

生产技术员II

Job ID
REQ-10053841
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China

Summary

生产技术员在放射配体疗法（Radioligand Therapies，简称 RLT）的日常生产中发挥积极作用，同时负责仪器和设备的设置与准备。生产技术员在履行职责时遵守监管要求，按照批记录和标准操作规程（SOP）执行生产任务。相关职责在团队中完成，并根据指定的生产轮班时间表进行。生产技术员与经理和主管密切合作，确保生产过程安全、及时地执行。

About the Role

主要职责：

- 执行与放射配体疗法（RLT）产品制造相关的所有活动。职责包括操作和维护A级隔离器，专注于关键绩效指标（KPI）目标，并确保遵守所有州级、联邦及诺华的辐射安全指南。
- 负责按时成功完成所需的培训课程，包括必要的标准操作规程（SOP）、无菌技术、更衣资格认证以及与该岗位相关的其他培训（包括健康、安全与环境 HSE）。
- 支持与生产准备相关的所有技术方面，包括手动清洁工作单元和使用过氧化氢蒸汽对隔离器进行灭菌。
- 根据要求进行常规和动态的环境监测。
- 推动“勇于发声”的文化，确保所有cGMP合规活动得到遵守。
- 准备相关文件和记录，如批记录、运输文件和培训材料。
- 鉴于产品的时间敏感性，该职位可能需要临时加班以确保流程的连续性和完成。
- 灵活穿戴洁净室服装和个人防护装备（PPE）
- 近距离视力相当于20/20，且无色觉障碍。允许使用矫正镜片以达到所需的视力水平。
- 在受限区域内禁止使用化妆品、佩戴首饰、涂指甲油、使用香水/古龙水及其他可能成为微生物来源的物品。
- 搬运或提举最多达35磅（约16公斤）的物品。
- 根据需要，可能会分配其他职责。

关键绩效指标：

- 批记录执行“第一次即正确”，无重复偏差。
- 遵守出勤指南及所有与安全相关的操作程序。
- 与A级隔离器或B/C级区域相关的审计中无重大或关键性发现。
- 生产过程符合所有良好文件规范（GDP）和良好生产规范（GMP）原则。
- 无菌/洁净室行为符合GMP指南要求。

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other.

Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

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<https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Operations

Business Unit

Innovative Medicines

Location

China

Site

Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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