CareerCross

GVP specialist（安全管理スペシャリスト）

安全性情報（臨床開発・製販後GVP）のご経験のある方は歓迎です。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
非公開

Job ID
1463343

Industry
Medical Device

Company Type
International Company

Job Type
Permanent Full-time

Location
Kanagawa Prefecture

Salary
6 million yen ~ 7 million yen

Work Hours
09:00 〜 17:45

Holidays
【有給休暇】初年度 10日 1か月目から 【休日】完全週休二日制 土 日 祝日 GW 年末年始 ※有給休暇日数は入社月により変動

Refreshed
June 19th, 2024 02:00

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2062430】
【（1） GVP Control】
（1） Develop and maintain local GVP process in accordance to Japan GVP Ordinance while ensuring the local procedures are not in contradiction with Global PMS process.
（2） Review and update SOPs/WIs for local GVP processes periodically
（3） Conduct Self Inspection for GVP processes periodically

（4） Communicate with MAH Manager Domestic Quality Representative QMS Representative and other relevant stakeholders on any updates related to GVP Control as and when necessary
【（２） Post Market Safety Activities】
（1） Collect and review the following quality/safety information at regular interval and to determine whether there are any necessary actions to be taken
All related product quality complaints reported from Japanese market
All related post market information received from Avanos Medical Inc.
Data on adverse events and malfunctions through published literatures
Data on Field Actions occur outside Japan by regular searching of the relevant foreign websites
Other safety and vigilance information if required
（2） Assess the reportability of PMS event and record its result
（3） Communicate with MAH Manager Domestic Quality Representative QMS Representative and other relevant stakeholder on any updates related to PMS activities
（4） Communicate with Global PMS team if necessary
（5） Document all PMS actions taken
（6） Manage and monitor PMS activities following the instructions from the local government authorities including those arise during new product registration
（7） Develop and maintain procedure to collect PMS information
（３）【 Filing MDR （Medical Device Reporting）】
（1） Submit report on adverse events and/or product malfunction events to relevant Japanese government authorities in accordance to Japan GVP guideline
（2） Manage inquiry from the relevant Japanese government authorities
JZ3HR F01R00
（3） Communicate with MAH Manager Domestic Quality Representative QMS Representative and other relevant stakeholders including GPMS Team if necessary
（４） Risk Management
（1） Lead Risk Management process
Develop and maintain risk management process
Conduct Risk Management as and when required on product realization process field action IFU/DFU update
Determine and implement actions required to reduce identified risks
Communicate with MAH Manager Domestic Quality Representative QMS Representative and other relevant stakeholders including GPMS Team on risk management matter as necessary
（５）【Local IFU Management】
（1） Lead IFU development for newly launched product
Develop draft version of local IFU and forward it to assigned reviewer/approver
Communicate with 3PL on its implementation
（2） Lead IFU review/update
Assess and review IFU’s update based on the following inputs:
・ DFU update
・ Regulatory information
・ QA/MKTG request to address adverse event prevention and complaint reduction
Develop draft version of updated IFU and forward it to assigned reviewer/approver
Communicate with 3PL on its implementation
Disseminate updated information with the relevant stakeholders
（3） Develop and maintain information collection process

Required Skills

【必須経験】 医療機器業界で安全管理の業務経験（2年以上） ・論理的思考力 ・問題解決能力 ・ISO 13485/9001 監査経験 ・ISO 14971　医療機器リスクマネジメント

Company Description

ご紹介時にご案内いたします