INFINION
永創醫療器材股份有限公司

職位說明
JOB DESCRIPTION

職稱：研發工程師
TITLE: R&D Engineer

直屬主管：研發管理階層
REPORTS TO: R&D Management

部門：研究與開發處
DEPARTMENT: R&D

職務摘要 / 職責說明：
SUMMARY / RESPONSIBILITIES:

本職位將協助參與醫療器材從概念發想、細部產品開發至新產品導入量產的所有設計與開發階段。此職位需能獨立或與其他工程師合作，參與新產品之創意發想、概念設計與實現（原型製作）。職責包括創新問題解決、假設驗證、測試方法開發、設計文件撰寫、規格制定、原型製作、產品測試、數據分析及報告撰寫。

This position will be assigned to assist in all phases of design and development of medical devices from concept work through detail product development and new product introduction manufacturing. They will participate in creative brainstorming, conceptualization, and realization (prototyping) of new devices independently and in conjunction with other engineers. Responsibilities will include creative problem-solving, hypothesis testing, test method development, design documentation, specification setting, prototyping, testing, data analysis, and report generation.

主要職責：
ESSENTIAL DUTIES AND RESPONSIBILITIES:

- ***技術設計與創新***
  Technical Design & Innovation
  - 在團隊合作工作中，同時具備自主能力，進行新產品及現有產品改良之研究、設計與開發。
    Work collaboratively but act autonomously to research, design, and develop new products and improvements for current product.
  - 參與或主導創意發想活動以產生新的智慧財產，並與資深人員及／或專利律師合作撰寫與研究專利申請範圍。
    Participate in and/or lead brainstorming sessions to generate new intellectual property and work with senior staff and/or attorneys in writing and researching patent claims.
  - 可能需直接與客戶合作，確認產品設計需求、使用者介面需求，以及產品與其他醫療系統或產品整合之可能性。
    May work directly with customers to determine needs in product design, user interface, and possible integration of products with other medical systems or products.
  - 在兼顧成本效益與時程的前提下，協助設計新產品或產品改良，並熟悉產品之製造方式。
    Assist in the design of new products or product enhancements in a cost-effective and timely manner and with an understanding of how the product will be manufactured.

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- ***設計管制與法規遵循***
  Design Controls & Compliance
  - 建立詳細產品規格、製作原型，並測試新產品或現有產品改良版本。
    Create detailed specifications, construction of prototypes, and testing of new products or current product enhancements.
  - 設計並開發研究與實驗，依專案計畫執行產品測試與測試流程。
    Design and develop studies and experiments, execute product testing and protocols in accordance with project plans.
  - 研究、評估、建議及／或選擇設計所需之供應商或委外製造商。
    Research, evaluate, recommend, and/or select vendor/contract manufacturer choices for designs.
  - 研究、評估並建議設計所需之材料選擇。
    Research, evaluate, and recommend material choices for designs.
  - 確保產品文件符合品質系統要求。
    Ensure that product documentation is in accordance with Quality System requirements.
  - 可能需提供使用者訓練，並協助開發相關支援文件。
    May provide user training and contribute to the development of support materials as required.
  - 可能主導或參與產品由研發轉移至製造階段之流程，包括製程開發、治具設計及製程驗證。
    May lead or contribute to the process of transferring product from development to manufacturing including process development, fixture design, and process validation.
  - 依品質系統要求建立設計圖面、測試報告、工程報告及其他技術文件。
    Create documentation including design drawings, testing reports, engineering reports, and other technical documents in accordance with our quality system requirements.
  - 確保技術活動均有適當文件紀錄。
    Ensure technical activities are properly documented.
  - 積極推動並支持品質管理系統、品質目標及品質政策。
    Actively promote and support the Quality Management System, Quality Objectives, and Quality Policy.

- ***專案領導與跨部門合作***
  Project Leadership & Collaboration
  - 可能需監督技術員完成產品測試／檢驗及原型製作工作。
    May supervise the activities of technicians in completing device testing/inspection and prototype construction.
  - 以安全且有效的方式執行職務，並確保所監督之人員遵守公司安全規範。
    Perform job functions safely and effectively. Ensure that employees under their supervision are adhering to the safety procedures of the company.
  - 若發現產品品質相關疑慮，應通知相關負責人員。
    Inform responsible personnel of concerns involving product quality.

- ***臨床與法規支援***
  Clinical & Regulatory Support
  - 與研究醫師互動，以辨識潛在產品機會及進一步市場發展機會。
    Will interact with research physicians to identify potential product and further market opportunities.
  - 提供 510(k)、PMA 或 CE Mark 法規申請所需之技術論證與數據資料。
    Provide technical rationale and data for 510(k), PMA, or CE Mark regulatory submissions.
  - 提供符合美國及其他國家法規機關核准要求之工程測試與文件資料。
    Provide engineering testing and documentation that is in accordance with regulatory requirements for approvals of products by the US and foreign regulatory agencies.

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- ***其他***
  Others
  - 以安全且有效的方式執行工作職責。
    Perform job functions in a safe and effective manner.
  - 其他主管指派事項。
    Other duties as assigned.

資格條件與技能：
Qualifications & Skills:

- ***學歷與經驗***
  Education & Experience
  - 機械工程、生醫工程或相關工程領域學士學位，並具 3 年以上相關經驗；或碩士學位（無經驗亦可）；或具醫療器材或其他受法規管制產業之同等學經歷。
    Bachelor's degree in Engineering: mechanical, biomedical, or related discipline and 3+ years of related experience or a Master's degree without experience; or equivalent combination of education and work experience in the medical device or related regulated industry.
  - 具血管內介入技術與器材經驗者佳。
    Experience in endovascular techniques and devices a plus.
  - 具產品從概念設計至法規核准上市之相關經驗。
    Previous experience in product design from concept to regulatory marketing approval
  - 具於受法規管制品質系統下工作經驗，例如 GMP、ISO 9001、ISO 13485 及 MDD。
    Experience working under regulated quality systems such as GMPs, ISO 9001, ISO 13485 and the MDD.
  - 熟悉設計管制程序與相關要求。
    Familiar with Design Control procedures and requirements.
- ***技術能力***
  Technical Competencies
  - 熟悉統計分析軟體（如 Minitab 或類似軟體）。
    Statistical Analysis Software (Minitab or similar).
  - 熟悉 CAD 軟體（SolidWorks、ProE 或類似軟體）。
    CAD (Solidworks, ProE, similar).
  - 具操作機械加工設備（銑床、車床、鑽床等）經驗者佳。
    Operation of machine shop equipment (mill, lathe, drill press, etc.) a plus.
  - 具 3D 列印設備操作經驗者佳。
    Operation of 3D printing equipment a plus.
  - 具備優秀之英文書面與口語溝通能力。
    Demonstrate excellent written and verbal communications skills (English).
  - 熟練使用 Microsoft Office 軟體。
    Proficiency with Microsoft Office products.

- ***軟實力***
  Soft Skills
  - ➢ 熟悉問題解決工具與方法論。
    Knowledge of problem-solving tools and methodologies.
  - ➢ 能獨立完成專案，亦能與團隊合作。
    Ability to complete projects individually as well as part of a team.
  - ➢ 能同時處理多項任務並保持準確性。
    Must be able to perform multiple tasks concurrently with accuracy.

管理責任：
SUPERVISORY RESPONSIBILITIES:

- 可能需管理技術員級人員。
  May supervise technician-level staff.

工作環境：
WORK ENVIRONMENT:

☑ 工作可能接觸人類血液傳染病原或其他潛在感染性物質。
Work includes potential exposure to human bloodborne pathogens or other potentially infectious materials.

☑ 工作可能於導管實驗室環境中接觸放射源（如透視儀 fluoroscope）。
Work includes potential exposure to radiation sources such as fluoroscope in a catheter laboratory setting.

☑ 工作可能接觸化學物質。
Work includes potential exposure to chemicals.

☑ 需偶爾出差至臨床場所或製造廠。
Occasional travel to clinical sites or manufacturing facilities.

☑ 必要時需能於受控環境（無塵室）內工作。
Ability to work in a Controlled Environment Room (Cleanroom) as required.