



JOB DESCRIPTION

DATE:	June 2021
POSITION:	Investigational Product Coordinator (Pharmacist)
BUSINESS UNIT:	Almac Clinical Services
LOCATION:	Craigavon
REPORTING TO:	TBC
RESPONSIBLE FOR (PEOPLE):	None

OVERALL ROLE OBJECTIVE:

This role will work alongside Pfizer colleagues/contractors and unblinded CRAs to provide IP handling and management support to investigator sites. The Pfizer IP Coordinator (PIPC) shall provide site guidance and training to pharmacy personnel in all aspects of IP handling, preparation, and administration as directed by the Pfizer Clinical Research Pharmacy.

JOB SPECIFIC RESPONSIBILITIES:

The post holder will:

Responsibilities

- Review reports and maintains site specific trackers/dashboards for enhanced monitoring of the unblinded IP handling activities;
- Monitor usage of site inventory through reviews of study documentation, including but not limited to, IP shipment documents, inventory dashboards, IRT reports, data visualizations, preparation records, duties and investigational product accountability logs/forms;
- Assess local site inventories to ensure adequate IP and ancillary supplies are available for the next two-days of scheduled participants;
- Coordinates IP for predictive enrollment to ensure adequate supplies are available to complete the study design;
- Provides support to ensure temperature excursion assessments are resolved in a timely manner;
- Review dose preparation records and accountability logs daily to ensure the physical inventory accurately reflects the IP containers dispensed and there is adequate IP remaining for future vaccinations;
- Reviews documents that are uploaded and filed in Florence or a site's equivalent system that maintains the electronic Investigator Site File (eISF) and source documents (eSource) (e.g. unblinded source documents);
- Maintains effective and ongoing communication with investigator site, unblinded study team members (e.g. unblinded Pfizer and ICON Study Managers, unblinded CRAs and Site Care Partners, as needed), and appropriate Pfizer Global Clinical Supply colleagues throughout the duration of the study;

- Assist with overseeing the day to day unblinded IP handling activities of the study including problem solving, communication and IP management;
- Responds to appropriate unblinded IP handling queries in consultation with Global Clinical Supply colleagues;
- Completes all required IP handling training as required.

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	<p>M.Pharm in Pharmacy or equivalent.</p> <p>Hold a current registration with a relevant pharmacy Regulator e.g.GPhC, PSNI, PSI or be eligible to do so</p>		CV and Documentary Evidence
EXPERIENCE	<p>A minimum of three years post registration experience of practising as a Pharmacist in an industrial, hospital or retail setting.</p>	<p>Previous experience and/or understanding of clinical trials</p> <p>Previous experience of working in a CRO</p> <p>Experience of using an IRT system</p>	CV and Interview
KEY SKILLS	<p>Excellent communication, interpersonal, and organizational skills</p> <p>Strong understanding of Microsoft Office packages</p> <p>Full current driving licence and ability to travel across multiple sites</p>	<p>Extensive knowledge of the use of Microsoft Excel</p> <p>Ability to speak a second language e.g. French, German</p>	CV 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