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| **Job Description** | | | |
| **Team /Part** | MSAT/ MT Cell Culture | **Title** | Lead Scientist |
| **Position** | | | |
| Provide strategic and Lead level leadership for the Manufacturing technology part planning, organizing, directing and evaluating all activities of the MSAT to ensure the safety and reliability of client products, and to comply with quality and regulatory requirements. Work closely with manufacturing and quality to ensure process robustness and product quality. Identify potential risks associated with MSAT and lead teams to resolve technical transfer/ deviation/ process monitoring issues. | | | |
| **Responsibilities** | | | |
| **[Tech transfer]**   * Read and request customer technical document * Author/Review/Approve Technical Transfer Documentation and process validation study protocol/report * Final review and align MBR/QC sample SOP with PCS * Review/finalize training material)   **[Deviation & change control]**   * Lead and assign deviation investigation * Set up CAPA/ Effectiveness Check * Author/Review/Approve deviation investigation & change control   **[Process Monitoring]**   * Review/Approve process monitoring/trending data for cell culture process parameter * Review the issue related to process parameter excursion and suggest resolution * Review/Oversee process monitoring result to customer and SBL internal department * Author/Review process monitoring plan * Author/Review/Approve Campaign Summary Report   **[Supplemental Sample]**   * Review and approve Supplemental Sample Technical Memo and review MBR attachment * Review supplemental sample result for lot release and required document for supplemental sample shipping. | | | |
| **Qualification / Requirements** | | | |
| **MT**  Education:   * Bachelor’s degree or advanced degree in Microbiology, Biology, Chemistry or other Science.   Experience:   * At least thirteen years’ experience in FDA related manufacturing facility, process development or technology transfer * Knowledge of Quality Systems/ or Process Operation is preferred * Advanced degree personnel requirements will be modified in commensurate with the degree achieved.   Special Skills or Abilities:   * Excellent oral and written communication skills in English * Excellent organization skills and attention to details * Knowledge of ICH, EU and FDA regulations and cGMPs * Demonstrated ability to handle confidential information * Expertise in using Microsoft Word, Excel, Access, Power Point, JMP, Discoverant | | | |

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