



JOB DESCRIPTION

JOB DESCRIPTION CREATION DATE:	December 2023
POSITION:	PS CR Production Technician (Packaging)
BUSINESS UNIT:	Almac Pharma Services
LOCATION:	Craigavon
REPORTING TO:	Production Team Leader (Packaging)
RESPONSIBLE FOR (PEOPLE):	N/A

OVERALL ROLE OBJECTIVE:

The role of a Production Technician is to provide technical expertise within work centres ranging from manufacturing, primary and secondary packaging. The principal function of the role is to ensure the efficient and effective running of technical operations, in accordance with associated protocols & batch documentation whilst maintaining schedule adherence. The Production Technician must also ensure operational compliance with Quality Management Systems (QMS), and adherence to Health and Safety policies.

JOB SPECIFIC RESPONSIBILITIES:

The post holder will be required to conduct a variety of tasks and functions pertaining to their assigned work centre, some of which are listed below;

Qualification/ Validation Support and Routine Production

- Provide support to Production Operators/ Senior Operators, Supervisors and Technical Staff by assisting in process development, qualification and validation experiments as well as routine GMP operations.
- Provide support to Production Operators/ Senior Operators, Supervisors and Technical Staff during equipment installation/ operational qualification and validation experiments.
- Communicate and interact with staff from other departments including Technical Support, Quality Control, Quality Compliance, Technical Quality, Engineering & Facilities to ensure that operations are planned and executed in an efficient manner.
- Ensure GMP standards are maintained at all stages of manufacture and packaging in line with internal procedures and regulatory requirements. Report any incidents to management that have the potential to impact the quality of the process/ equipment or product.

Technical Subject Matter Expert

- Operate process equipment according to internal procedures controlling process parameters with limits as defined within SOPs, Protocols and Master Batch Records. As part of this requirement, it may be necessary to instruct and direct work centre staff (operators, Grade 2 and Grade 3 staff) in the completion of their duties.
- Where required become the subject matter expert (SME) for specific pieces of equipment or processes, including equipment set-up, optimum operation, strip down and cleaning, product changeover.

- Develop an awareness of basic maintenance and calibration to enable input to process troubleshooting as well as taking responsibility for monitoring and ordering spare change parts and consumables as necessary.
- When / where required, liaise with equipment manufacturers to resolve issues or improve line efficiency.

Documentation

- Accurately record and complete technical information and GMP documentation during production operations associated with pharmaceutical development, manufacturing and packaging operations.
- Review executed batch records and associated documentation.
- Support in the generation/ revision of operational procedures/ batch documentation.
- Support in the generation/ execution of qualification and validation documentation for new equipment and processes.
- Monitor critical process parameters (CPPs) and critical quality attributes (CQAs) of a given process and report any unexpected observations to senior Formulation, Technical Support or Production personnel.

Training & Personal Competencies

- Ensure training has been received before undertaking specific duties and that all training is recorded in training records.
- Assist with the design and delivery of training material to other Almac personnel for equipment or processes where they are considered to be SME. This will include assessment of competency following such training.
- Communicate clearly and effectively when processing challenges arise, proactively consider and suggest potential remedial actions.
- Display a high degree of flexibility in the fulfillment of the role in order to support operational efficiency and any particular client needs.

GENERAL ROLE RESPONSIBILITIES:

Quality	Ensure GMP is adhered to in all areas of work. <i>Almac Pharma Services' Quality Mission;</i> <i>To operate within a quality excellence framework that is both efficient and effective and continually assures safe and efficacious product to the patient.</i> The post holder will, support the quality mission of the business by: - Ensuring exceptional and reliable quality in all aspects of work and recognising that quality determines the extent of success. - 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. - 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.



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	ESSENTIAL REQUIREMENT	DESIRABLE REQUIREMENT	ASSESSMENT METHOD
QUALIFICATIONS	A-Level (or equivalent) qualifications Or, Significant relevant experience working within the Pharmaceutical industry	HNC, HND (or higher) in a Life Science or Engineering subject	Application and Documentary Evidence
EXPERIENCE	Previous relevant experience working with technical processes, equipment and associated documentation within a regulated Industry i.e. pharmaceuticals, food, aerospace etc.	Previous experience within a GMP or regulated environment	Application and Interview
KEY SKILLS	Proven ability to adopt a methodical approach, managing multiple tasks simultaneously whilst maintaining a high level of accuracy in all work carried out Ability to work effectively on own initiative and effectively contribute within a team environment Willing to learn and apply new skills Ability to maintain a high level of accuracy in all work undertaken Practical problem solving skills Proficiency in the use of Microsoft Office packages (to include Word, Excel, Outlook and PowerPoint)	Working knowledge of GMP and associated regulations	Interview

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