**Director, RNA LNP Process Development and Scale-up**

**Location: Catalent Oxford, UK**

**Position Summary:**

The BioModalities Director, Product Development (PD) - Oxford will be responsible for leading the PD team working on RNA and LNP based therapies at our new Oxford, UK site. The Director will be part of a larger PD team which includes process development (upstream/downstream), analytical development, RNA/LNP development, and MS&T. Driving rapid but robust tech transfer of programs will be key. The Director is expected to have a comprehensive understanding of RNA IVT/LNP development and manufacturing to drive solutions for early and late-stage client programs. Collaboration and connection with the full Biologics network including Catalent’s US and European sites will be an opportunity and expectation. Catalent is a rapidly growing, dynamic company and the role offers excellent career opportunities.

**The Role:**

* Leading early phase and late phase process/analytical development for RNA/LNP to ensure speed to IND and commercial launch.
* Leading technical activities for development, process scale-up and tech transfers (internal and external).
* Recruiting and developing a talented staff, ensuring lab and equipment readiness, and establishment of platform process capabilities.
* Supporting tech transfer, batch record preparations and resolution of major and critical deviations led by the MS&T team & participating in innovation efforts to evolve Catalent platforms and evaluate new technologies.
* The Director will manage the RNA LNP process team including conducting performance management for staff, effectively setting expectations, driving execution of project work and developing a talented, diverse and inclusive staff.
* Interact routinely with Business Development and Commercial operations team & managing budget and assure support to deliver revenue goals.
* Work with business development, project management and tech leads to review client proposals, drive project completion and lead discussions with clients.
* Collaborate with the site General Manager (GM) and site leadership colleagues (SLT) to deliver on Catalent business goals.

**The Candidate:**

* PhD in Biochemistry, Chemical Engineering, Biotechnology or related field preferred, with 5 plus years of relevant industry experience in biologics development and manufacturing support.
* M.S./M.A. in Chemistry, Biochemistry, Chemical Engineering, Pharmaceutical Science, Biotechnology, or related field, with 10 years of relevant experience.
* Experience in in RNA/LNP and biologics formulations, drug substance and drug product scale-up and technical transfer with demonstrated knowledge of current industry best practices for biologics.
* Experience in gene therapy, RNA and related drug substance development, tech transfer and processing platforms
* Experience and/or working knowledge of developing analytical methods for RNA and LNP molecules, familiarity with biologics drug product formulation and molecule control strategy including regulatory expectations
* Strong working knowledge of current bioanalytical methods and specifications for RNA LNP and experience/knowledge of QbD in process and product characterization