Role purpose

The Quality Manager is responsible for the delivery of the Quality Management System, Compliance and Improvement initiatives for the Operations function. This key role is required to maintain a high level of awareness of relevant legislation, policy, guidance, at both National and State levels, and have a sound understanding of international requirements for accreditation purposes.

Reporting to

Director of Operations

Objectives

The objectives of this role are to:

* Maintain the Quality Management System (QMS) ensuring alignment with all accreditation requirements.
* Ensure that Bellberry undertakes and adheres to all relevant accreditation processes and standards (NHMRC & AAHARP)
* Oversee the creation, management and storage of key quality documents (eg. Procedures, guidance and audit reports.
* Lead external and internal auditing and reviews to assess the effectiveness of the QMS, identifying any non-conformance.
* Identify corrective actions and liaise with internal stakeholders to deliver continuous improvement opportunities.
* Ensure that staff are adequately trained on quality standards, processes and best practice.

What does the role do?

The key accountabilities unique to this role are (3-6 required):

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| **Key accountabilities** | **Output/measures** |
| Committees Function | * Lead external site audits and internal quality audits to support the HRECs oversight of research under its remit, and to identify internal processes are efficient and effective. Work with stakeholders to identify correction actions and drive continuous improvement. * Reviewing information regarding drugs and devices submitted to determine any restrictions, dangers or other relevant information that the committees may not be aware of. * Responding to complex and diverse enquiries using expertise and judgement to analyse and solve problems and provide informed advice and support to the HREC’s. * In conjunction with the Director of Operations ensure the ongoing effectiveness of the site monitoring program. * Monitor the skills required to perform committee functions and recommend to the Committee Manager recruitment drives for required expertise. * In conjunction with the Committee Manager assisting with the recruitment of new committee members and where necessary assist with their orientation and induction. * Maintaining current knowledge of contemporary trends and developments in research ethics and governance of research and recommend their application to the Bellberry HREC’s where appropriate. * In conjunction with the Member Manager ensure an effective educational program is in place for the committee members. * Ensure effective eProtocol training for both internal and external users including the maintenance of relevant user guides. * Ensuring that Bellberry HREC’s policies and practices and decisions are consistent with all relevant State and Commonwealth Acts, Regulations, Codes, policies and standards. * Ensure the Committee terms of reference are met. * Monitoring relevant regulatory and policy developments to ensure changes are incorporated in HREC policies and procedures. * Investigate complaints in conjunction with the Committee Chair and aim to resolve matters as quickly as possible. * Provide and/or prepare relevant reports as required by the Director of Operations. |
| Ensure a safe working environment by: | * Adopting procedures and practices which comply with the Work Health and Safety Act. * Taking reasonable care to protect the health and safety of self and others. * Ensuring that all accidents and incidents are reported. * Attending training programs to maintain knowledge and awareness of Work Health and Safety practices, as appropriate. * Making proper use of all safeguards, safety devices and personal protective equipment (as required in undertaking the duties of the position). |
| Contribute effectively to the team ensuring efforts are aligned toward achieving team goals  **(Mandatory)** | * Implement the direction set by your people leader. * Complete specific tasks allocated. * Collaborate effectively to ensure team goals are achieved by providing input into decision making and problem solving. * Actively contribute to creating a high performing and collaborative culture. |
| Adhere to Bellberry operating procedures and policies, and relevant legislative requirements including:  **(Mandatory)** | * Policies and Procedures outlined in the Bellberry Employee Handbook. * NHMRC National Statement on Ethical Conduct in Human Research (2023). * SA Work Health and Safety Act 2012. * Privacy Act 1988. |

Essential and desirable knowledge, skills, experience, and qualifications

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| **Knowledge, skills, experience, and qualifications** | **Essential/Desirable** |

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| Experience leading Quality Management System and undertaking audits | Essential |
| Highly developed organisation skills and the ability to manage competing issues and meet deadlines. | Essential |
| High level communication skills, both written and verbal with an ability to build strong relationships | Essential |
| This position requires excellent interpersonal, consultation and negotiation skills at all levels. | Essential |
| Previous experience in a management role and with managing people within a clinical research setting. | Essential |
| A post graduate qualification (or current study towards such qualification) in relevant field. | Desirable |
| High level of knowledge and expertise in ethical issues related to health and medical research and clinical practice, including issues confronted by HREC’s in the performance of their functions and relevant guidelines. | Desirable |
| Demonstrated knowledge of healthcare, research and the National Approach with current industry needs and a sound understanding of NHMRC, TGA, legislation codes, guidelines relevant to clinical research and ethics and other guidelines whilst having the ability to network within this area. | Desirable |
| Demonstrated experience and knowledge with Human Research Ethics Committees and the performance of their functions. | Desirable |
| Demonstrated advanced document preparation skills ensuring detail and accuracy by using various software applications including but not limited to Windows, Excel. | Desirable |
| Knowledge of research processes and applications, with a broad understanding of research methodologies and applied clinical pharmacology | Desirable |

Bellberry Values & Behaviours(Organisational Contribution)

Making a difference

We support and improve quality human research in Australia through our services and philanthropic endeavours. We do this by continually setting benchmarks, acting prudently and being purposeful in our decision-making.

Working together with integrity and respect

We are a community of members and staff working together with our clients in a caring, collaborative, and supportive way with the common goal of protecting and improving research participant welfare and autonomy. We do this by being warm and welcoming, actively listening, building connections, trust and understanding, being honest and fair, providing a safe environment, valuing the diversity and perspective of every individual, and acknowledging contributions.

Professional and responsive

We strive for quality and excellence in all that we do, to be rigorous, transparent and to take responsibility for our actions. We do this by being knowledgeable, responsive, reliable, consistent yet adaptable, using good judgement and displaying a positive attitude.

Future looking and forward thinking.

We are independent, unbiased, innovative, and courageous, seeking to influence change and continually drive improvement across the research sector. We do this by being proactive, open to new ideas, asking challenging questions, pushing boundaries, having a thirst for knowledge and being proud to make a difference.

Key stakeholder relationships

* All staff across Bellberry
* This position serves as a link between the Bellberry Human Research Ethics Committee, Bellberry Limited and the Australian Research Community.
* External stakeholders

Special conditions

* This role has been classified as a position of trust. The incumbent may be subject to a satisfactory criminal history/record check in line with Bellberry policies.
* Occasional out of hours support for business related issues may be needed.
* A flexible working policy is in place, as well as the ability to build time in lieu for Christmas shutdown periods.
* Remote working is expected from time to time.

**Your PD outlines what the requirements of your role are. The behaviours you demonstrate are equally as important and form part of your PD.**