



JOB DESCRIPTION

DATE:	Jun 2023
POSITION:	CS CR Production Team Leader
BUSINESS UNIT:	Clinical Services
LOCATION:	Craigavon and Dundalk
REPORTING TO:	CS CR Production Manager
RESPONSIBLE FOR (PEOPLE):	CS CR Production Supervisors CS CR JTM Supervisors

OVERALL ROLE OBJECTIVE:

The principal function of the Production department is the packaging and labelling of clinical supplies.

The Production Team Leader will be required to represent the Production Manager at meetings, on projects etc. as and when required.

The Production Team Leader will be responsible for the coordination of all aspects of Production processes in both Primary and Secondary departments.

The Production Team Leader will be the point person for Production Supervisors to assist with queries relating to operations and their scheduling on a day to day basis.

The Production Team Leader is responsible for the overall management and performance of the team, ensuring that processes and procedures comply with Almac and regulatory requirements.

JOB SPECIFIC RESPONSIBILITIES:

Responsible for personnel involved in manufacture, packaging and labelling of Almac Clinical Services production operations and JTM Work Orders.

Production (Primary, Secondary & JTM):

1. Allocating operations / work orders to supervisors and teams, where possible, ensuring continuity throughout a study / protocol.
2. Monitoring outputs and efficiencies thus ensuring that reject rates are kept to a minimum and job runs do not exceed the planned hours allocated.
3. Identifying bottlenecks and problem areas with a view to putting corrective actions in place, or modifying procedures, to eliminate them.

Planning:

1. Maintaining the production schedule, ensuring resources are utilised in the most effective manner.

2. Assisting with providing a breakdown of man-hours involved in each operation for costing purposes.
3. Ensuring production analysis details are completed promptly and accurately as soon as possible after completion of operations.
4. Identify and implement a process to ensure operations are moved to Complete - No Charges on completion.

Reporting:

1. Reconciling planned hours against actual man hours highlighting:
 - Gross deviations from planned hours
 - Downtime per machine
 - Booking in time
 - Set-up time
 - Run time
 - Reconciliation time
 - Delays incurred and any trends identified
2. Perform formal trending of miscellaneous transactions and LPN splits and put in place measures to reduce or eliminate their occurrence.

Standard Operating Procedures:

1. Achieve a thorough understanding of policies and procedures.
2. Take ownership of production SOPs and update as necessary to ensure all processes and procedures are covered.
3. Ensure SOPs are adhered to by having a physical presence in operations observing personnel at all levels perform tasks. Address non-compliance with an aim to change behaviours and promote best practice.

Communication Planning:

1. Provide feedback on document templates with a view to producing more user friendly and accurate documents.
2. Co-ordinate with Quality Assurance Manager that production batch documents are ready for dispatch immediately after completion of operations / work orders.
3. Identify and implement a process to ensure the right first time for batch records is achieving department targets / KPIs with the aim to minimise / eliminate errors, omissions etc.
4. Discuss and agree with engineering and service requirements for production on a daily / weekly basis. Implement the use of label applicators / dispensers in all secondary operations to improve efficiencies.

Recruitment:

1. Review resources within the team and ensure sufficient, trained personnel are available to perform the tasks. In doing so, lead the recruitment and selection process.

Investigations & Trending:

1. Provide support to the Lead Investigators during the conduct of an investigation to enable them to perform a thorough root cause analysis.
2. Raise investigations in a timely manner so departmental KPIs are achieved.
3. Complete investigations and reports when necessary (i.e. perform the role of LI).
4. Ensure any CAPA / Follow-up items assigned to you or to those who you are responsible for are actioned in a timely manner.
5. Discuss trends and investigations with team members during Tier 1 meetings to promote awareness and prevent recurrence. Identify trending from information gathered from routine monthly reports and provide relevant process improvement initiatives.
6. Represent Production Management at Tier 2 Quality Management meetings with Almac Senior personnel. Be able to discuss trends and the necessary follow up actions to prevent a recurrence.

General Responsibilities:

1. Consider opportunities for business improvement and be forthcoming with ideas / suggestions regarding process simplification and improved compliance. Be proactive regarding implementation of such through the generation / revision of SOPs and ensure good engagement with global counterparts in order to gain agreement (as required).
2. Act as a Production representative on assigned business projects. Be able to lead and make decisions when changes in processes are required, ensuring a positive approach to continuous improvement (i.e. generate CRPR's, Risk Assessments, Regulatory Reviews, User Requirement Specifications documentation etc.)
3. Host factory tours for customer visits or audits. Provide formal written responses to audit findings where required.
4. Apply problem-solving skills to a wide range of issues and act in a Production advisory capacity. In doing so interact with relevant departments in order to address issues.
5. Attend or chair teleconferences / meetings / customer visits, as required, representing the Production department.
6. Provide data as required for customer meetings in relation to Production activities.
7. Review and approve GMP documentation as detailed in the relevant procedures.
8. Work to a consistently high standard, even when under pressure. React to requests (inside & outside of department) in a timely manner.
9. Fulfil any necessary administrative duties associated with the role, as and when required.

Personnel Management:

1. Be accountable for staff performance, perform annual PMPs, provide routine feedback on performance to ensure departmental Key Performance Indicators (KPIs) and personal objectives are met.
2. Generate team objectives to address ongoing behavioural issues within the department, as well as business needs.
3. Investigate and chair formal discipline meetings when **serious / potentially serious** breaches of GMP compliance or matters of concern arise.
4. Arrange overtime as required, manage annual leave and address lateness.

During periods of high-volume work requests this role will require additional coverage beyond normal working hours and it is a condition of your employment that you are able to fulfil this requirement of the role.

In addition, the individual must be able to flex their start and end times when required so attendance at meetings or in projects can be accommodated.

GENERAL ROLE RESPONSIBILITIES:

Quality	Ensure GMP is adhered to in all areas of work.
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	The successful candidate will hold a degree or significant supervisory experience	Previous Team Leader experience in a similar role	Application Form and Documentary Evidence
EXPERIENCE	<p>Significant experience of managing / supervising</p> <p>Experience of packaging Clinical Trials and / or working in a QC or Production environment</p>	<p>Significant experience of managing / supervising, preferably within a pharmaceutical / biotechnology manufacturing and packaging environment</p> <p>Previous experience in both Primary and Secondary Packaging</p>	Application Form and Interview
KEY SKILLS	<p>Excellent written and verbal communication skills</p> <p>Attention to detail, a quality orientated approach, the ability to foster teamwork</p> <p>Demonstrate the ability to develop and coach others and will demonstrate a logical approach to problem solving</p> <p>Knowledge of cGMPs</p> <p>Ability to manage project resources and timescales, and work to a consistently high standard when under pressure.</p>	Previous experience in the completion of risk assessments, generation & approval of SOPs and customer interactions.	Application Form and Interview

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