**“Design & Development Project Leader”**  
Implantable Medical Devices - innovative biomaterial products (permanent contract, Belgium)

Our company is specialized in the production of implantable medical devices made from biomaterials for biomedical applications. We focus on the development, manufacturing and commercialization of safer and efficient medical devices and implants in compliance with requirements of European regulations and ISO 13485 quality standards.

To sustain new products developments, we are currently seeking a **“Design & Development Project Leader”**:

**REQUIRED QUALIFICATIONS:**
- Scientific background, minimum master in chemistry or life sciences or engineer, preferentially a PhD.
- At least 5-year experience in the development of implantable devices,
- Ability to conduct all stages of the value chain from pre-clinical activities till process transfer / industrialization
- Knowledge of Design and Development activities required for CE marking of implantable devices,
- Knowledge of the European regulations applied to medical devices for CE marking,
- Background in biopolymers is an asset.
- Effective project management and leadership skills.
- Strong analytical and problem-solving skills, result- and customer-oriented,
- Ability to work in dynamic, fast-moving environment,
- Excellent communication and reporting skills, incl. French / English both verbally and in writing,
- Computer skills (Microsoft Office suite) and knowledge of project management tools,
- Strong interest in innovative medical technologies, Intellectual Property and value creation,
- Travel time ~10%.

**MISSION:**
The D&D Project Leader will take a leading role in Design & Development (D&D) programs in relation to the strategic development roadmap of the company. He/she will ensure the effective management and leadership of the program. He/she will provide scientific advices with respect to design controls required for CE marking of implantable devices and will consequently provide a clear definition of the scope of work of the program. He/she will establish the project plan into appropriate work packages and will contribute actively to the progress of the project plan. He/she will ensure that the right product is developed and delivered to meet Company’s strategy and quality standards. Strongly result- and customer-oriented, he/she will lead the program with a focus on meeting established projects milestones in compliance with the budget and timelines. He/she will report on progress and issues to all stakeholders of the project and will provide thorough control of subcontracted activities.

He/she will report to the Chief Operating Officer of the company and may interact transversally with the commercial team.

**TASKS AND RESPONSIBILITIES:**

1. Lead the development programs in relation to the strategic development roadmap of the company,
2. Provide scientific recommendations on design requirements, controls and specification in accordance to regulatory requirements,
3. Develop a project plan and identify project timelines and milestones,
4. Translate the project plan into well-defined task orders and communicate effectively to both internal (project team, D&D lab, production) and external (subcontractors) partners involved on the project,
5. Lead the project team. Plan, organize and coordinate the execution of tasks with the internal/external partners involved on the project,
6. Identify, qualify and negotiate with external partners,(within an appropriate contractual framework)
7. Recording and managing project issues and escalating to the management where necessary,
8. Provide scientific guidelines for troubleshooting and adapt the project strategy and goals,
9. Develop and implements recovery plans for off-schedule and unanticipated occurrences,
10. Review and verify project estimates periodically and manage project budget and controls expenses effectively,
11. Support the management in decision making in line with product development,
12. Report to all stakeholders of the projects, both internally and externally,
13. Prepare periodic management and/or customer reports and presentations,
14. Organize and archive the documentation in compliance with Quality standards for Design & Development,
15. Contribute to the preparation of documents for regulatory purposes,

If you are interested in that job opportunity, please send your application (cv and motivation letter) to our recruitment partner, Plus One, at sgravy@plusonesearch.be

www.plusonesearch.be
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