610 Main Street
Cambridge, MA 02139
HR@satellite.bio
https://www.linkedin.com/company/satellite-bio

Director, Analytical Development – Cell Therapy

Satellite Biosciences is pioneering the development and implementation of proprietary, off-the-shelf, implantable satellite organs as living therapeutic solutions that can transform the lives of millions of patients who suffer from serious diseases. Building on 25 years of work in award-winning labs at top academic institutions, the platform is supported by a strong IP portfolio and is backed by a top tier syndicate, led by Polaris Partners, Lightspeed Ventures, and aMoon.

You will report directly to the Chief Technology Officer. We are seeking an experienced, creative, and motivated **Director** to join our rapidly growing team. In this role you will contribute to the company's platform technology of engineered satellite organs. Specifically, you will fill a leadership role on our cross-functional team leading analytical methods development for CMC and preclinical studies. This will involve a wide range of cutting-edge technologies and a high degree of technical rigour and creativity. You will also build and directly manage a team and participate in a leadership role within our technical organization.

This role is a unique opportunity to join an early-stage, well-funded Biotech startup. This position is full-time with laboratory time being on-site at our facilities located in Cambridge, MA.

Responsibilities:

- Lead analytical development for cell therapy and biomaterials CMC manufacturing process.
- Advise and support pilot use of concept-stage methods for CMC and preclinical studies.
- Work within a broader cross-functional team to evaluate product quality attributes, process parameters, phase-appropriate control strategies, and select test methods for CMC.
- Develop in-process, product characterization, stability, and product release tests.
- Optimize, qualify and validate biomarker approaches based on biofluids and imaging using analytes suitable for a range of matrix and tissue types.
- Establish a robust development framework with including reference materials, reagents quality, benchmarking processes, and documentation.
- Build and manage a bioanalytical laboratory and provide technical oversight for third-party laboratories.
- Transfer selected assays to third-party laboratories as determined.
- Build and lead a strong team with core technical expertise and prioritize learning and team member development
- Lead planning, project, and experimental design, and actively manage several direct reports in day-to-day execution of specific projects.
- Present key results at group meetings, project teams, and stake-holders.
- Participate in regulatory submission documents, internal document preparation, and scientific publications.

Required Qualifications & Experience:

- PhD in Biochemistry, Cell & Molecular Biology, Genetics or related discipline and greater than 8+ years industry experience in assay /analytical development plus 5 years management experience required.
- Direct experience in CMC analytical methods development
- Previous experience leading a team of scientists required

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- Expertise with multiple cellular, molecular, biochemistry, and analytical techniques (e.g. more than one of microscopy, flow cytometry, ELISA, MSD, ddPCR, qPCR, DLS, cell-based functional assays, enzyme assays, biomaterials testing, and sequencing) is required.
- Proven ability to lead an analytical program through development, clinical initiation and marketing authorization highly desired
- Knowledge of GMP, GLP and other regulatory requirements for biological product characterization and release assay strongly desired.
- Experience in authoring and critically reviewing technical documents, study protocols and reports related to assay development, validation, and clinical sample testing required.
- Practical experience with managing and overseeing analytical activities at third party contract research organizations (CROs) a plus.
- Direct experience interacting with regulatory authorities and supporting regulatory submissions & regulatory queries, and inspections a plus.
- Excellent written and verbal communication skills, documentation skills and attention to detail, with the proven ability to build open and collaborative relationships and work effectively as a member of a multidisciplinary team
- Excellent organizational skills, technical writing, record keeping and ability to manage multiple projects
- Excellent leadership, communication, and collaboration skills, along with the ability to be nimble and work in a fast-paced environment are crucial.
- The successful candidate will be an ambitious self-starter, have a strong work ethic, be able to generate high quality work under tight deadlines, and enjoy working in a fast-paced team environment.

Please submit your resume (.pdf format) to HR@satellite.bio

As an equal opportunity employer, Satellite Biosciences does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin or veteran status. We value diversity and are committed to creating an inclusive environment for team members from all backgrounds.