JOB DESCRIPTION	
DATE:	October 2026
POSITION:	PS CR Associate Director – Manufacturing
BUSINESS UNIT:	Pharma Services
LOCATION:	Craigavon
REPORTING TO:	PS CR Director – Operations, Manufacturing
RESPONSIBLE FOR (PEOPLE):	Production Managers (Manufacturing Operations) Operations Support Manager (Manufacturing Support)

OVERALL, ROLE OBJECTIVE:

The Associate Director – Manufacturing will provide leadership and technical direction for all elements of GMP Manufacturing within the Technical Operations Department. The post holder will be accountable for safe, compliant and efficient manufacturing operations and will act as the senior technical lead for process validation, cleaning validation, the introduction of new equipment, facilities and utilities, and technical support to clients, ensuring products are manufactured to the highest standards of quality in line with regulatory and client expectations.

Key objectives of the role include:

- Providing strategic direction, leadership and people development for the manufacturing team(s).
- Ensuring GMP manufacturing operations are conducted in a safe, compliant, and efficient manner in line with the expectations of regulatory agencies and clients.
- Providing technical leadership and support for process validation and continued process verification across the product lifecycle.
- Providing technical leadership for cleaning validation and the introduction of new equipment, facilities and utilities.
- Providing manufacturing technical support and driving continuous improvement, operational excellence and inspection readiness.
- Acting as a senior technical point of contact for clients, including leading technical client calls and meetings.
- Representing Almac during client audits and regulatory inspections.
- Providing technical support to business development activities.

JOB SPECIFIC RESPONSIBILITIES:

The post holder will:

<u>Leadership and People Management:</u>

1. Provide strategic and operational leadership to Manufacturing Operations and Manufacturing Support, setting clear objectives aligned to Technical Operations and site goals.
2. Lead, coach and develop direct reports, taking responsibility for recruitment, performance management, succession planning and staff development.
3. Promote a strong safety, quality and right-first-time culture through visible leadership on the manufacturing floor, fostering accountability, engagement and teamwork.

4. Provide information to key stakeholders in order to make best possible use of available capacity and to forecast and address potential resource constraint issues; contribute to departmental budget and resource planning.
5. Represent Technical Operations on multi-disciplinary teams and leadership forums, ensuring that responsibilities are clear and understood.
6. Deputise for the PS CR Director – Operations, Manufacturing as required.

GMP Manufacturing Operations:

7. Ensure all manufacturing operations are conducted in a safe, compliant and efficient manner in line with EU GMP, FDA cGMP (21 CFR Parts 210/211), the expectations of regulatory agencies and clients, and Almac procedures.
8. Use KPIs and metrics (e.g. safety, quality, delivery, cost and equipment effectiveness) to monitor performance and drive improvements.
9. Lead or provide technical oversight on more complex process-related issues (such as deviations, investigations, complaints and product performance issues), ensuring robust root cause analysis, effective CAPA and timely closure.
10. Own and approve manufacturing change controls, risk assessments (ICH Q9) and GMP documentation (e.g. batch records, SOPs and work instructions), ensuring data integrity (ALCOA+) principles are applied.
11. Maintain a continuous state of inspection readiness and represent Almac as a subject matter expert in customer audits and regulatory inspections, leading responses and associated actions.
12. Drive continuous improvement and operational excellence using Lean and Six Sigma tools to improve right-first-time performance, capacity and cost.

Process Validation and Product Lifecycle Management:

13. Lead activities associated with product lifecycle management, providing technical leadership for process validation in line with the FDA Process Validation Guidance, EU GMP Annex 15 and ICH Q8–Q10, including validation strategy, process performance qualification (PPQ) protocols and reports, and continued process verification (CPV).
14. Ensure the technical transfer and scale-up of client products into GMP manufacturing is robust and risk-based, with a clear understanding of critical process parameters, critical quality attributes and the control strategy.
15. Review process data and statistical trending to confirm processes remain in a state of control, and provide technical input to product quality reviews.

Cleaning Validation:

16. Provide technical leadership for the cleaning validation and verification of manufacturing equipment and facilities, including risk-based cleaning strategies, product grouping and worst-case assessments, and health-based exposure limits (PDE/ADE) in line with EU GMP Annex 15 and relevant regulatory guidance.
17. Ensure cleaning procedures, validation protocols and reports, and ongoing monitoring programmes remain robust and compliant, and that the introduction of new products and equipment is assessed for cleaning and cross-contamination impact.

New Equipment, Facilities and Utilities Introduction:

18. Lead the introduction of new equipment, facilities and utilities within manufacturing, from user requirement specification (URS), vendor selection and factory/site acceptance testing (FAT/SAT) through commissioning, qualification (DQ/IQ/OQ/PQ) and handover to operations.

19. Develop business cases for capital investment and ensure projects are delivered in a timely manner in accordance with an agreed project strategy, scope and budget, maintaining effective communication with other relevant departments so that activities are planned and co-ordinated effectively.
20. Drive innovation based on industry knowledge, using it to shape strategic investments and operational plans, and develop and disseminate subject matter expertise within Technical Operations.

Client Technical Support and Business Development:

21. Act as a senior technical point of contact for clients, leading technical client calls, project meetings and site visits, and communicating clearly on manufacturing, validation and investigation matters.
22. Support business development through technical assessment of RFPs, technical input to proposals and attendance at client facility visits / meetings to maintain and increase departmental revenue targets. Manage clients to maximise and recognise business opportunities.
23. Build effective working relationships with Quality, Engineering, Project Management, Supply Chain, Development and Commercial teams to ensure client projects are delivered right first time.

This role will require coverage beyond normal working hours as and when required. It is a condition of your employment that you can fulfil this element of the role.

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 workplace.
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.

Personnel Specification	
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	ESSENTIAL REQUIREMENT	DESIRABLE REQUIREMENT	ASSESSMENT METHOD
QUALIFICATIONS	BSc (Hons) or higher degree in a Life Science, Pharmacy, Chemistry or Engineering subject.	PhD in a Life Science or Engineering subject. Lean Six Sigma certification (Green Belt or above).	Application and Documentary Evidence
EXPERIENCE	Significant hands-on experience in pharmaceutical development and GMP manufacturing, including experience in a leadership role. Proven experience in the technical transfer and process validation (PPQ/CPV) of new drug products. Working knowledge of cleaning validation principles and practice, including health-based exposure limits. Experience in the introduction, commissioning and qualification of new manufacturing equipment. Experience supporting client audits and regulatory inspections. Experience in dealing with clients and presenting on technical topics. Experience supporting business development activities.	Experience leading managers and teams involved in the manufacture of drug product. Experience in developing drug product formulations and processes suitable for phase I, II and III stages of pharmaceutical development. Experience in a CDMO / contract manufacturing environment. Experience of capital project management.	Application and Interview

KEY SKILLS	Strong leadership and people management skills In-depth knowledge of EU / FDA GMP and associated guidance (e.g. Annex 15, ICH Q7–Q10) Excellent communication and stakeholder management skills, including with clients and regulators Practical, structured problem-solving and risk-based decision-making skills Flexible multi-tasker, able to prioritise competing demands Team player Excellent attention to detail Proficiency in use of basic IT applications (Word, Excel, Outlook)	Experience in the use of statistical tools (e.g., Minitab). Experience of formal problem-solving methodologies (e.g., lean six sigma). Experience of electronic quality management systems.	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