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| **Job Description** | | | |
| **Team /Part** | MSAT/ MT Cell Culture | **Title** | Senior Scientist |
| **Position** | | | |
| The MT Cell Culture Senior Scientist will oversee management of technology transfer activities, planning, organizing, and evaluating all MSAT activities 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. | | | |
| **Responsibilities** | | | |
| **[Tech transfer]**   * Read and request customer technical document * Author and update Technical Transfer Documentation and process validation study protocol/report Final review and align MBR/QC sample SOP with PCS * Review/ finalize training material and perform training   **[Deviation & change control]**   * Author and approve investigation technical report * Set up CAPA/ Effectiveness Check * Author/Review/Approve deviation investigation & change control   **[Process Monitoring]**   * Review/Approve process monitoring/trending for cell culture process parameter * Review issue related to process parameter excursion and suggest resolution * Provide reviewed process monitoring result to customer and SBL internal * If required, open trend excursion * Author and update process monitoring plan and finalize Campaign Summary Report   **[Supplemental Sample]**   * Review and approve Supplemental Sample Technical Memo and review MBR attachment * Review supplemental sample result for lot release, required document for shipping and discuss with customer if required. | | | |
| **Qualification / Requirements** | | | |
| Education:   * Bachelor’s degree or advanced degree in Microbiology, Biology, Chemistry or other Science.   Experience:   * At least eight 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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