Position Description

Role: Quality Systems Administrator

Grade: J

Area of Expertise:

Location / Team & Group: Wellington / GlycoSyn

Reports To: QA Manager

Delegations:
Financial: None
People: None

Relationships:
Internal: QA Manager of the GlycoSyn Group; GlycoSyn staff members
External: Partnerships:

Purpose:
This role is positioned to administer the:
• GlycoSyn document management system
• Deviation, change control and CAPA systems
• Training system
• Validation programme
All other duties as and when required by the QA Manager.

Your position within IRL:
IRL’s intranet shows your role within IRL’s business structure.

Cultural Values

Make an Impact on NZ’s wellbeing
Engage to identify, develop and deliver solutions
Be Professional to meet the highest standards of performance, integrity, to advance the quality of IRL operations

Corporate Contribution: Contribute to the vision, goals, strategic priorities and outcomes of IRL by acting professionally, engaging fully, and committing to making an impact on the wellbeing of New Zealanders.

Advice, Support and Communication: Use expertise to guide and assist others towards IRL value creation. Establish and maintain effective working relationships based on trust and constructive feedback with all stakeholders.

Reputation and Image: Act as advocate, ambassador and industry champion to best represent IRL in the broadest sense, and build a high profile within our industry to internal and external stakeholders.

Personal Growth: Take responsibility to assertively identify and implement learning and development opportunities to drive improved personal performance and career satisfaction.

Health and Safety: Take personal responsibility for ensuring adoption of the company’s health, safety and environmental plans, policies and procedures are understood and personal obligations are met.

Behavioural Expectations:
• Communicates positively and effectively and interpersonal style elicits the best from all stakeholders
• Operates with orientations toward innovation, creativity, resilience, persistence, commitment and professionalism
• Exercises functional and role expertise and leadership
• Adopts broad knowledge-share principles (people/customers/stakeholders, environment, technology, systems, IP) to leverage IRL information, knowledge, expertise to enhance and effect delivery of IRL’s business performance
• Celebrates diversity and adopts a culturally appropriate approach to engagement and implementation; respects principles of Te Tiriti o Waitangi
• Self-manages use of time, resources and workflow to manage pressure, peaks and troughs
• Uses IRL business processes, systems and technology responsibly with integrity to optimise internal efficiency and effectiveness
• Uses insight and self-reflection to continuously improve personal performance and career satisfaction

Is an ambassador and champion for IRL
• Ensures that individual work activity is consistent with team and overall organisation strategy
• Communicates vision, helping people to understand what we are doing and why
• Breaks down silos, works across boundaries and collaborates with others to achieve organisational results and strategic objectives

Connects with people
• Is customer focused and continuously looks to improve
• Tailors messages to the audience
- Values diversity and is culturally aware
- Effectively negotiates mutual expectations and builds rapport
- Builds and manages relationships

**Is a team player**
- Is seen as a team player and can represent own interests yet be fair to other groups
- Can be candid with peers while encouraging collaboration
- Is trusted and supported by peers
- Ensures their approach to collaborative issues is appropriate and positive

**Deals with ambiguity**
- Copes effectively with change
- Is able to work in an environment of uncertainty
- Can comfortably handle risk and uncertainty

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**Role Activities:**
Below are your primary and contributory activities around how you plan, implement, evaluate and report in this position, and how these are aligned with the performance indicators that show how your role impacts and contributes to the work of IRL.

<table>
<thead>
<tr>
<th>Accountabilities</th>
<th>Audits</th>
<th>Data Management</th>
<th>Health and Safety</th>
<th>Personal Growth</th>
<th>Compliance</th>
<th>Other Features</th>
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<tbody>
<tr>
<td><strong>Document Management</strong></td>
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<tr>
<td>Review draft documents for compliance with QMS requirements</td>
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<tr>
<td>Issue approved documents for use</td>
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<td>Archive obsolete and superseded documents</td>
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<tr>
<td>Liaise with document owners to ensure document reviews are undertaken on time</td>
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<td><strong>Deviation Reporting System</strong></td>
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<td>Issue DR numbers to newly reported deviation reports</td>
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<tr>
<td>Liaise with deviation owners to ensure deviations are closed on time.</td>
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<td>Report potential issues to the QA Manager</td>
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<td><strong>Change Control Request System</strong></td>
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<td>Issue CC numbers to newly raised change requests</td>
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<td>Liaise with CC owners to ensure CCs are reviewed and approved in a timely manner.</td>
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<td>Liaise with action owners to ensure actions are completed on time.</td>
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<td><strong>Corrective Action / Preventive Action System.</strong></td>
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<td>Issue CAPA numbers to newly raised CAPA investigations</td>
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<td>Liaise with CAPA owners to ensure CAPAs are reviewed and approved in a timely manner.</td>
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<td><strong>Training System</strong></td>
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<td>Log completed training in the training register</td>
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<td>Maintain employee training records</td>
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<td>Liaise with employees and line managers to ensure each employee has an up to date training plan.</td>
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<td>Maintain the GlycoSyn signature log</td>
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**Audits**
- Participate in internal audits as necessary.
- Act as the key contact for document management during regulatory and client audits.
- Participate in H&S audits of work areas within GlycoSyn as required.

**Data Management**
- Ensure that GlycoSyn data is captured and retained in accordance with GlycoSyn’s QMS.

**Health and Safety**
- Collaborate with the Health and Safety Co-ordinator to ensure that all steps are taken to comply with Health and Safety legislation, rules and regulations.
- Report incidents and near misses in accordance with IRL policy.
- Take responsibility for Work Area Management as required.

**Personal Growth**
- Take responsibility and implement action plans for personal growth and development to ensure improved performance and career satisfaction.
- Liaise closely with all other GlycoSyn staff members.

**Compliance**
- This role is expected to comply with the requirements of cGMP as defined by the GlycoSyn Quality Management System and with H&S rules and regulations as required by IRL site policies and procedures.

**Other Features**
- This role is expected to comply with the requirements of cGMP as defined by the GlycoSyn Quality Management System and with H&S rules and regulations as required by IRL site policies and procedures.
**Validation Program**
- Issue Validation Project numbers to newly raised projects
- Track the creation and completion of validation documents
- Liaise with system owners to ensure routine revalidation activities are completed in accordance with the schedule.
- Report potential issues to the QA Manager

This role is successfully and effectively delivered by demonstrating high levels of the following:

<table>
<thead>
<tr>
<th>Capabilities, Attributes, Knowledge, Qualifications, Skills, and Experience:</th>
<th>Qualifications</th>
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<tbody>
<tr>
<td><strong>Qualifications</strong></td>
<td>Tertiary qualification in science is preferred but relevant experience is more important than academic qualification.</td>
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<tr>
<td><strong>Experience/Skills</strong></td>
<td>Previous experience working in a GMP environment essential</td>
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<td>Experience in document management preferred</td>
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<td>Excellent working knowledge of Word and Excel</td>
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<td>Good communication skills both written and oral</td>
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**Job Specific Competencies**

**Detail Focus**
- Shows exceptional attention to detail and high level of accuracy

**Customer Focus**
- Appropriately identifies and responds to internal and external customer needs
- Understands and appropriately responds to customers’ requirements

**Understanding IRL’s Business**
- Demonstrates an understanding of GlycoSyn’s business needs.

**Innovation and Creativity**
- Demonstrates an ability to take initiative and originate actions to solve customer needs and improve processes.

**Leadership**
- Demonstrates an ability to efficiently manage workload with minimal supervision
- Demonstrates an ability to work independently and with colleagues as required
- Provides technical training as required

**Teamwork**
- Works effectively in a team
- Establishes appropriate working relationships with colleagues

**Networks**
- Shows sound judgment in seeking advice of colleagues

**Oral and Written Communication**
- Clearly expresses ideas
- Produces reports and business communications for internal and external customers with minimal supervision.
Please refer to the intranet for the latest version of this document
Last updated 24 July 2012