

Outstanding career opportunity in pharmaceutical quality

- Make a lasting impact on global health equity
- Your next career step leading Quality across GMP and GCP activities
- Melbourne office with flexible hybrid working

The Company

Medicines Development for Global Health (MDGH) develops medicines to ease the burden of neglected diseases on underserved communities worldwide. Our approach is to bring together the ideas of researchers with our development expertise and passion to develop new products that will be life changing for millions. We are a non-profit company with an innovative funding model - all funds in excess of expenses are devoted to this purpose.

Our team brings a depth of expertise from within the pharmaceutical and global health sectors in clinical studies, project management, pharmaceutical development, regulatory submissions and medicines access. With a growing product portfolio, we are seeking an experienced quality professional to lead and actively manage quality activities while strengthening our Quality Management System across our regulated development program.

Quality Manager

As the responsible person for Quality at MDGH, you will manage the MDGH Quality System across regulated activities (GxP), with particular focus on Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP). Working closely with our CMC, Regulatory and Clinical teams, external vendors and network of consultants, you will provide quality expertise and guidance while actively managing and delivering quality activities. You will promote a strong quality culture and ensure our development activities meet applicable quality and regulatory requirements.

Your responsibilities will include:

- Manage and maintain the MDGH Quality System, including the development, review and maintenance of SOPs, working practices, GxP training, document control, CAPA and change control.
- Provide quality leadership and advice across MDGH and actively manage quality issues, identifying and escalating quality risks, and preparing and providing regular Quality Management Reviews to senior management.
- Lead the internal and external audit program, vendor assurance activities and preparation for, support of and responses to regulatory inspections.
- Manage quality activities supporting CMC, including quality agreements, vendor and CMO performance, deviations and investigations, technical audits, and review and approval of manufacturing and laboratory records.
- Manage quality activities supporting clinical development, including CRO and vendor quality matters, clinical trial master file audits and clinical site audits.
- Monitor quality data and trends, initiate and drive effective corrective actions and continuous improvement activities, and work collaboratively across functions to maintain a strong culture of quality and compliance.

Our ideal candidate will be energised by new challenges and keen to roll up their sleeves and work across functional teams to embed a consistent focus on quality throughout our development program. You will bring strong quality expertise and be equally comfortable providing leadership and actively managing and delivering the day-to-day work.

You will have an excellent working knowledge of Quality Management Systems with at least five years' direct experience in a quality role. Knowledge of relevant GxP regulatory requirements, particularly GMP and/or GCP is required, together with a willingness to learn. Whilst experience in a GMP pharmaceutical manufacturing environment and/or clinical operations will be highly regarded, we will support you to grow in areas where you've had less experience.

We would love to hear from you if you've enjoyed working in a small to medium-sized company and the variety that brings or feel that is something you want to try. Essentially, we need a practical, solutions-focused quality professional

with excellent communication and organisational skills, strong attention to detail, and a willingness to learn and grow with us.

A degree in a science discipline, preferably chemistry, biology or microbiology, is required, with a relevant postgraduate qualification in quality, research and/or pharmaceutical development well regarded.

This role is based in Melbourne, with flexible hybrid working by agreement.

Why work for us?

This is a great opportunity to join a friendly, inclusive team committed to making a difference. We put people first, with a strong focus on employee well-being and professional growth and development.

MDGH is a place where everyone has a voice. We pride ourselves on our teamwork and openness, both with our staff and in our relationships with our partners, study participants, and other like-minded organisations where we share ideas and information to advance global health equity. We champion diversity, inclusion and equality, and encourage talented people from all backgrounds, abilities and identities to apply. If there is anything we can do that can help you take part in our recruitment process more comfortably, please let us know.

We offer flexible hybrid working, recognising the value of both focused individual work and effective collaboration with colleagues and partners.

We offer a competitive market-based salary package, including fringe benefits which are tax exempt for Australian based staff. The role is an ongoing part-time position, hours to be negotiated.

The successful candidate will be required to undergo a police check and working with children check.

Interested?

Please email your resume to Janine Pickering, MDGH Head of People at recruitment@mdgh.com or call Narelle Mahony on 0421 286 744 for more information.