# Samsung Bio JD

**HRCap, Inc.** is the largest Korean-American global executive search firm in the United States. We currently provide HR consulting services to a robust clientele ranging from medium-sized businesses to Global Fortune 500 companies across various industries including Biopharma, ICT (Information & Communication Technology) and Financial Services. We are the primary recruiting agency for Samsung Bio in the U.S.

This is an exciting international expat opportunity within an emerging Global Contract Manufacturing Organization (CMO) backed by a major multinational corporation working with major Global Biopharma companies. Our client is seeking experts in Biopharmaceutical / CMO to manage and lead manufacturing operations in many different areas. Although positions require relocation to outside of US, this could be once in a lifetime opportunity to be part of a world leading organization, where you can utilize the best of your abilities.

- **Upstream Cell Culture Manufacturing – Manager to Director:**
  - Upstream mammalian cell culture manufacturing activities ranging from vial thaw, inoculum, media development, media optimization, cell line development, and stainless steel bioreactor operations
  - Upstream cell culture scale-up, Technology transfer, and Process validation activities

- **Downstream Purification Manufacturing – Manager to Director:**
  - Downstream protein purification activities - Column chromatography, Filtration (UF, DF, TFF), Harvest and recovery
  - QbD (Quality by Design), Scale down studies, Process range studies, PAT, Statistical analysis, Process robustness studies, and Six Sigma

- **MS&T – Manager to Director:**
  - Subject Matter Expert for upstream cell culture/fermentation activities and downstream purification activities ranging from vial thaw, inoculum, media development, media optimization, cell line development, stainless steel bioreactor operations, chromatography, filtration and recovery

- **Fill Finish – Manager to Director:**
  - Aseptic liquid filling of vials, Aseptic Lyophilization filling of vials, and Aseptic preparation of pre-filled syringes

- **Validation – Manager to Director:**
  - Broad set of validation activities including facility validation, equipment validation, computer systems validation, process validation and manufacturing support
  - IQ/OQ/PQ qualification and validation activities

- **Quality Control – Manager to Director:**
  - QC testing, methods development, and characterization including Biochemical, Chromatographic, Electrophoretic, ELISA, Western Blot, PCR, bioassays, and Cell-based assays
  - PAI readiness, BLA/ CMC filings, and FDA/EMEA audits & inspections
  - cGMP compliance and GMP documentation

- **Quality Assurance – Manager to Director:**
  - Regulatory inspections, Inspection readiness activities, and PAI
  - Leadership with QA, Quality System, Quality Compliance, Document Control, Quality Engineering, Validation, and Technical Operations capacities

- cGMP compliance, Global regulatory agencies - FDA, EMEA, MHRA, Health Canada, PMDA, and KFDA

• **Quality and Compliance – Manager to Director:**
- Leadership with R&D QA, Quality system, Quality compliance, Document control, Quality engineering, Validation, and Technical operations capacities
- cGMP compliance, Global regulatory agencies - FDA, EMEA, MHRA, Health Canada, PMDA, and KFDA

• **Automation and Manufacturing Systems – Manager to Director:**
- Key Automation Systems – DeltaV, Syncade, Werum PAS-X, Aegis Discoverant, Maximo, Velquest, and/or SAP systems
- Lean Six Sigma principles
- cGMP compliance within FDA regulated environment

• **Regulatory Affairs – Manager to Director:**
- Site Master Files and other regulatory documents
- Quality systems/ Quality assurance experience, SOPs within FDA/cGMP compliance

• **Auditing and Compliance – Manager to Director:**
- Investigation of assigned incidents/deviations and CAPAs for resolution
- Regulatory inspections, Inspection readiness activities, and PAI
- Experienced with global regulatory agencies - FDA, EMEA, MHRA, Health Canada, PMDA, and KFDA

• **Project Management – Manager to Director:**
- Project on Upstream mammalian cell based cGMP biologics manufacturing, Downstream purification, Analytical methods Technology transfer, and Process validation activities
- Quality assurance and Quality control experiences, cGMP compliance and GMP documentation

• **Business Development – Manager to Director:**
- Locates or proposes potential business deals by contacting potential partners; discovering and exploring opportunities thoughout the industry – contracting, in & out licensing, due diligence

• **Business Development Planning – Manager to Director:**
- Lead, align, and execute multiple projects in CMO perspective. Develop strategy and execute plans to support business expansion and company growth through market intelligence, market research, financial & data analysis

• **Requirements & Qualifications:**
- Relevant undergraduate degree in related field
- 10+ years of relevant experiences in BioPharma (cGMP, CMO)
- Strong Scientific, Quality and Engineering experiences in the manufacturing of recombinant protein and monoclonal antibodies

• **Company will support for Relocation, Housing and Int'l school for your children**