



JOB DESCRIPTION

DATE:	January 2022
POSITION:	Technical Quality Placement Student
BUSINESS UNIT:	Pharma Services
LOCATION:	Craigavon
REPORTING TO:	Senior Technical Quality Specialist
RESPONSIBLE FOR (PEOPLE):	N/A

OVERALL ROLE OBJECTIVE:

Assisting the Technical Quality team with the delivery of a range of business and continuous improvement projects. This can include a multitude of activities, ranging from the qualification of essential Equipment, Facilities, Utilities and Software Systems; to the validation of manufacturing and packaging processes.

JOB SPECIFIC RESPONSIBILITIES:

The post holder will:

1. Actively assist in co-ordinating and be involved in the execution of all stages of the validation life cycle including:
 - Assisting with development of project design documentation.
 - Generating validation plans for larger projects.
 - Risk assessing validation requirements.
 - Assessing systems against pre-defined standards to ensure they meet current regulatory expectations
 - Propose remediation actions to resolve issues relating to regulatory compliance
 - Liaise with non-Pharma Services personnel (including manufacturers, suppliers, external validation resources, clients)
 - Preparation of validation protocols and reports
 - Collation and analysis of process validation data
 - Performing and witnessing validation activities
 - Provide advice / guidance to the business on Almac's validation and qualification procedures, policies and expectations
2. Perform the monitoring and periodic re-evaluation of equipment, systems and processes.
3. Regularly update the Technical Quality schedule with the status of current validation projects.
4. Liaise with key personnel within project teams to ensure validation tasks are planned, monitored and completed in a timely manner.
5. Assist in the execution of testing to meet operational requirements

6. Liaise with Quality Control / Analytical Support to ensure that all relevant validation testing is performed and reported.
7. Liaise with Quality Compliance to ensure GMP is adhered to in all areas of validation testing and that systems are fully validated and all documentation completed before they are released for use.
8. Undertake additional duties or specific projects as required

Almac Pharma Services' Quality Mission:

To operate within a quality excellence framework that is both efficient and effective and continually assures safe and efficacious product to the patient.

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".

This role may require coverage beyond normal working hours as and when required. It is a condition of your employment that you are able to fulfil this requirement 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 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	GCSE Maths & English (or Equivalent) at Grade A-C Educated to A Level (or equivalent) level Currently studying at Undergraduate/Postgraduate Level in a Sciences or Technical (Engineering or IT) related discipline.	Additional course or qualification in a Sciences or Technical (Engineering or IT) related discipline.	Application Form and Documentary Evidence
EXPERIENCE	Experience working in a fast paced environment eg. part-time job/work experience.	Experience in co-ordinating and liaising with various personnel within an organisation Previous experience working within a regulated quality system.	Application Form and Interview
KEY SKILLS	Proficiency in use of IT applications (Word, Excel, Outlook, etc) Excellent communication skills (both written and oral) Proven ability to follow written work instructions Proven ability to manage multiple tasks simultaneously whilst maintaining a high level of accuracy in all work carried out Proven ability to work effectively on own initiative and effectively contribute within a team environment Proven ability to see activities through to completion	Knowledge of the regulatory requirements for validation within the pharmaceutical industry	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