

<h1 style="margin: 0;">Senior Quality Officer</h1>	
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Business unit/Department:	PlusLife (Perth Bone & Tissue Bank) - Operations
Classification:	Entry level – Delivery Band

Primary Responsibilities

As part of the Quality and Regulatory Affairs team, provide support and administrative functions in the development, implementation and maintenance of a robust quality system that meets and exceeds regulatory and legislated requirements whilst being efficient and effective.

Reporting relationships

Role Reports to:	Quality & Regulatory Affairs Manager
Positions Directly Reporting to this role:	NIL


About PlusLife

At PlusLife, we collect, screen, store and distribute donated human bone and tissue allografts. We pride ourselves on exclusively retrieving 100% Australian donated bone and tissue to produce the highest quality allografts in our facility located in Midland, Western Australia.


As a Therapeutic Goods Administration licensed tissue bank, we are committed to providing medical professionals with safe and effective allografts for use in surgical procedures to treat patients with conditions such as spinal deformities, arthritic joint disease, bone cancers, sports injuries; and facial and dental reconstructive surgeries.

Why we exist	To enhance Australian lives through the precious gift of human bone and tissue donation.
Who we are	We are custodians of the safest and highest quality Australian bone and tissue, ethically sharing from donors to recipients as needed.
Every day we aspire to	Be a preeminent organisation in the field of tissue banking and related research, delivering on our commitment centred around the needs of each recipient, supported by uncompromising respect for every donation.


How we act



Always act with care



Never compromise on standards



Always tell the truth

Summary Of Responsibilities	
Brief summary of duties	<ul style="list-style-type: none"> • Provide Quality system administration and ensure quality system tasks are completed. • Coordinate change control initiatives within the quality area and participate in change initiatives lead by other departments. • Ensure the Quality Management System is established and implemented as a robust, effective, and efficient system. • Authorise the release of conforming tissue for processing and allograft for implant. • Dispatch / follow up samples for external testing. • Manage updates to the regulatory filing for PlusLife products. • Maintenance of production equipment and consumable items. • Partake in risk management processes including non-conformities / incidents, assessment, correction, and monitoring processes in co-operation with the Quality and Regulatory Affairs Manager. • Complete internal and supplier audits and provide support for 3rd party audits. • Provide guidance and explanation of quality principles and systems to other departments. Foster a participative team environment and promote PlusLife policies and procedures. • Manage the validation program including the Validation Master Plan and perform validation activities as required. • Ensure that the implemented quality systems and models meet the requirements of the Therapeutic Goods Administration Code of GMP for Blood and Tissues and other relevant standards. • Maintain quality system documentation • Develop and create periodic review reports verifying the performance of products, processes, facilities. • Issue Hazard Alerts and maintain the biovigilance system as required. • Act as Quality Nominee in the absence of the Quality and Regulatory Affairs Manager. • Demonstrate positive commitment to Equal Employment Opportunity, Work Health and Safety, Code of Conduct, Quality improvement and Confidentiality throughout the course of their duties • Actively participate in fund-raising and public relations activities. • Undertake other appropriate activities as allocated by the direct manager.
Building relationships	<ul style="list-style-type: none"> • Build and maintain effective relationships with PlusLife staff, to contribute in the development of a continuous improvement culture. • Participate positively towards a team environment and promote PlusLife policies, procedures, and systems. • Work cooperatively with external stakeholders by building and sustaining relationships to achieve a common goal or outcome. • Promote Pluslife activities at community events.
Requirements For The Role	
Essential criteria	<ul style="list-style-type: none"> • Completed tertiary education (TAFE or Bachelor level degree) or prior working experience in a quality setting. • High level organisational skills and ability to prioritise tasks • Excellent written and interpersonal skills • Ability to work autonomously under broad direction and as part of a multi-disciplinary team • Proficient with Microsoft office suite • Possession of current driver’s license.
Desirable criteria	<ul style="list-style-type: none"> • Awareness of legislative and ethical issues related to tissue and organ donation • Awareness of TGA Code of Good Manufacturing Practice – Human Blood and Tissues, or similar regulatory/ compliance environment

Appointment pre-requisites	<ul style="list-style-type: none">• Proof of working rights• Provision of 100-point identification• Successful criminal record screening clearance (issued within the last three (3) months)• Successful pre-employment medical check• Provision of COVID 19 Vaccination status
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