



Sr./Research Associate, Analytical Development

at Be Biopharma, Inc. ([View all jobs](#))

Kendall Square, Massachusetts, United States

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Role: Be Biopharma is seeking several candidates at various levels to build the Analytical Development (AD) department. AD is responsible for characterizing B cell drug products as well AAV vectors. There are three significant responsibilities within AD- establishing molecular, cell-based, and impurities methods associated with drug products and AAV. Roles and responsibilities will be given based on experience and knowledge in the cell therapy analytical development field. This is an excellent opportunity for career growth as you would interact with various programs teams and be involved in regulatory document preparation.

Responsibilities:

- Developing, implementing, and executing characterization and release assays for identity, purity, strength, and potency (techniques may include cell counting, flow cytometry, ELISA/ELIspot, ddPCR, sequencing, etc)
- Lead efforts to support Process Development product characterization activities.
- Develop and qualify methods related to impurity (residual host DNA/protein, plasmids) associated with drug products and AAV
- Design and perform analytical assay transfers internally with team members in Quality Control or externally to CDMOs.
- Provide routine analytical testing for stability and drug substance samples.
- Execute the assay design criteria using Design of Experiments (DOE)
- Perform method qualification to establish test methods' specificity, sensitivity, linear range, precision, and accuracy.
- Manage analytical reagents inventory, including reference standard materials as per regulatory standards.
- Maintain excellently written documentation of completed experiment (ELN) and maintain knowledge share systems (MS-Teams and share points).
- Generate all training procedures for users to ensure the smooth operation of the test method.
- Be a strong team player contributing to group priorities and deliverables.

Experience, Education, Specialized Knowledge, and Skills:

- BS or MS in Chemical Engineering, Biology, Analytical Chemistry, Biochemistry, Cell & Molecular Biology, or related discipline with 0-2 years of industry experience.



- Hands-on experience with cell culture, PCR, q-PCR, ddPCR, flow cytometry and cell-based functional assays
- Demonstrated understanding developing analytical methods in compliance with ICH
- Experience in writing technical documents including development technical reports, qualification protocols and qualification reports.
- Excellent communication and presentation skills with the proven ability to solve complex problems and to work effectively as a member of a multidisciplinary team, detail oriented, and critical thinker.
- Ability to use literature to design proof of concept studies.

About us

Be Biopharma is pioneering a new class of medicines, unleashing the power of B cells to create the new field of Engineered B Cell Medicines. B cells are the body's protein producing factories, most widely known for making antibodies. Our leading B cell therapy platform, developed by the top scientific KOLs in the field and with strong IP protection, harnesses this capability to engineer B cells to produce any protein with potential therapeutic application. This creates a unique opportunity to rapidly design and develop a broad portfolio of disease changing products (our platform affords ready swapping in *new genes for different disease indications*) and to significantly scale the company to realize substantial value in a short period of time.

Importantly, and in contrast to other cell therapy modalities, Engineered B Cells engraft naturally (and thus are not expected to require preconditioning chemotherapy). They are also "naturally allogeneic", and we expect most or all of our portfolio to be "off-the-shelf" medicines. We have a rich pipeline of initial medicines under development in Oncology and Severe Genetic Disease, and we will subsequently expand to other important indications (e.g. Infectious Disease, Autoimmune Disease, etc).

Our Cambridge-based team is led by highly experienced, mission-driven executives all of whom are experienced cell therapy veterans who played key roles in developing several of today's most impactful marketed gene and cell therapies. The team is rapidly expanding, with 20 employees joining in the first half of 2021. We are making major strides in our proof-of-concept studies for our lead programs in Oncology and Rare Disease, which are on track for near-term clinical development. Be Biopharma was founded in 2020 with a 52M Series A financing round supported by a syndicate of leading biotech investors (Longwood Fund, Atlas, RA Capital, Alta).

Culture

The beating heart of Be Bio is our People and together we are building a culture driven by purpose, passion, and that's full of character. We are "all-in" as we align ourselves with patients who need our



medicines, and we embrace the highest standards of transparency, excellence, candor, collaboration, and team-based science with a shared ownership of company milestones and successes.

Our commitment to our team members is to deliver a compelling, dynamic work experience that enables them to continually stretch, grow, and learn, that enriches their lives, that fosters a sense of belonging and community, and that goes above and beyond to support them in big, meaningful ways in both their personal and professional lives. Be Bio is a team that works hard, plays hard, and supports each other on our shared journey to get transformative medicines to patients who need them.