

Process Development Scientist

About Regenerative Patch Technologies (RPT)

Regenerative Patch Technologies LLC (RPT) is a California-based biotechnology company focused on the development of stem cell-based implant technology for the treatment of retinal diseases. RPT has developed a bioengineered, composite subretinal implant, termed the California Project to Cure Blindness-Retinal Pigmented Epithelium 1 (CPCB-RPE1), consisting of a polarized monolayer of human embryonic stem cell-derived RPE cells (hESC-RPE) on an ultrathin, synthetic parylene substrate designed to mimic Bruch's membrane. The company has successfully filed an IND on the product and completed enrollment and three-year follow-up of subjects in a Phase 1/2a clinical trial with the advanced form of dry age-related macular degeneration known as geographic atrophy. RPT is actively advancing scientific, manufacturing, and clinical development of the implant and preparing for a Phase 2b clinical trial in patients with geographic atrophy.

Position Summary:

The position of Product Development Scientist will work with RPT's R&D team to oversee cGMP manufacturing of the implant and develop, scale, and optimize methods to manufacture the implant in preparation for advanced clinical trials and eventual commercialization. The person in this position will have the opportunity to interface with R&D scientists, engineers, physicians, regulatory, quality and manufacturing specialists to develop production processes for the implant that could have positive impact for the >1 million people in the US and >5 million globally who suffer from advanced age-related macular degeneration. This position will be located in Santa Barbara, CA.

Responsibilities:

- 1. Participate in oversight of CPCB-RPE1 cGMP manufacturing at RPT's designated Contract Manufacturing Organization (CMO).
- 2. Train new RPT and CMO personnel on the CPCB-RPE1 cGMP manufacturing process as required.
- 3. Review CMO SOP's, batch records and associated manufacturing documentation to identify areas of improvement in manufacturing.
- 4. Plan and execute shipping and stability studies.

- 5. Execute process development and optimization studies on the manufacture, processing, storage, transport, and characterization of RPT's CPCB-RPE1 product.
- 6. Prepare protocols and reports detailing and summarizing the results of studies.
- 7. Participate in planning/management meetings with other RPT personnel.
- 8. Manage laboratory supply chain and equipment maintenance.
- 9. Participate in other projects as mutually agreed.

Job Requirements:

- 1. Bachelor's or advanced degree in biological, biochemical, molecular sciences.
- 2. Demonstrated experience in mammalian cell culture.
- 3. Experience in R&D laboratory setting in the development of cell-based therapies preferred.
- 4. Experience in cGMP production of cellular therapeutics preferred.
- 5. Ability to think both creatively and critically and work within a multidisciplinary team to develop scaled and efficient processes to manufacture RPT's implant.
- 6. Excellent fine motor skills.
- 7. Demonstrated good oral and written documentation skills.
- 8. Skilled in computer-based documentation and analytical software.

To apply:

Please send your current CV with cover letter to inquiries@regenerativepatch.com