| JOB DESCRIPTION | |
|---|---|
| DATE: | June 2020 |
| POSITION: | Manufacturing Support Specialist |
| BUSINESS UNIT: | Almac Pharma Services |
| LOCATION: | Craigavon |
| REPORTING TO: | Production Group Leader |
| RESPONSIBLE FOR (PEOPLE): | Manufacturing Support personnel (e.g. associates and technicians |

# OVERALL ROLE OBJECTIVE:

The post holder will support the Manufacturing Technical Operations department to monitor and drive departmental KPIs and objectives.

The post holder will support the GMP (Clinical and/or Commercial) Manufacturing group to ensure essential elements are in place to allow operations to commence and run to scheduled timelines.

The post holder will review manufacturing processes and implement process improvements.

# JOB SPECIFIC RESPONSIBILITIES:

The post holder will:

**Quality**

- Raise, investigate and execute Quality documentations (Change Requests, Deviations, CAPAs and Suspect Analytical Results)
- Investigate customer complaints related to manufacturing activities.
- Monitoring due and overdue departmental quality managemnet system (QMS) records.
- Communicate the status of departmental QMS records to production management on a weekly basis.
- Management of alarms within manufacturing areas.
- Assist with internal, customer and regulatory audits.
- Liase with other departments to ensure operational compliance is maintained.
- Ensure good manufacturing practice (GMP) standards are maintained at all stages of manufacture in line with internal procedures and regulatory requirements.
- Assist in the generation of training materials and the execution of training.

**Department KPIs and Capacity Planning**

- Generate and maintain KPI statistics showing departmental performance against business objectives and communicate / present findings to production management on a monthly basis.
- Assessment of production line utilisation and overall equipment efficiency.

- Assist production management in forecasting and capacity planning.
- Drive continuous improvement initiatives within manufacturing.
- Conduct trending of all executed batches.

**Equipment Qualification Validation, Process Validation and Production Support**

- Support validation activities within the department including new equipment qualification.
- Generation of data repositories to capture critical process parameters (CPPs) and critical quality attributes (CQAs) for commerical manufacturing processes.
- Conduct trending and process capability analysis of all executed commerical batches.
- Assist and / or lead Technical Quality in the generation of CPV protocols and reports.

**Documentation**

- Review and approval of bills of materials for commercial products.
- Generation and approval of manufacturing batch records.
- Be responsible for the review of executed master batch records to meet agreed timelines.
- Compiliation of new SOPs and periodical review of existing SOPs.
- Generation of rework documentation when required.
- Identify and drive improvements in manufacturing batch records.

**Other**

- Communicate and interact with staff from other departments including Technical Support, Quality Control, Quality Compliance, Engineering and Facilities to ensure operational compliance.
- Supervise a number of support personnel, assuming responsibilty for time management activities, annual appraisals and other HR related tasks.
- Additional duties as necessary.

# GENERAL ROLE RESPONSIBILITIES:

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| **Quality** | Ensure GMP is adhered to in all areas of work.<br><br>***Almac Pharma Services' Quality Mission;***<br>*To operate within a quality excellence framework that is both efficient and effective and continually assures safe and efficacious product to the patient.*<br><br>The post holder will, support the quality mission of the business by:<br><br>- Ensuring exceptional and reliable quality in all aspects of work and recognising that quality determines the extent of success.<br><br>- Engaging with the Pharmaceutical Quality System to ensure that quality records are completed accurately and proactively managed in line with committed timelines. Quality performance against set targets is a key goal and aligns with business objectives.<br><br>- Actively contributing to the Quality Vision outlined by the Senior Management Team of reducing the gap between "where we are today" versus "where we want to be today". |
| **Health & Safety** | Understand Company's Health & Safety Policy and follow all company HSE procedures. Report all accidents or any unsafe conditions in the work place. |
| **Training and Development** | Ensure training has been received before undertaking specific duties and that all training is recorded in training records. |
| **Human Resource Management** | Adhere to all HR policies and procedures, to include all absence policies and procedures. |
| **Communication** | Communicate within your own department to ensure that all relevant information is forwarded to the appropriate personnel on a regular and timely basis. Provide regular updates to your line manager regarding progress on required duties and the status of any projects. |
| **Equal Opportunities** | Observe and adhere to the company's Equal Opportunities and Dignity at Work policies ensuring that a neutral and harmonious work environment is maintained in which bullying and/or harassment does not occur. |
| **Core Competency Framework** | Ensure that all job specific responsibilities relating to the overall role objective are carried out in accordance with the requirements outlined within the Almac core competency framework. |

| **By signing this Job Description I accept that I have received and read the Job Description and have accepted the responsibilities identified therein.** | |
|---|---|
| EMPLOYEE'S SIGNATURE: | |
| PRINT NAME: | |
| DATE: | |

This job description should not be regarded as conclusive or definitive. It is a guideline within which the individual jobholder works. It is not intended to be rigid or inflexible and may alter as the Company's strategic direction changes.

# PERSON SPECIFICATION

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| | ESSENTIAL REQUIREMENT | DESIRABLE REQUIREMENT | ASSESSMENT METHOD |
|---|---|---|---|
| **QUALIFICATIONS** | Bachelor's degree (or equivalent) in a related Scientific/Technical discipline OR significant relevant experience working within the Manufacturing industry. | Master's degree (or equivalent) in a related Scientific / Technical discipline. | Application Form and Documentary Evidence |
| **EXPERIENCE** | Experience within a support role in the Manufacturing industry<br><br>Experience in documentation generation. | Knowledge of cGMP and manufacturing processes of pharmaceutical products<br><br>Experience in new product design and introduction including ongoing process monitoring<br><br>Experience in the qualification of process equipment and experience of process validation<br><br>Experience undertaking technical work / experiments which have involved problem solving<br><br>Experience of presenting approach to a project including summary of work undertaken, data generated and key findings<br><br>Knowledge and application of Lean Manufacturing Principles | Application Form and Interview |
| **KEY SKILLS** | Proficiency in the use of Microsoft Office applications (to include Word, Excel, PowerPoint, Project and Outlook)<br><br>Excellent communication skills (written and verbal to include delivering presentations) and fluency in English<br><br>Proven ability to work effectively on own initiative and effectively contribute within a team environment<br><br>Proven ability to compile both narrative and numerical reports | Excellent project leadership, organisation and planning skills with experience of working to aggressive timelines<br><br>Aptitude in analysing and resolving problems of a practical nature and determining root cause<br><br>Strong analytical and problem solving skills<br><br>Aptitude in analysing and resolving problems of a practical nature and determining root cause<br><br>Experience of working to aggressive timelines. | Psychometric Testing and/or Interview |

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| | of exceptional standard | | |

# ALMAC CORE COMPETENCIES

| COMPETENCY | BEHAVIOUR | ASSESSMENT METHOD |
|---|---|---|
| **RESULTS DELIVERY** | Delivers results on time, within constraints and in line with company policy and procedure and organisational strategy. Demonstrates a continuous drive for quality and a commitment to excellence. | Interview |
| **PROACTIVE SOLUTIONS** | Analyses and uses experience and logical methods to make sound decisions which solve difficult problems. Seeks practical/workable and innovative methods to deliver solutions. | Interview |
| **LEADS BY EXAMPLE** | Promotes a clear vision and mission. Acts as a positive role model for the organisation, fostering a climate of teamwork and development. | Interview |
| **COMMUNICATION** | Communicates clearly and effectively. Promotes the exchange of ideas and information across the organisation. Fosters dialogue to ensure everyone understands what is going on. | Interview |
| **CUSTOMER FOCUS** | Strives to exceed the expectations and requirements of internal and external customer; acts with customers in mind and values the importance of providing high-quality customer service. | Interview |
| **JOB SPECIFIC KNOWLEDGE** | Demonstrates required job knowledge and understanding to successfully and competently fulfill or exceed the requirements of their post. Follows correct procedures and guidelines (SOPs). Proactively demonstrates a desire to enhance and develop their job knowledge. | Interview |