PRODUCT QUALITY MANAGER

NOVEMBER 2026

POSITION SUMMARY

Location:	Hybrid – Parkville (or Orygen Digital interstate offices) and Work from Home		
Functional area:	Orygen Digital, with a functional reporting relationship to the Head of Sponsor Operations for agreed Research Quality Management System (QMS) deliverables.		
Classification/ Salary:	$135,000 – 145,000 pro rata commensurate with skills and experience + 12% super + access to $15,900 NFP salary packaging		
Reports to:	Governance & Regulatory Lead, Orygen Digital		
Employment type:	1.0 FTE		
Orygen Job Level	4		
Employment length:	12-month contract, with potential to extend		
Direct reports	0	Indirect reports	0

POSITION PURPOSE STATEMENT

The Product Quality Manager (PQM) is responsible for the operational leadership, implementation and continuous improvement of Orygen Digital's Product Quality Management System (QMS), ensuring the MOST product and associated processes meet applicable regulatory and compliance requirements, quality standards and organisational expectations. The role allocates 0.2 FTE to agreed, prioritised Research QMS deliverables, including procedures, document control and training resources. The Head of Sponsor Operations retains overall accountability for the Research QMS.

The role provides hands-on quality and regulatory expertise across the product and research lifecycle. For Orygen Digital's Product QMS, this will include quality planning, risk management, verification and validation, software quality assurance, change control, post-market surveillance and continuous improvement. The role works closely with a Regulatory Consultant and with product, design, engineering, clinical, research and operational teams to embed quality practices into product development and delivery.

The PQM will also provide practical oversight and support for software quality assurance activities, including test planning, release readiness, defect management and user acceptance testing (UAT). The role does not require software engineering delivery but requires strong level of understanding of software development and testing methodologies to effectively assure software quality and work with engineering teams.

Currently, MOST is pursuing Certification for MOST as software as a medical device is accredited against the National Safety and Quality Digital Mental Health Standards, and GDPR where MOST operates in Europe.

While aligning with Orygen Digital's Product QMS, Orygen's Research QMS framework will focus on quality by design principles, study management, participant safety, data lifecycle, and quality oversight activities that support the conduct of Orygen's research projects.

The role works within Orygen's wider enterprise governance frameworks and delegations of authority, aligning Orygen Digital's specialist governance and regulatory activities with existing corporate, clinical and research governance responsibilities.

The Governance & Regulatory Lead will agree a combined workplan with the Head of Sponsor Operations and the PQM, reflecting the 0.8 FTE Digital and 0.2 FTE Research allocation. Competing priorities will be resolved jointly, with unresolved matters escalated to the General Manager, Orygen Digital and Director, Research Operations. Workload, deliverables and capacity will be reviewed after three months, with any changes to the allocation jointly agreed.

About Orygen Digital and MOST

Orygen Digital is the technology division of Orygen. Our mission is to revolutionise the youth mental health system globally by integrating the best of technology, research, clinical expertise, and innovation. We are a national, high-impact, fast-growing team working at the intersection of emerging technologies and youth mental health services. Together, we are developing digital solutions that support young people and their families with accessible, effective and scalable care.

MOST is a digital mental health platform designed to support young people through a combination of expert clinical care, peer support, a safe online community, and personalised wellbeing tools. It is evidence-based and built on more than 15 years of research, helping users access mental health support, therapeutic content, and practical strategies in one place.

About Orygen Research

The research program at Orygen includes over 100 clinical research projects encompassing a diverse risk range from high-risk pharmaceutical interventions, Clinical Trials Notified studies through to negligible and low risk and quality assurance projects. The majority of our studies are sponsored by Orygen as the responsible Corporate Entity.

POSITION FOCUS

	Key responsibility area	Percentage
	Orygen Digital	**0.8 FTE**
1	QMS management, regulatory compliance & assurance	30%
2	Product quality across the lifecycle	30%
3	Quality systems, risk & continuous improvement	20%
4	Quality capability & collaboration	10%
5	Other	10%
	Research (Sponsor Operations)	**0.2 FTE**
1	QMS management, regulatory compliance & assurance	90%

2	Training and quality culture	10%

POSITION KEY RESPONSIBILITY AREAS

Orygen Digital

1. QMS management, regulatory compliance & assurance

- Own and manage the QMS, ensuring it builds on and integrates with Orygen's existing enterprise-wide systems, policies and process, with specialist requirements established, documented, implemented and maintained as required.
- Provide operational leadership for the QMS and ensure it remains suitable, effective and aligned with applicable regulatory requirements and standards, including ISO 13485, IEC 62304, IEC 82304-1, IEC 62366-1and ISO 14971 and the National Safety and Quality Digital Mental Health Standards.
- Maintain oversight of regulatory and customer requirements and promote awareness of these requirements across Orygen Digital.
- Oversee QMS document control in accordance with Orygen's Policy & Procedure Framework and review and approve key QMS documentation, ensuring every controlled document carries a named owner, a formal sign-off, a review date and audit evidence, and that it is current and appropriately implemented. The Head of Engineering is a named approver on technical governance documents.
- Establish, maintain and oversee the technical documentation required to support software-as-a-medical device conformity assessments, regulatory submissions, accreditation assessment and ongoing compliance activities including GDPR.
- Prepare and report QMS performance, quality objectives, risks, trends and improvement needs to management and to the Quality, Safety and Risk Committee, including the technical measures and reporting cadence the standards require.
- Facilitate and chair management review meetings and ensure actions arising from reviews are appropriately managed and closed.
- Support regulatory submissions and act as the authorised regulatory correspondent where applicable, including regulatory reporting to the TGA and other relevant regulatory bodies.
- Build and maintain the technical evidence for GDPR. Records of processing, data flow mapping, data protection impact assessments, the processor and data processing agreement register, Article 32 technical and organisational measures, breach notification readiness, and data subject rights in the product
- Provide product-quality assurance through monitoring QMS performance, compliance evidence and product risks, and report findings and recommended actions to the Governance & Regulatory Lead. Consult relevant Orygen stakeholders and escalate matters requiring enterprise advice or approval through agreed pathways.

2. Product quality across the lifecycle

- Manage the registration and support regulatory approval and market access activities for MOST, working with internal and external regulatory specialists as required.
- Provide quality and regulatory input across product development and production activities, including project planning, specifications, risk management, design reviews, verification and validation, design transfer and release.
- Advise project and product teams on QMS requirements and ensure appropriate quality controls are incorporated into product planning and delivery.
- Own the verification and validation evidence framework, including what evidence each release must produce, traceability from requirement to test to release record, and acceptance criteria. Test planning and execution stay with engineering.
- Ensure appropriate controls are in place, so products are distributed only in jurisdictions where required market authorisations have been obtained.

- Work with Engineering, Design and Product teams to set design controls across the software lifecycle, including design planning, design reviews, design transfer, verification and validation evidence and release records.

3. Quality systems, risk & continuous improvement

- Oversee Corrective and Preventative Action, engineering change control, the quality and regulatory aspects of relevant product complaint handling and customer feedback, post-market surveillance and related quality processes.
- Lead or coordinate internal and supplier QMS audits in accordance with the audit schedule, and coordinate responses to audit findings and corrective actions.
- Oversee regulatory processes for adverse event reporting, recalls, corrections and advisory notices where applicable, including coordination of production recalls and corrections.
- Monitor quality and regulatory risks in accordance with Orygen's Enterprise Risk Management Framework, identify systemic issues and drive continuous improvement initiatives that strengthen QMS effectiveness without creating unnecessary process burden.
- Use quality data, audit findings, complaints, incidents, non-conformances and post-market information to identify trends and inform improvement priorities.

4. Quality capability & collaboration

- Develop and oversee the QMS training program, ensuring required training is completed and that staff understand relevant quality and regulatory responsibilities.
- Build quality capability across multidisciplinary teams through coaching, practical advice, tools, frameworks and knowledge transfer.
- Build and maintain strong partnering relationships across product, design, engineering, clinical, research and operational teams, tailoring quality solutions to their needs while maintaining regulatory compliance.
- Communicate openly, effectively and respectfully with staff, customers, suppliers, auditors and regulatory stakeholders, and work collaboratively to achieve Orygen Digital objectives.
- Contribute quality and regulatory expertise to relevant strategic planning activities and undertake other duties as directed.
- Work closely with the Governance and Regulatory lead and the Service Safety and Quality Manager to coordinate and implement quality initiatives across Orygen Digital.
- Share quality and governance learnings across Orygen and work with relevant teams to identify opportunities to strengthen or scale effective systems and practices across the organisation.

5. Other

- Take ownership of individual and professional growth, engaging with the development opportunities and investment Orygen Digital provides, and demonstrating measurable progress over time.
- Participate in other development activities and responsibilities as directed by the Governance & Regulatory Lead and other senior managers within the Orygen Digital team.
- Promote, encourage and adhere to all workplace policies to support a safe and inclusive work environment.
- The responsibilities included in this position description may vary from time to time due to changes in business needs.

Research (Sponsor Operations)

1. QMS management, regulatory compliance & assurance

- Conceptualise, develop and review new Policies, Procedures and supporting documents as part of the Research QMS implementation.
- Establish document control processes, including version management, review cycles, approval workflows, and archiving requirements.

- Ensure the Research QMS aligns with ICH-Good Clinical Practice (GCP) guidelines, Australian National Statement on Ethical Conduct in Human Research and applicable regulatory requirements.

2. Training and quality culture

- Develop and maintain QMS-related training materials.
- Maintain staff training records and competency documentation.
- Promote a culture of quality, compliance, and continuous improvement across research teams.

EDUCATION / QUALIFICATIONS

Essential	• Tertiary qualification in science or a related discipline.
Desirable	• Formal training or qualification in quality management, regulatory affairs or risk management. • Lead Auditor qualification or equivalent formal audit training.

EXPERIENCE / SKILLS

Experience / skills	• Minimum 5 years' experience in a regulatory and quality role within the medical device industry. • Demonstrated experience with quality and regulatory activities for software-as-a-medical device, digital therapeutics, health technology or software-enabled medical devices. • Strong knowledge and practical application of medical device regulations and quality management standards, including ISO 13485, IEC 62304 and ISO 14971. • Demonstrated understanding of clinical research regulations and ICH-GCP requirements. • Demonstrated experience taking multiple products through product development, regulatory approval and market entry. • Proven experience managing quality initiatives and influencing multidisciplinary teams and business decisions to align with quality and regulatory requirements. • Demonstrated experience providing quality oversight across software/product development lifecycles, including verification, validation, testing and release activities. • Experience assuring software verification and validation evidence, including traceability from requirement to test to release record. • Experience with health service accreditation or an equivalent standards-based assurance regime, including producing evidence for external assessment. • Experience with data governance, covering classification, retention, release controls and cross border transfer. • Demonstrated experience across audits, CAPA, risk management, change and document control, validation, quality/regulatory oversight of product complaints, post-market surveillance and regulatory reporting. • Demonstrable experience as a specialist advisor and contributor to multidisciplinary scientific, technical and industry teams, with the ability to lead and foster knowledge transfer, open communication, coaching and collaboration. • Experience with software systems supporting quality management and controlled documentation (e.g., Confluence, Jira)

	• Knowledge of the European regulatory landscape is desirable.
Personal attributes	• Collaborative and influential, builds trusted relationships and achieves outcomes across multidisciplinary teams. • Pragmatic and solutions-oriented, applies regulatory requirements proportionately while maintaining quality and compliance. • Credible and accountable, demonstrates sound judgement, integrity and ownership of quality decisions and risks. • Analytical and improvement-focused, identifies systemic issues, interprets quality information and drives practical continuous improvement. • Clear communicator and coach, transfers knowledge effectively and builds quality capability across teams. • Calm and resilient, provides considered leadership when managing audits, quality issues, regulatory challenges and competing priorities. • Adaptable and self-directed, responds effectively to changing regulatory, product and organisational requirements.

KEY RELATIONSHIPS

Internal	• Orygen Digital's Governance & Regulatory Lead and Safety and Quality Manager • General Manager, Orygen Digital and Orygen Digital Leadership Team • Orygen Digital's Product, design, engineering, clinical, research and operational squad/teams • Head of Sponsor Operations • Orygen's Chief of Board Governance, Planning and Performance (Company Secretary) • Office of the Executive Director • Orygen's Chief of Research & Knowledge Translation, and all Research Office team members • Orygen's General Counsel and relevant central clinical governance, risk, privacy and IT leads
External	• Regulatory Consultants • Therapeutic Goods Administration (TGA) and other relevant regulatory authorities • External auditors, certification bodies and accreditation agencies

SPECIAL REQUIREMENTS

- Unrestricted right to live and work in Australia.
- A current National Police Check will be required.
- Any offer of employment is conditional upon receipt and maintenance of a satisfactory Working with Children Check.
- All Orygen employees are required to familiarise themselves with the institution's policies and procedures and to always adhere to them.
- This position may need to be based at home during certain periods. As such a reliable internet connection will be required.
- Orygen Digital works as part of a cross-functional, product-enabled team, bringing together diverse expertise from design, engineering, research, peer, content development, data analysis and youth perspectives. As such, you will also be expected to collaborate in an agile way for Business as Usual work, iterating quickly to develop, test, and refine community features that best support young people's needs.

SAFETY, HEALTH AND WELLBEING RESPONSIBILITIES

Employees are required to comply with all workplace health, safety, quality and wellbeing policies and procedures of Orygen. In addition, employees are expected to:

- Take reasonable care for their own health and safety and that of others who may be affected by their actions or omissions and cooperate with Orygen's health, safety and wellbeing requirements.
- Champion a culture of safety and wellbeing by following relevant policies, procedures, training and guidelines, and promptly reporting incidents, hazards, near misses and safety concerns.
- Deliver work in accordance with Orygen's quality standards, clinical and practice guidelines governance, regulatory requirements, and continuous improvement processes.
- Contribute to culturally safe, respectful and inclusive workplaces and services, and support the safety, wellbeing and safeguarding of all children, young people and families engaged with Orygen.
- Recognise that work may involve exposure to sensitive information and potentially distressing content, including information related to mental health, and take steps to monitor and manage its impact on their own wellbeing.

ACKNOWLEDGEMENT

Confirming this position description has been read and understood by:

Name	[insert name]
Signature	[insert signature]
Date	[insert date]