The R&D Department in our HIPRA CAMPUS (Aiguaviva, Girona) is seeking a talented and highly motivated **Head of MSAT Team (MSAT)** to establish and lead our new Technology Transfer function.

This role will cover the transfer of both Drug Substance processes (cell culture and purification) and Drug Product processes (formulation and fill-finish). The Head of MSAT will define the strategy, build the team, and ensure the robust and compliant transfer of manufacturing processes from Process Development into GMP Manufacturing for internal programs, and from external customers in a CDMO context — covering early- and late-stage projects. The scope includes both internal pipeline projects and external CDMO collaborations, making this a highly strategic role with strong cross-functional impact.

In addition to leading MSAT activities, the Head of MSAT will act as the technical owner of transferred manufacturing processes across their lifecycle, ensuring deep process understanding, technical robustness, and continuous process verification (CPV). This includes supporting deviation assessment, process performance monitoring, and improvement initiatives to maintain process consistency over time.

The Head of MSAT will also establish governance models, standardized documentation templates (e.g., MSAT Plan, Risk Assessment, MSAT Report), and alignment with Quality Systems and Project Management frameworks to ensure consistency across internal and external projects.

Furthermore, this role will drive the implementation of MSAT best practices — integrating process characterization, validation readiness, and knowledge management frameworks to support lifecycle management and regulatory

compliance. The Head will ensure strong collaboration between Process Development, Manufacturing, Quality, Regulatory Affairs, and Engineering to enable data-driven decision making and QbD deployment throughout the product lifecycle.

Key Responsibilities

- Leadership & Team Building
    - Establish and lead the MSAT group within [Technical Operations or R&D].
    - Recruit, develop, and mentor specialists in Drug Substance and Drug Product transfer.
    - Define best practices, procedures, and KPIs for MSAT activities.
    - Define and maintain governance tools and dashboards for tracking transfer readiness, execution, and closure.
    - Represent the MSAT function in project governance boards and client meetings.
    - The team will lead process risk assessments (FMEA) and criticality analyses during MSAT activities and late-stage programs to ensure process understanding and control strategy definition prior to PPQ. Support the execution of engineering and PPQ batches through technical oversight and training.
    - Coordinate cross-functional risk review meetings and ensure mitigation actions are tracked and implemented.
    - Establish and maintain standard templates and deliverables for transfer activities (e.g., MSAT Plan, Risk Assessment / FMEA, Gap Analysis, Comparability Report, MSAT Report).
    - Define governance models, KPIs, and digital tools to monitor transfer readiness, execution status, and knowledge flow between functions.
    - Drive technical investigations and provide expert support for deviation assessment, root cause analysis, and CAPA definition related to process performance or MSAT activities.

- Support the definition and continuous improvement of the **Process Control Strategy** in collaboration with Process Development, Manufacturing, and QA.
- Maintain **process knowledge repositories and trending tools** (e.g., CPV dashboards) to ensure ongoing process monitoring and lifecycle management.
- Contribute to the **evaluation and implementation of process changes or improvements** under change control, ensuring scientific justification and regulatory alignment.

- Process & Product Transfer Management
  - Oversee planning, execution, and documentation of MSAT activitiess for both Drug Substance (upstream & downstream) and Drug Product (formulation & fill-finish).
  - Ensure successful scale-up, process adaptation, and Process Performance Qualification (PPQ).
  - Guarantee knowledge transfer and training of Manufacturing and Fill-Finish personnel.
  - Lead the generation and review of formal transfer documentation (MSAT Package, Risk and Gap Assessments, Readiness Reports, and MSAT Reports).
  - Oversee engineering and demonstration batches to ensure technical readiness before GMP execution.
  - Ensure traceability and data integrity of all transfer-related documentation.

- Cross-functional Collaboration
  - Act as the main interface between Process Development, GMP Manufacturing, Fill-Finish Operations, QA, Regulatory Affairs, and Engineering.
  - Provide technical leadership and act as a subject-matter expert for internal development projects and CDMO client programs.
  - Support troubleshooting and continuous improvement in commercial manufacturing and formulation.

- Partner closely with Project Management to define scope, timelines, and deliverables for each transfer.
- Act as the primary technical liaison with client technical teams for CDMO transfers, leading technical kick-off and progress meetings.
- Collaborate with QA and Regulatory Affairs to provide technical input for CMC and GMP compliance, while ensuring ownership of quality systems remains with QA.
- Coordinate with Analytical Development and QC to ensure analytical method readiness for MSAT activities and validation stages.
- Collaborate with QA and Manufacturing to evaluate **process deviations, atypical trends, and OOS/OOT events**, ensuring science-based assessments and CAPA effectiveness.
- Partner with Engineering and Validation to define **qualification and validation strategies** for new equipment or single-use systems impacting process performance.

- Compliance & Regulatory
    - Ensure all transfer activities comply with GMP and global regulatory requirements.
    - Provide input to CMC regulatory documentation for both Drug Substance and Drug Product.
    - Support audits and regulatory inspections as the transfer subject-matter expert.
    - Participate in client audits and technical due diligence related to MSAT activities.
    - Support change control, deviation management, and CAPA processes associated with transfer execution.
    - Contribute to the preparation and review of **Process Validation Master Plans (PVMP)** and **PPQ protocols/reports**.
    - Support **continuous process verification (CPV)** activities, trending, and annual product reviews in alignment with GMP lifecycle expectations.

- Provide **scientific justification for process and analytical changes** in regulatory submissions (e.g., CMC updates, comparability sections).

Qualifications & Experience

- PhD in Biotechnology, Biochemistry, Pharmaceutical Sciences, Chemical Engineering, or related field.
- Minimum **10 years of experience in the biopharmaceutical industry, with at least 5 years in MSAT, MS&T,** late-stage Process Development, or Formulation Development.
- Solid experience in Drug Substance MSAT activities (cell culture and purification) is required. Additional experience in Drug Product (formulation and fill-finish) will be considered a strong asset.
- Proven experience in process scale-up, MSAT activities, and validation under GMP.
- Familiarity with CMC regulatory requirements and process validation guidelines.
- Experience in both internal development projects and CDMO collaborations is highly desirable.
- Excellent leadership, communication, and stakeholder management skills.
- Fluent in English; additional languages are an asset.
- Experience in establishing new functions or teams within MSAT or MSAT organizations is a strong plus.

If you are interested, please apply directly with this link:

https://career2.successfactors.eu/sfcareer/jobreqcareer?jobId=6890&company=laboratoriP