



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。

募集職種

人材紹介会社

株式会社ジェイ エイ シー リクルートメント

採用企業名

非公開

求人ID

1488664

業種

医療機器

会社の種類

外資系企業

雇用形態

正社員

勤務地

神奈川県

給与

600万円 ~ 700万円

勤務時間

09:00 ~ 17:45

休日・休暇

【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

更新日

2024年08月01日 15:22

応募必要条件

キャリアレベル

中途経験者レベル

英語レベル

ビジネス会話レベル

日本語レベル

ネイティブ

最終学歴

大学卒 : 学士号

現在のビザ

日本での就労許可が必要です

募集要項

【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

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(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

スキル・資格

【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

会社説明

ご紹介時にご案内いたします