

## Sr. Quality & Safety Manager

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Company: Novo Nordisk

Location: Bagsværd

Category: other-general

Key responsibilities Maintains oversight of the management of safety information, safety risk management and all other pharmacovigilance (PV) activities in NNSH GSP for both Drug and Device. Ensure PV medical compliance (NN policies and standards, global and local regulation requirement) and inspection readiness. Design and execution of safety strategy and ensure high quality deliveries. Develop and implement safety related quality system. Independently perform proactive safety surveillance and risk management to effect product safety signal detection and evaluation, risk assessment and safety risk mitigating. Timely collecting and reporting AE from costumer to local HA AE system related NNSH. Analysis and evaluate AE trends, develop risk reduce plan. Monthly PV metrics/report calculation and preparation. Deviation identification and reporting to Head of GSP QA. Support data collection and preparation for MAH. Cooperate group level PV team to make sure NN internal compliance. Engagement in audit and inspection readiness and support as PV SME. Safety/PV related training material development and execute in NNSH GSP level. Drug &MD PV related regulation collection in China and Shanghai level. Regulation collection and analysis. Quality related document management support. Quality Audit support for NNSH GSP. Vendor, supplier, distributor quality management support. RDC quality oversight. AE related record management. Other duties as assigned by line manager. Qualification Bachelor degree or above in pharmacy, biology, chemistry, medicine or other related area Above 5 years product safety and PV experience. Good English skill at reading, writing, listening and speaking. Good communication skills of both scientific and non-scientific information. Professional knowledge in local regulations. Problem solving ability and skills. Ability to face

challenge and self-learning. We commit to an inclusive recruitment process and equality of opportunity for all our job applicants. At Novo Nordisk we recognize that it is no longer good enough to aspire to be the best company in the world. We need to aspire to be the best company for the world and we know that this is only possible with talented employees with diverse perspectives, backgrounds and cultures. We are therefore committed to creating an inclusive culture that celebrates the diversity of our employees, the patients we serve and communities we operate in. Together, we're life changing. Print job Send to e-mail

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