1. Play a key role in the safe, efficient and effective IP preparation and administration in clinical trials.
2. 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.
3. Process risk assessment review where applicable.
4. Assist in site/pharmacy/lab 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.
5. Close collaboration with the Drug Product Development (DPD) team and the Drug Preparation Administration Team (DPAT) around IPPI.
6. Attend primary DPAT kickoff meeting as ad hoc member as needed.
7. Early connection with investigational site pharmacy and IP administration staff to review site IP process and equipment.
8. Close collaboration with GTL, SM, TM, Independent Drug Monitor (IDM) and Pharmacy and Site Investigational Product Specialist (PIPS/SIPS) for all IPPI related topics.
9. Evaluate and support process for IP and ancillary supplies/preparation kits are compatible with the pharmacy equipment/practice in the country/investigational site.
10. Review of site's dispensing, preparation and accountability records to ensure key information is captured and documented and to confirm dose delivery and administration is documented i.e. infusion rates/volumes.
11. Review translation of IPPI and/or related documents into local language per policy and regulations.
12. Provide feedback on eCRF setup regarding IP preparation and administration.
13. Collaboration on IP training material development with key stakeholders.
14. Attend key site initiation visits. Responsible for training of all versions of IPPI through dose escalation and administration 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.
15. Set up and attend mock runs on IPPI preparation before first formal IP preparation at the investigational site if applicable.
16. Observe first IP preparation and dosing on site and/or support SM/IDM/SIPS if allowed according to local guidelines and blinding requirements.
17. Point of contact for the internal study team in the country for questions related to the IP preparation.
18. Review any modification of IPPI, SIPPM manual, specific forms related to IP preparation, administration and dosing during the applicable phases of the trial.
19. Fully document trial related activities with respect to IPPI site training and monitoring (e.g. writing of visit reports and completion of follow-up letters to investigators). Documentation and escalation of major deviations and issues to appropriate stakeholders.  Ensure timely corrective actions are completed and documented.  Coordinate documentation with SM/IDM, as appropriate.
20. Lead and/or participate in special initiatives as assigned for IPPI and SIPPM development.
21. Establish and maintain good and productive working relationships with internal and external stakeholders (e.g. pharmacists, investigators…).