PHARMACY INVESTIGATIONAL RODUCT SPECIALIST PIPS-SIPS

This a great opportunity for a Site Pharmacist to join an international team within a strategic pharmaceutical company

Role and Responsibilities:

-Play a key role in the safe, efficient and effective IP preparation in clinical trials.

-Review and provide input on IPPI, Site Investigational Product Procedures Manual (SIPPM), monitoring guidelines and all specific forms related to IP preparation and dosing before finalization as applicable.

-Process risk assessment review where applicable.

-Assist in site/pharmacy assessments, pre-trial site/pharmacy assessment activities and/or study feasibility assessments, providing recommendation from local area about site/investigator selection in collaboration with the trial team.

-Close collaboration with the Drug Product Development (DPD) team and the Drug Preparation Administration Team (DPAT) around IPPI.

-Attend primary DPAT kickoff meeting as ad hoc member as needed.

-Early connection with investigational site pharmacy and IP administration staff to review site IP process and equipment.

-Close collaboration with PM, CTM, CRA, Independent Drug Monitor (IDM) and Site Investigational Product Specialist (SIPS) for all IPPI related topics.

-Evaluate and support process for IP and ancillary supplies/preparation kits are compatible with the pharmacy equipment/practice in the country/investigational site.

-Review of site's preparation and accountability records to ensure key information is captured and documented.

-Provide feedback on eCRF setup regarding IP preparation.

-Collaboration on IP training material development with key stakeholders.

-Attend key site initiation visits. Responsible for training of all versions of IPPI through dose escalation and preparation according to internal Standard Operating Procedures (SOPs)/Work Instructions (WIs)/Instructions for Use (IFUs) and policies. Support IP issue resolution and work closely together with the IDM to ensure site training for blinded trials.

-Observe first IP preparation on site and/or support SM/IDM/SIPS if allowed according to local guidelines and blinding requirements.

What is Required:

Education: Pharmacy Degree

Experience: Site Pharmacist, Pharmacy Resindecy

Knowledge of Microsoft Office applications especially Excel

English: Fluent spoken & written. Mandatory

Good interpersonal skills demonstrated as proactive, enthusiastic, and independent thinker

Ability to collaborate and build strong relationships with all functions involved in the trial

Works and meets deadlines with some supervision

Must be able to travel in accordance with company and project requirements

What is Offered:

We offer a permanent contract, full time and partially home based in Madrid.

This is a great opportunity for a Site Pharmacist looking for a new challenge! You will be part of an International Pharmaceutical Company, working on a cutting-edge projects.