Central Manchester University Hospitals NHS
NHS Foundation Trust

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1. JOB DESCRIPTION

Job Title:	Clinical Scientist, EMQN
Division:	St Mary's Hospital
Directorate:	Genetic Medicine
Department:	EMQN[1]
Salary Band:	7[2]
Hours of Duty:	37.5 Hours per week
Responsible to:	EMQN Deputy Director
Accountable to:	EMQN Director
Liaises with:	EMQN Board, EMQN Colleagues, Users of EMQN services

2. JOB PURPOSE

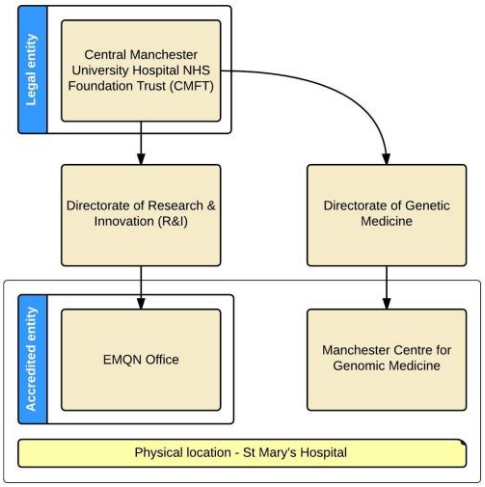
- To supply specialised International External Quality Assessment (EQA) services provided by the European Molecular Genetics Quality Network (EMQN) to the standards required by the EMQN Board and the United Kingdom Accreditation Service (UKAS).
- To ensure the efficient and effective logistical management of aspects of services provided by EMQN.

3. DIMENSIONS

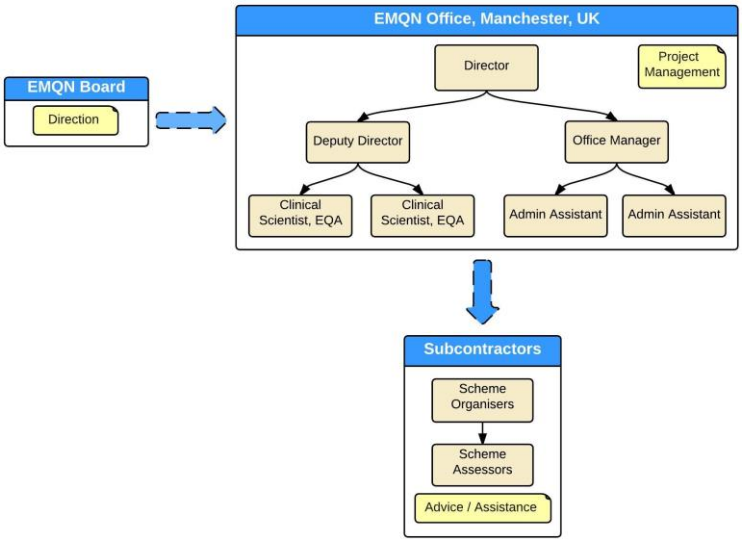
EMQN monitors laboratory performance nationally and internationally and accordingly contributes to Clinical Governance on a national and international level. The service aims to reduce harm to patients caused by erroneous test results, and to improve test quality by education and demonstration of best practice. The post-holder assists with supervision of the administrative staff and liaises with the numerous external providers of subcontracted services relevant to the provision of the EQA schemes organised by EMQN. *[Additional background information is provided in Appendix I.]*

4. ORGANISATIONAL POSITION

EMQN / Host Organisation



EMQN Office



Note: National / International Accountability is to the EMQN Board

[1] hosted within the Genome Diagnostics Laboratory
[2] State registration required for band 7 position

5. ROLE OF DEPARTMENT

EMQN is an External Quality Assessment (EQA) provider, with an international role serving more than 1500 laboratories in 52 countries. It has routine, educational and research components, hosted by Central Manchester University Hospitals NHS Foundation Trust (CMFT) and based within the Genome Diagnostic Laboratory located in St Mary's Hospital, Manchester, United Kingdom.

6. KEY RESULT AREAS

Managerial

- To assist the Deputy Director in the proper running and further development of EMQN, as directed and mandated by the EMQN Director and Board.
- To assist the Deputy Director in ensuring the EMQN's adherence to the Quality Standards required to maintain accreditation by United Kingdom Accreditation Service (UKAS) including taking responsibility for a designated component of quality management / governance (for example, document control, audit etc).
- To achieve high operational standards by prescribing and promulgating these standards to the relevant EMQN staff,
- To assist in the management of junior staff as required, according to its Organisation's policy and procedures.
- To be responsible for aspects of EQA scheme project management including planning and implementation of logistics in support of EMQN.
- To provide expert scientific advice and interpretation on external quality assessment to Scheme participants, Specialist Advisory Groups, Committees, the EMQN Board, and to other EQA Organisers and colleagues.
- To contribute actively to the setting of national and international standards and policy, to support standard-setting as appropriate and to initiate and carry out audit of these standards as required.

Scientific and Technical

- To oversee the preparation of EQA specimens in accordance with EMQN specifications and policies and to undertake analytical procedures of an advanced or highly complex nature as appropriate, requiring special knowledge for their execution and involving handling of biological material (e.g. blood, DNA and/or unfixed/ fresh tissue samples) and noxious chemicals as required by the post.
- To undertake complex calculations, manipulations and interpretation of data requiring long periods at the computer and a high degree of accuracy, so as to ensure the accuracy and appropriateness of all reports - annual and monthly (including expert commentaries and surveys of recent literature sent to all participants and written and verbal communications with individual participants) - prepared by the post holder and to keep records of these as required by UKAS, often working under considerable time pressure in order to meet essential deadlines.
- To be responsible for and carry out proactive surveillance of participants' performance to assist the Director / Deputy Director in providing regular reports to relevant regulatory authorities, reports which may result in clinical laboratories with unacceptable performance being required to stop performing tests
- To assist the Director / Deputy Director in identifying the need for and preparing reports on adverse method performance and other relevant clinical incidents relating to all analytes monitored by EMQN for the Medicines and Healthcare products Regulatory Agency (MHRA) as appropriate.
- To ensure the efficient and effective logistical management of all services provided by EMQN.

Laboratory Informatics

- To comply with local and national policies for the safe, secure and confidential processing and storage of technical and other information provided by EMQN participants or related to patients treated at CMFT or elsewhere, in accord with local, national and other policy and to use EMQN Databases according to authorised protocols.
- To be competent in the use of Microsoft office (or equivalent) including spread sheets and processing of data for audit, research and other scientific information gathering, including preparation of complex graphs for EMQN Annual Reviews and other reports.

Clinical

- To provide expert advice to multidisciplinary professional groups developing regional, national and international services relevant to diagnostic tests within the remit of EMQN.

Research and development

- To undertake research (which may include the evaluation of new and improved procedures, instruments and reagents) within the remit of EQA activities.

- To publish research work in peer reviewed journals, to present the work nationally and internationally (usually to audiences of 20 to 200 specialists and non-specialists) and to referee papers for scientific journals.

Educational

- To undertake limited undergraduate and postgraduate teaching in the CMFT hospitals, community - including supervision of research projects, training of medical scientific and technical staff, education of users of the EMQN service nationally and internationally – while maintaining current awareness of issues related to all aspects of molecular testing through participation in relevant CPD activities at all levels.

General

- To comply with the policies and procedures of the CMFT Organisation, by observing and adhering to local and national health and safety policies, maintaining good work relations with all members of staff, promoting effective teamwork, and treating everyone associated with CMFT and all EMQN participants with courtesy and respect, at all times maintaining and promoting the professional image of EMQN and CMFT Organisation.
- To be personally responsible for his/her own work and workload management, working with a high degree of autonomy, subject to the supervision and direction of the EMQN Deputy Director or other designated senior staff.

7. EQUIPMENT AND MACHINERY

The post holder has:

- Wide ranging knowledge of molecular testing equipment, technologies and methods used by EMQN participants.
- Responsibility for the daily operation, staff training, maintenance and performance quality of highly specialised laboratory investigations and highly complex laboratory instrumentation, used by EMQN.

8. SYSTEMS

The post holder is required to spend long periods of time in front of the computer, and has knowledge of and uses:

- The EMQN computer system and its use for data input and analysis, and production of reports for participants, manufacturers, and national, international, and other advisory groups.
- The CMFT computer system for Intranet access and e-mail communications, word processing and statistical and graphical applications (e.g. Excel).
- The Genetic Medicine Quality Management System for document control, audit and other associated QMS activities including error logging.
- NHS and other Project Management methodology.
- CMFT incident reporting procedures (e.g. Ulysses).
- Relevant local, national and international standards (e.g. UKAS and ISO standards) and guidelines (e.g. Clinical Molecular Genetics Society Best Practice Guidelines, NICE, Royal College of Pathologists, College of American Pathologists).

9. ASSIGNMENT AND REVIEW OF WORK

The post holder:

- Works autonomously, with a high level of individual responsibility, with or without scientific and technical support, within the overall direction of the EMQN Director.
- Participates in monthly meetings of all EMQN staff to discuss strategic objectives, evaluate progress, audit EMQN errors (agreeing remedial action to be taken), and agree on assignment of work.
- Is subject to annual appraisal by the EMQN Deputy Director.

10. DECISIONS AND JUDGEMENTS

- Works autonomously to implement managerial and clinical policies, procedures and guidelines relating to the work of EMQN.
- Assists the Director / Deputy Director in managing the EMQN workload, staff deployment and allocation of resources.
- Organises their own time and prioritises work accordingly.
- Contributes to the supervision of trainee and other scientific, technical and administrative staff as appropriate.

11. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

- As a Clinical Scientist within EMQN, communicating with other CMFT staff, individual participants and colleagues or larger groups of scientists and clinicians (from hospitals, universities or diagnostic manufacturers nationally and internationally), whether in writing, by telephone or in person, is a challenge that requires both specialist knowledge and excellent communication skills.
- Assessing and interpreting EMQN data is a demanding role requiring specialist knowledge, analytical and mathematical skills, and the ability to concentrate on and manipulate large amounts of numerical laboratory data for long periods of time.
- The nature of the work is often unpredictable, requiring multitasking and frequent changes to work prioritisation, as well as being subject to frequent interruptions e.g. from telephone calls and other members of staff seeking advice. An ability to work under pressure, to handle complaints effectively and to communicate clearly with all grades of staff in many different organisations is essential.

12. COMMUNICATIONS AND RELATIONSHIPS

The post holder is required to:

- Explain the analytical and clinical significance of highly complex results to a range of staff including Consultant Heads of Department of participant laboratories and senior executives in diagnostics manufacturers.
- Communicate effectively with staff from the host laboratory, CMFT, and University of Manchester.
- Interact with clinical scientists and other health care professionals as required at local, national and international level, including participating in professional networks of staff.
- Interact with biomedical and other scientific staff about work prioritisation, work quality etc.
- Present research and development results, audit findings, and new policies and guidelines at local, national and international meetings.
- Teach laboratory staff in formal lectures and seminars in both small and large groups, and provide instructional training and on-going education as required.
- Investigate, identify, troubleshoot and communicate about analytical or clinical problems in order to ensure their effective and rapid resolution.
- Motivate and train junior staff.
- Maintain participant confidentiality in line with EMQN policy.

13. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical

- Combination of sitting, standing and walking.
- Occasional requirement for lifting (e.g. equipment).
- Frequent requirement for sitting in a restricted position for long periods of time in front of a VDU while preparing reports at computers, while retaining a high degree of concentration and requiring keyboard skills.
- Accurate hand-eye coordination for fine pipetting (measurement of very small volumes).

Mental

- There is frequent requirement for prolonged intense concentration (e.g. assessment of EQA data requires the ability to concentrate for long periods of time while reviewing and validating large numbers of computerised laboratory results with frequent interruptions for enquiries, immediate clinical advice, handling complaints etc.). These interruptions are unpredictable and may require multi-tasking and reprioritisation of work pattern.
- Occasionally need to challenge vigorously medical or managerial opinions, maintaining conviction in own knowledge and opinions.

Emotional

- Occasionally required to direct staff to implement changes with which they may not agree to some aspect of work procedures or priorities.
- Occasionally need to challenge vigorously medical or managerial opinions.

Environmental

- Occasional exposure to unpleasant working conditions (e.g. uncontained blood, unfixed/fresh tissue samples), toxic/carcinogenic chemical hazards and potentially infectious (Category III) agents.

14. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

See person specification.

15. OTHER

- This job description will be reviewed as part of staff appraisal.
- This job description is an outline of the current position and may be amended in detail or emphasis in the light of the future requirements for the service. All amendments and changes to the job description will be agreed with the post holder.

16. RISK MANAGEMENT

It is a standard element of the role and responsibility of all CMFT staff that they fulfil a proactive role towards the management of risk in all of their actions. This entails the risk assessment of all situations, the taking of appropriate actions and reporting of all incidents, near misses and hazards.

17. CONFIDENTIALITY AND INFORMATION SECURITY

As a CMFT employee the post holder is required to uphold the confidentiality of all records held by the trust, whether patient records or trust information. This duty lasts indefinitely and will continue after the post holder has left trust employment. All Information that identifies individuals in whatever form (paper/pictures, electronic data/images or voice) is covered by the 1998 Data Protection Act and should be managed in accordance with this legislation.

18. TRUST POLICIES

CMFT operates a range of policies (available on the Trust intranet). All CMFT employees must observe and adhere to the provisions outlined in these policies.

Smoking control policy

- CMFT has a smoking control policy, which applies to all staff, patients and visitors and extends to the hospital grounds as well as internal areas. Staff appointed will agree not to smoke on hospital premises..

Alcohol

CMFT has an alcohol policy. In addition, you must not consume alcohol during the working day. Consumption of alcohol affects your work and presents a significant clinical risk.

Team briefing

- CMFT operates a system of team briefing that is based on the principles that people will be more committed to their work if they fully understand the reasons behind what is happening in their organisation and how it is performing.

Infection control

- It is a requirement for all staff to comply with all infection control policies and procedures as set out in the CMFT Infection Control manual.

Security

- The post holder has a responsibility to ensure the preservation of all EMQN and NHS property and resources.

Equal opportunities and fair treatment

- The postholder will immediately report to their line manager any breach or suspected breach of both equal opportunities and fair treatment guidelines.

19. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each post holder to whom the job description applies.

Post Holder's Signature: Date:

Head of Department Signature: Date:

Appendix I. Remit and organisation of EMQN

Background
EMQN has been providing EQA since 1997. EMQN is hosted by CMFT and physically located within the Genome Diagnostics Laboratory, a section of the Directorate of Genetic Medicine.

Operational policies and staffing
EMQN has a formal service level agreement with the CMFT Organisation. It employs four dedicated members of staff and has its own dedicated space within the host laboratory. Under the overall direction of the EMQN Director, the day-to day scientific activities of the EMQN Service are delivered independently from the host organisation, while in other matters (e.g. safety, staff conditions of employment) the EMQN service works closely with CMFT staff in implementing organisational policy.

Range of tests monitored
The EMQN provides quality monitoring for specialised genetic tests ranging from monogenic disorders, prenatal diagnosis, newborn screening for inherited disorders to molecular pathology tumour testing and technical aspects of the genetic testing process. The field of molecular genetics is continually expanding and EMQN is committed to meeting the expanding need for EQA provision.

Volume of service and workload
EMQN provides over 38 different EQAs for a variety of diseases to approximately 1500 laboratories worldwide. Many EQAs are provided for rare diseases and therefore the need for EQA is even greater as laboratories do not have high throughput of samples and are often limited in the range of mutations seen. Appropriate samples along with clinical case scenarios are distributed to participants and they are required to test the samples using the most relevant test in their repertoire and submit to the EQA centre interpretative reports using their routine format. These reports are assessed (blind) for genotyping accuracy, interpretation of the results and clinical accuracy by a team of assessors. The EMQN centre then issues a report to each laboratory detailing scores for each clinical case, the mean scores and feedback comments for the assessors. A scheme report is published for every EQA run for each disease detailing performance levels and discussing any issues arising from that EQA run. All EQAs are provided according to a strict timetable.

Quality Assurance of EMQN activity
All hospital laboratories must show satisfactory performance in the EMQN (or other equivalent accredited EQA scheme) in order to gain Accreditation. EMQN undertakes regular quality monitoring to ensure that its service is both reliable and valid. It is accredited to ISO standard 17043 and therefore subject to regular external independent review by the United Kingdom Accreditation Service (UKAS).

Liaison with other EQA providers
EMQN is one of a number of organisations based within the UK that together provide a comprehensive quality monitoring service for all commonly performed tests done in hospital laboratories. EMQN collaborates with other EQA organisations to provide shared EQA schemes (e.g. the Next Generation Sequencing EQA scheme is run jointly by the EMQN and the UK NEQAS for Molecular Genetics).

Presentation of data at national and international meetings, and through publications
Education of EMQN staff is recognised as a key strategy to improve quality of performance and forms a major part of the work of the EMQN.

Financial Management
EMQN is entirely self-funding through fees paid by participating laboratories. Reflecting the continual expansion of the schemes, the EMQN income has increased tenfold since 2002. This increase has been gradual and sustainable.

EMQN and the Host Organisation
Although the activities of EMQN are largely independent of the Host Organisation's core activities, there is a mutually supportive relationship between EMQN and the Host Organisation (CMFT). The recognition of EMQN as a quality centre raises the profile of CMFT nationally and internationally.