Mission within Quality Assurance R & D

Position
Job title: Quality Assurance work linked Education Department: Global Research and Development Line Manager: Global Research and Development VP Quality or delegate

Purpose of the position
Participate to department activity in different areas: - Maintaining an effective and efficient Quality Systems for the operational units involved in clinical research, e.g.: Clinical Operations to ensure compliance with Ipsen's quality standards, good working practices and local, national, regional and international legal, ethical and regulatory requirements. - Promote a culture of continuous improvement - Oversee and ensure timely systematic investigation of the root causes of identified quality issues or identified risks - Oversee and ensure timely closure and efficiency of CAPAs by tracking progress, providing summaries and metrics

Main responsibilities and tasks	
Main Responsibilities	**Main Tasks**
▪ **Clinical Study QA representative**	▪ Works with the QA representative leads for studies under development and in Global Medical Affairs to ensure good clinical practices and relevant regulatory requirements are fulfilled ▪ Participate to project meeting and ensure timely assistance for all quality related topics ▪ Participate to Vendor's Quality Assurance Meetings and ensure quality oversight ▪ Works with QA representative for non-Clinical activities under her responsibilities ▪ Ensure all documentation accurately filed
▪ **SOP Process**	▪ Participate to creation of quality documents and/or lifecycle quality document revision for all key aspects of the process in collaboration of the QMS Manager. ▪ Manage the review/approval process, track and report status. ▪ Liaise with authors and customers to ensure collaboration and efficiencies ▪ Provide the Key Performance Indicator ensuring the monitoring of the process.
▪ **Other QMS Process**	▪ Corrective and Preventive Actions (CAPA): Collaborate with the deviation and Capa manager for: ○ Report CAPA status and metrics, escalating any issues regarding delayed timelines or ineffectiveness of CAPA, as needed ○ Ensure timely delivery by following up with CAPA owners and scheduling meetings as necessary ▪ Deviations and major breach ○ Ensures documentation, investigation, and tracking of major deviations and potential Serious Breaches in GCP ○ Organize and coordinate deviation assessment meetings, providing meeting minutes and ensuring communication and escalation as appropriate

▪ **Audits and Inspections**	▪ Support the audit activities: provide information to audit group for their risk assessment and audit activities, facilitate further investigation of observations (when needed), root cause analysis and definition of CAPA. ▪ Provide responses and address questions and observations during inspection when observations are related to the role or responsibilities of the QA function. ▪ Assist in the preparation and conduct of inspection as required.
▪ **Training**	▪ Run reports from ILP to obtain training metrics ▪ Escalate delays and non-compliance to the requirements as applicable
▪ **Department Objectives**	▪ Participate to administrative department activities and events ▪ Involvement in Corporate projects and initiatives ▪ To perform any other activity as per priorities linked to the job and competencies (e.g. inspection, for-cause audit…) ▪ Participate to Improve department visibility and embed quality value within Ipsen

Other Useful Information		
Prepared by Manager: Dounia Sbaï	Signature:	Date:
Accepted by Employee	Signature:	Date