

## Production Specialist

**Essential duties and responsibilities include, but are not limited to, the following:**

- Operate in the manufacture of biologic drug products for pre-clinical studies and clinical trials (upstream, downstream and fill & finish)
- Writing of IQ (installation qualification)/OQ (operational qualification)/SOPs for equipment and production techniques as needed
- Batch Production Record (BPR) preparation, organization and revision
- Identification and Investigation of product/process deviations (DEV, OOS and CAPA)
- Training of Production personnel

**Basic Qualifications:**

- Degree in Biotechnology, Chemical/Biochemical Engineering, Pharmaceutical Sciences, Biochemistry or related sciences
- At least 2 years of GMP production experience

**Preferred qualifications:**

- Good knowledge of international and national guidelines applicable to production (namely GMP)
- Knowledgeable in downstream techniques with special focus on chromatography
- Cleanroom Class A, B and C manufacturing operations under GMP environment
- Strong interpersonal skills
- Excellent written and verbal communication skills (including technical writing and presentations) with ability to communicate and collaborate effectively with technical and senior management staff
- Experience in process development and Tech Transfer is a plus
- Experience with FDA and INFARMED inspections is a plus

## Quality Assurance Manager

**Quality Assurance Manager will be responsible for implementation, maintenance, and continuous improvement of the Quality Management System, including CAPA, non-conformities, deviations, training, BPR revision, supplier management, etc. This role will ensure compliance with applicable domestic and international standards and regulations.**

**Essential duties and responsibilities include, but are not limited to, the following:**

- Maintain knowledge of all procedures, change to specifications (Process, Training Manuals, Material Specifications, etc.), and regulations related to their area of responsibility
- Leading and managing Change Control records for analytical method revisions, equipment installation and validation
- Providing Quality oversight of Deviations, CAPA and EV records
- Providing Quality oversight on the day to day supply and management of raw materials, packaging and components
- Reviews, edits, completes, and revises completed batch records, Logbooks, and SOPs in accordance with GMP standards
- Supports inspection readiness activities across Quality Control, and site audits and inspections
- Assure compliance with all in-house or external specifications to standards.
- Identify quality issues/discrepancies and effectively resolve discrepancies within the organization
- Identify training needs and take action to ensure company-wide compliance

### **Basic Qualifications:**

- Scientific degree (namely Pharmaceutical Sciences, Pharmaceutical Biotechnology or Biological Engineering)
- At least 3 years of Quality experience

**Preferred qualifications:**

- Relevant biotech or pharmaceutical industry experience with biologics (Cleanroom Class A, B and C Manufacturing operations under GMP environment)
- Previous experience in Quality Systems (Investigations, CAPAs, Change Controls)
- Proficiency in Excel, Word, and Power Point
- Strong interpersonal skills
- Excellent written and verbal communication skills (including technical writing and presentations) with ability to communicate and collaborate effectively with technical and senior management staff
- Experience with FDA and INFARMED inspections is a plus
- Previous experience in QC is a plus

## Finance and Project Manager

**The Finance and Project Manager will be responsible for financial support to the company, submission of applications & management of I&D projects and its financial execution**

**Essential duties and responsibilities include, but are not limited to, the following:**

- Financial controlling
- Management of R&D funded projects
- Application to funding entities (IEFP, P2020, H2020, FCT)

### **Basic Qualifications:**

- Degree in Economics, Finance or related area
- At least 3 years of experience in similar roles

### **Preferred qualifications:**

- Knowledge of financing mechanisms and financial execution rules (namely for FCT, H2020, PT2020, etc)
- Experience in project management
- Excellent office software skills (namely Excel, Primavera)
- Strong interpersonal skills and team work capacity
- Excellent written and verbal communication skills with ability to communicate and collaborate effectively with technical and senior management staff
- Good English language understanding, speaking and writing
- HR related activities experience is a plus
- Dynamic person and enthusiastic about identifying process improvement opportunities