**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
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.