

Job Description

TITLE	Quality Assurance Specialist (ISO 17025)	GRADE:	8
FUNCTION/AREA	Quality Assurance		
REPORTING TO	Head of Quality Assurance		

PURPOSE OF THE ROLE

- To manage the quality assurance processes to ensure conformity and accreditation to ISO 17025
- To work constructively with laboratory staff and senior management to identify risks, and opportunities to ensure improvement to working practices, systems and processes both to comply ISO 17025 and to enhance efficiency and cost effectiveness.
- To provide advice on to senior management relating to ISO 17025 quality management issues.

MAIN INTERFACES

INTERNALLY: All Bourn Hall Clinical Science staff, Andrology staff and senior management

EXTERNALLY: Suppliers, external assessors.

KEY TASKS & RESPONSIBILITIES

Responsible for the ISO 17025 Quality Management System carrying out the following:

- Planning and executing the internal audit programmes
- Ensuring supplier and subcontractor compliance
- Investigating non-conformances and identifying effective corrective actions in collaboration with the laboratory staff
- Supporting investigations and complaint handling
- Identifying risks, improvements and opportunities, to present to senior management with an aim to improve laboratory and management processes.
- Responsibility for reviewing and maintaining risk assessments related to ISO 17025
- Planning and conducting ISO 17025 management reviews
- Reviewing and writing Standard Operating Procedures
- Preparing and hosting regular meetings with laboratory staff
- To assist in the preparation for and taking part in ISO 17025 UKAS assessments
- To assist members of the Quality department to ensure compliance to other regulatory standards where required.

MANAGEMENT/LEADERSHIP

N/A

ACCOUNTABILITY AREA

Quality Assurance activities within the Bourn Hall Group.

AUTONOMY & AUTHORITY

To recommend actions to the Quality Assurance team/ senior management on quality related issues.

FUNCTIONAL KNOWLEDGE/BUSINESS EXPERTISE

- Experience of managing laboratory quality management systems
- Knowledge and experience of working in a clinical laboratory and or an andrology laboratory
- Working knowledge of other applicable standards including ISO 9001

PROBLEM SOLVING

To collaborate with others to identify workable solutions to quality related problems.

NATURE & AREA OF IMPACT

To promote quality awareness and compliance.

INTERPERSONAL SKILLS

To communicate clearly and concisely with the ability to recognise the need to reconcile compliance and practicality in dealings with all staff.

SPECIAL PROJECTS

Flexibility and enthusiasm to work on any special projects as required by business need.

CANDIDATE'S PROFILE

EDUCATION/PROFESSIONAL EXPERIENCE

- Proven experience of successfully managing laboratory quality management systems
- Experience of conducting quality audits and hosting inspections
- Previous experience of working to an ISO 17025 or ISO 15189 standard
- Ideally with a science degree and experience in a quality assurance role

LANGUAGES

Excellent spoken and written English.

SKILLS & COMPETENCIES

- Interpersonal skills to forge co-operative and collaborative relationships with internal and external contacts-
- Ability to represent the company professionally and confidently when meeting external parties.
- Excellent IT skills-
- Excellent organisational skills-
- Excellent organisational and communication skills
- Strong attention to detail
- Able to work independently and as part of a team with a flexible approach to support any aspect of the quality assurance function

APPROVALS

JOB HOLDER:

DATE:

LINE MANAGER:

DATE: