Position Description – *Quality and Regulatory Affairs Officer*

Updated 12 November 2026

POSITION DETAILS	
College/Portfolio	***Deputy Vice Chancellor Research***
Organisational Unit	***Flinders Factory of the Future***
Supervisor (Title)	***Head of FORGE Medical Devices, Flinders Factory of the Future***
Classification	***Higher Education Officer level 6***
Employment Type	***Fixed-term, full-time***

POSITION SUMMARY

The Quality and Regulatory Affairs Officer supports the delivery of quality and regulatory activities across FORGE Medical Devices and its client projects. Working under the general direction of the Head of FORGE Medical Devices, the position contributes to the implementation, maintenance and continuous improvement of FORGE's Quality Management System and supports medical device development in accordance with relevant quality standards and regulatory requirements.

The role undertakes a range of quality and regulatory activities, including quality documentation and records, risk management, regulatory research, clinical and technical documentation, audit preparation, and identification and interpretation of applicable standards and regulatory requirements. The position applies professional judgement to support the resolution of quality and regulatory issues, escalating complex or higher-risk matters where appropriate.

The position also contributes to FORGE Medical Devices client projects, supporting the development of fit-for-purpose quality and regulatory documentation and regulatory pathway activities. Working collaboratively with technical specialists, researchers, industry and other stakeholders, the role supports the translation of medical device innovations from early-stage development towards commercialisation.

UNIVERSITY EXPECTATIONS AND VALUES

All staff at Flinders are responsible for understanding their obligations and responsibilities as set out in the University's code of conduct and are expected to:

- demonstrate commitment to the University's values of Integrity, Courage, Innovation and Excellence
- demonstrate consistent alignment with the University's strategic priorities through daily decisions, teamwork and behaviours that reinforce the strategic intent.
- contribute to the efficient and effective functioning of the team or work unit to meet the University's objectives. This includes demonstrating appropriate and professional workplace behaviours, providing assistance to team members, if required, and undertaking other key responsibilities or activities as directed by one's supervisor;
- promote and support an inclusive workplace culture which values diversity and embraces the principles of equal opportunity;
- perform their responsibilities in a manner which reflects and responds to continuous improvement; and



- familiarise themselves and comply with the University's *Work Health and Safety, Injury Management and Equal Opportunity* policies.

Flinders University is committed to providing a safe, respectful and inclusive environment, free from gender-based violence. Appointment to this role is conditional on the completion of required pre-employment checks and declarations, each of which must be satisfactory to the University. This includes a Gender-Based Violence declaration, in accordance with the National Higher Education Code to Prevent and Respond to Gender-Based Violence (2025), and a Nationally Coordinated Criminal History Check.

KEY POSITION RESPONSIBILITIES

The Quality and Regulatory Affairs Officer is accountable for:

1. Quality management
    - Support the implementation, maintenance and continuous improvement of the FORGE Medical Devices Quality Management System.
    - Develop, review and maintain quality documents and records, including procedures, templates, registers and project documentation.
    - Support document control, training, audits, non-conformances, corrective and preventive actions, change control and quality reporting.
    - Monitor assigned quality activities and identify, resolve or escalate issues in accordance with established procedures.
2. Regulatory and technical support
    - Research and interpret applicable medical device regulations, standards and guidance under general direction.
    - Support the development of regulatory strategies, submissions and supporting technical documentation for FORGE and client projects.
    - Assist with clinical evaluation, risk management, and other regulatory evidence activities.
    - Maintain accurate regulatory records and monitor relevant changes to regulatory and standards requirements.
3. Client and project support
    - Support FORGE clients to develop fit-for-purpose quality and regulatory documentation appropriate to their stage of development.
    - Apply professional judgement to resolve routine and moderately complex matters.
    - Contribute to training, workshops and resources that build quality and regulatory capability.
4. Collaboration and continuous improvement
    - Work collaboratively with engineering, research, commercialisation and project teams.
    - Contribute to the improvement of FORGE processes, systems, templates and service delivery.
    - Maintain current professional knowledge and undertake other responsibilities consistent with the level of the position.



KEY POSITION CAPABILITIES

- A relevant degree with subsequent experience, or an equivalent combination of education, training and experience.
- Knowledge of medical device quality and regulatory principles, including familiarity with ISO 13485, ISO 14971 and applicable regulatory frameworks.
- Experience preparing, reviewing or maintaining quality, regulatory, scientific or technical documentation.
- Ability to interpret standards, regulations and technical information and apply them to defined activities and projects.
- Demonstrated analytical, organisational and problem-solving skills, with the ability to exercise judgement and escalate matters appropriately.
- Ability to plan and manage assigned work, meet deadlines and maintain accurate records across concurrent activities.
- Well-developed written and interpersonal communication skills, including the ability to work effectively with technical and non-technical stakeholders.
- Demonstrated capacity to work collaboratively and contribute to process improvement in a multidisciplinary environment.

