**HSS Registered**

# Quality Assurance Officer

## Health Salaried Officers Agreement: Level G-5

**Position Number: 00013892**

**WA Hospital's Central Pharmaceutical Manufacturing Facility / AUSPMAN**

**Sir Charles Gairdner Hospital / QEII Nedlands**

### Reporting Relationships

Chief Pharmacy
HSO P6
Position Number: 00012070

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General Manager
HSO G9
Position Number: 00013886

⬆

**This Position**

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Reporting to this position:

| Title | Classification | FTE |
|---|---|---|
| • Nil | | |

⬅

Also reporting to this supervisor:
- Production Manager G8
- Quality Control Manager G8

**Key Responsibilities**

Assists in ensuring the operation of the pharmaceutical manufacturing facility is maintained at a high standard by conducting quality assurance activities across all functional areas.

## Brief Summary of Duties

1. **Operational Management**
   - Assists the General Manager, in collaboration with the Quality Control Manager, in managing the facility's Quality Assurance program.
   - Assists in evaluating suppliers for suitability, ensuring materials are purchased from appropriate suppliers and correctly supplied and used.
   - Assists with verifying that finished products are correctly manufactured with manufacturing controls, in-process checks and product/process validations appropriately conducted.
   - In conjunction with the Quality Control and Production Managers, conducts regular internal audits to verify the effectiveness of the quality management systems.
   - Ensures all aspects of the quality management systems are correctly applied through regular review and communication with relevant work areas.
   - Monitors the stability program to ensure testing compliance is maintained and product expiry periods are appropriate.
   - Conducts Product Quality Reviews to verify consistency of processes and identify issues and potential improvements.
   - Maintains the validation master plan and co-ordinates validations and revalidations relating to facility, utilities, equipment, test methods and products and processes.
   - Assists with preparation and maintenance of standard operating procedures for all facility activities.
   - Maintains relevant documentation according to procedure.
   - Contributes to training of staff in quality assurance activities.
   - Contributes to investigation of manufacturing deviations, out of specification test results and other relevant issues.

2. **Research, Quality and Innovation**
   - Conducts quality assurance program activities, reviews results and reports on program effectiveness.
   - Assists in research and development projects for new products and production methods.
   - Assists with review, development and implementation of analytical procedures.

3. **Other Duties**
   - Undertakes rostered shifts and rotations in the Department/Unit at the direction of the General Manager including participation on the on-call/after-hours / weekend / on-call roster if required.
   - Actively participates in continuing education programmes to maintain currency of own knowledge and to assist in education of other staff.

**4. CAHS Governance, Safety and Quality Requirements**

- Takes reasonable care for own health and safety and that of others and participates in the maintenance of a safe work environment**.**
- Participates in the Child and Adolescent Health Service (CAHS) performance development review process.
- Supports the delivery of safe patient care and the consumers' experience ensuring services are family centred. This includes participation in continuous quality improvement activities in accordance with the requirements of the National Safety and Quality Health Service Standards and other recognised health standards.
- Completes mandatory training (including safety and quality training) as relevant to role.
- Performs duties in accordance with Government, WA Health, CAHS and Departmental / Program specific policies and procedures.
- Abides by and upholds the WA Health Code of Conduct, CAHS Vision, Mission and Values, Occupational Safety and Health legislation, the Disability Services Act and the Equal Opportunity Act.

**5. Undertakes other duties as required.**

## Work Related Requirements

### Essential Selection Criteria

1. Demonstrated comprehensive understanding of the current Australian Code of Good Manufacturing Practice.
2. Demonstrated ability to follow written procedures and work within set standards and protocols.
3. Demonstrated interpersonal skills and the ability to communicate effectively, verbally and in writing, including the writing of scientific reports, procedures and other technical documentation.
4. Demonstrated high level of competence with computer systems, including word processing, spreadsheets and databases.
5. Conceptual, analytical and research skills and the ability to contribute to practical and innovative solutions to problems in a timely manner.

### Desirable Selection Criteria

1. Possession of a bachelor degree (or higher) in a relevant field.
2. Demonstrated problem solving and analytical abilities.
3. Demonstrated experience in quality control or quality assurance functions in a TGA licensed therapeutic goods manufacturer (or equivalent regulatory authority).
4. Current knowledge and commitment to Equal Opportunity in all aspects of employment and service delivery.

### Appointment Pre-requisites

Appointment is subject to:

- Pre-employment medical screening satisfying requirements of the Australian Code of Good Manufacturing Practice – Part One (2.14).
- Availability for after hours and rostered duties when required – may include weekends, public holidays and evening rosters.
- Completion of 100 point identification check
- Successful Criminal Record Screening Clearance
- Successful Pre-Employment Integrity check
- Successful Pre-Employment Health Assessment

## Certification

**The details contained in this document are an accurate statement of the duties, responsibilities and other requirements of the position.**

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|---|---|---|---|
| **Manager / Supervisor Name** | **Signature** **or** | **HE Number** | **Date** |
| **Directorate/ Dept. Head** | **Signature** **or** | **HE Number** | **Date** |

**As Occupant of the position I have noted the statement of duties, responsibilities and other requirements as detailed in this document.**

| | | | |
|---|---|---|---|
| **Occupant Name** | **Signature** **or** | **HE Number** | **Date** |

**HSS Registration Details** (to be completed by HSS)

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|---|---|---|---|
| **Created on** | Insert date | **Last Updated on** | He119831 18/01/2018 |