



Job Title	Senior Director, AOC Process Development & Manufacturing – Oligonucleotide
Position Type	Full-Time
FLSA	Exempt
Department	Tech Ops/CMC
Reports To	Vice President, Tech Ops
Salary Range	\$266,000 - \$295,000

Job Summary:

The Director/Senior Director of AOC Process Development and Manufacturing – Oligonucleotide will lead all aspects of oligonucleotide process development and manufacturing, including establishing technology transfer for Phase 1/2 programs and scale-up to Phase 3 and commercial production. This role requires deep expertise in oligonucleotide synthesis, modifications, purification techniques, and analytical methods, as well as a strong understanding of cGMP and CMC strategy. Prior experience serving as a CMC lead at the program level is highly desirable. The position also includes responsibility for authoring and reviewing Module 3 sections of INDs and BLAs related to oligonucleotide manufacturing.

Job Responsibilities:

- Lead Atrium’s oligonucleotide process development and manufacturing activities at CMOs.
- Serve as CMC lead for one or more programs
- Provide subject matter expertise in oligonucleotide process development, scale-up, and technology transfer.
- Develop and execute late-stage process characterization, validation, and manufacturing strategies in collaboration with CMOs.
- Manage tech transfer activities between CMOs and/or within CMOs for scale-up.
- Partner with QC, QA, and Analytical/Formulation teams to refine oligonucleotide specifications and control strategies for late-stage clinical trials and commercialization.
- Coordinate regulatory support with vendors and ensure alignment between Avidity RA and CMOs.
- Author and review regulatory submissions, including INDs, amendments, and BLAs.
- Oversee oligonucleotide stability programs and shelf-life extensions in collaboration with QC.
- Ensure compliance with FDA, EMA, ICH, GCP, GMP, and Atrium policies.

Education and Experience Requirements:

- Bachelor’s degree in chemistry, chemical engineering, pharmaceutical science, or related field required; advanced degree (MS/PhD) preferred.
- Minimum 10 years of pharmaceutical industry experience in large-scale oligonucleotide synthesis and purification.
- Proven experience in cross-functional CMC teams



- Expertise in oligonucleotide process development, manufacturing, scale-up, and technology transfer.
- Hands-on experience with Phase 3/commercial readiness, process characterization, PPQ, and regulatory requirements for late-stage manufacturing.
- Strong background in GMP manufacturing and regulatory guidelines (US, EU, JP).
- Prior experience with IND and BLA/NDA filings.
- Knowledge of cGMP, ICH, FDA, and EMA guidelines for oligonucleotides.
- Demonstrated ability to collaborate effectively internally and externally.
- Excellent communication, leadership, and problem-solving skills.
- Ability to manage multiple priorities in a fast-paced environment.

Knowledge, Skills and Abilities:

- Excellent interpersonal skills, ability to work in a matrix environment and develop relationships with key stakeholders.
- Excellent communication and presentation skills to efficiently relay information to staff, project teams, executive leadership and other key stakeholders
- Proven ability to work independently and be self-motivated

Work Environment & Physical Requirements

- This position operates in a professional office and/or laboratory environment.
- Standard office equipment such as computers, phones, photocopiers, filing cabinets, and fax machines are used regularly.
- The role may occasionally require work in controlled laboratory or manufacturing settings, following applicable safety and PPE requirements.
- Noise levels are generally low to moderate, consistent with office or lab environments.
- Some roles may involve occasional travel between company sites or to external meetings, conferences, or events.
- Prolonged periods of sitting at a desk and working on a computer.
- Frequent communication with others, including speaking, hearing, and seeing to exchange accurate information.
- Occasional standing, walking, bending, or reaching may be required.
- Must be able to lift up to 20 pounds occasionally (e.g., office materials or lab supplies).
- Specific roles may require the use of specialized lab equipment, manual dexterity, or fine motor skills.



- Many of the essential functions of this role are captured by the Job Responsibilities, Knowledge, Skills and Abilities, Work Environment and Physical Requirements. The company is committed to providing reasonable accommodations to qualified individuals with disabilities to enable them to perform the essential functions of their jobs, in accordance with applicable federal, state, and local laws.
- Job descriptions are intended to describe the general nature and level of work performed; they are not an exhaustive list of all responsibilities, duties, and skills required. Other duties may be required