ANODYNE
Nanotech

VP of R&D and Product Development (Full-time; Boston)

At Anodyne Nanotech, we believe that the delivery of necessary medication should not and will not be a painful process. For anyone involved. For hundreds of years, needles and syringes have been used to deliver medicine, and innovation is long overdue. The company's patent-pending, porous microneedle technology provides the first practical and cost-effective platform, Hero Patch, to deliver clinically meaningful doses of macromolecules or small molecules, and the ability to begin replacing antiquated and cumbersome injections.

If you are interested in redefining drug delivery with us, please submit your CV to careers@theheropatch.com

Description

The VP of R&D and Product Development will lead the development of a drug/device combination product from its current pilot stage to clinical application, including the transition from lab-scale production to GMP manufacturing. The initial focus will be defining a prototype for a specific drug product, creating V&V processes that include the full preclinical testing required while optimizing the manufacturing process to support pre-clinical and clinical stage studies. You will be joining a very passionate, driven team that enjoys challenges. We are very excited about the potential of Anodyne and want a candidate that shares that excitement!

Responsibilities

- Lead a multidisciplinary team of engineers and scientists through product definition and verification
- Develop and implement a quality system to support research and production operations
- Optimize existing and establish new protocols to follow latest FDA and ISO regulations
- Lead the manufacturing scale up from its current pilot stage to support preclinical and clinical studies
- Develop budgets and allocate R&D resources to meet business objectives
- Facilitate effective, science-based business decisions including scenario planning, (including resource allocation, team capacity, and risk management)

Qualifications & Skills

- Extensive experience bringing polymer- based medical devices to clinical trials and working in a GMP environment (minimum 10 years)
- Proven track record of successfully converting innovative technologies into viable new products
- Demonstrated ability to scale manufacturing from a laboratory to GMP facility
- Demonstrated, clear understanding of the regulatory landscape for combination products
- Strong drive to meet timelines, establish clear priorities and hold self and others accountable for results
- Experience with transdermal drug delivery applications strongly preferred
- Strong project/product management skills, with demonstrated experience