knowledge of Information technology to include Microsoft Word, Excel, Access and Power Point. Knowledge of current legislation and guidelines relating to pharmaceutical PQMS, GMP, GLP, GCP. Knowledge of validation requirements for pharmaceutical facilities, equipment and processes. Advanced knowledge of microbiological techniques. Knowledge of Health and Safety at Work act, COSHH legislation and laboratory safety issues and risk assessments. Understanding of waste management regulations.	Y Y Y Y Y Y Y	
Other requirements Required to wear full PPEs as appropriate for work in laboratory environment or in sterile aseptic facilities and work sitting or standing for prolonged periods of time, The post holder may be required to work in aseptic facilities Required to have the ability to carry and handle moderately heavy equipment. Required to have the ability to occasionally work at height and also in confined spaces. Required to be flexible and willing to work out of hours and at weekends to meet customer service demands. Ability to travel easily between Trust Sites Experience and evidence of engagement around equality, diversity and inclusion issues in relation to policy, service development and service delivery in respect of both services to users and the management of staff Role model our Trust values every day	Y Y Y Y Y Y Y Y	