tetrascience

Playbook

Accelerate Bioprocess Development and Optimization with Data-Driven Insights and AI-Enabled Tools

The biopharmaceutical industry is evolving rapidly, with biologics requiring more **sophisticated and precise development** than traditional small molecules. A major challenge in bioprocess development is accurately predicting and identifying the critical process parameters (CPPs) essential for ensuring the stability, efficacy, and safety of biologics. The inherent complexity of bioprocessing, combined with **fragmented and siloed data,** makes it difficult for scientists to **optimize these critical parameters efficiently,** which are essential for driving faster development and product quality.

Traditional approaches to processes such as **clone selection, media optimization, purification,** and **analytical** methods are often **labor-intensive, expensive, and slow.** Scientists must manually collect, analyze, and interpret data from scattered instruments, systems, and formats, wasting valuable time and resources. The lack of **actionable intelligence** slows development timelines and limits an organization's ability to make **real-time, data-driven decisions.**

The Why: Current Industry Challenges

Companies face several challenges in optimizing bioprocessing:

- **Low Scientific Productivity**
  Scientists spend significant time manually searching for and gathering data, detracting from critical analysis and decision-making activities. For example, at a top 10 pharmaceutical company we partnered with, scientists spent an estimated **25 to 100 hours per week** manually recording chromatography results into electronic lab notebooks (ELNs), significantly slowing workflow efficiency. Similarly, at Alexion, the purification group spent over **1,000 hours per year** manually merging chromatograms and preparing technical reports, with insights often taking up to **a week to gather,** causing further delays in downstream processes.
- **High Costs from Excessive Complexity**
  Due to the nature of working with living cells, bioprocess development is **inherently complex and expensive.** Extensive iterative experimentation is required to identify optimal conditions for processes such as **cell culture media formulation,** which can take up to **2 years.** Scientists at a large pharmaceutical company manually tested media compositions across **80 different conditions** for **80 to 150 components,** resulting in **significant time and resource expenditure.**
- **Data Fragmentation, Incompatibility, and Lack of AI Readiness**
  Scientific data from instruments, analysis software, and informatics solutions (e.g., ELN and LIMS) is often **scattered across silos** and locked in incompatible formats. At a top 10 biopharma company we worked with, each process development study generated over **200 chromatograms** from fast protein liquid chromatography (FPLC) and high-performance liquid chromatography (HPLC) in different proprietary formats. These process and analytical parameters had to be manually aggregated in Excel for analysis, **hindering the development of mechanistic models** that could accelerate process development and improve outcomes.

The What: Driving Scientific Outcomes with Predictive Tools and Dashboards

TetraScience addresses these challenges by transforming process development through the **Tetra Scientific Data and AI Cloud™.** The platform centralizes and harmonizes scientific data into a **vendor-agnostic format,** making it available through **Tetra Analytics and Scientific AI Apps** that support predictive modeling and real-time visualization. These solutions empower organizations to make more **informed, data-driven decisions,** enabling them to reach **milestones faster** while significantly **enhancing lab productivity.**

Some of the Tetra Analytics and Scientific AI apps we've built for the bioprocess development and optimization workflow include **Lead Clone Selection Assistant, *In Silico* Media Optimizer, Purification Insights, Chromatography Insights,** and Cell Culture Insights as shown in Figure 1.

1. *Lead Clone Selection Assistant:* This AI-powered tool uses predictive modeling to help scientists **identify the most promising lead clones** with the highest titer, viability, and stability. This approach reduces the traditional clone selection process from **5 months to just 1 month,** improving success rates and overall efficiency. This **80% reduction in time** also allows scientists to focus on other high-value activities. Learn more >>
2. *In Silico Media Optimizer:* This app leverages AI to **predict the best formulations** for a given cell line, eliminating the need to manually test 80 to 150 components. As a result, it frees up time for value-added activities and can **reduce wet lab experiments by up to 88%,** significantly accelerating this phase of the workflow. Learn more >>
3. *Purification Insights:* By integrating purification process and analytical data into a single interactive visualization dashboard, process engineers and scientists can identify the **purification parameters** for achieving the **highest product titer and quality.** Automating this process allowed one group of 15 scientists to save **$375,000 per year in labor costs.** Scaling this solution across teams could result in **millions of dollars in savings** while increasing the probability of success. Learn more >>
4. *Chromatography Insights:* This dashboard consolidates data from multiple chromatography data systems (CDSs) across groups and sites, providing a unified view of performance trending. With this real-time view, scientists and technicians can monitor trends in method, column, and instrument performance, **catching deviations early and preventing out-of-spec events.** Manually compiling this data would **take days or weeks** and only provide a static snapshot of the data. Learn more >>
5. *Cell Culture Insights:* The Cell Culture Insights Dashboard seamlessly consolidates online bioreactor process data with offline and at-line analytics like titer and metabolites data, delivering real-time insights to optimize upstream process development. With automated data integration and monitoring, scientists can make **faster, data-driven adjustments, improving culture performance** and accelerating development timelines.

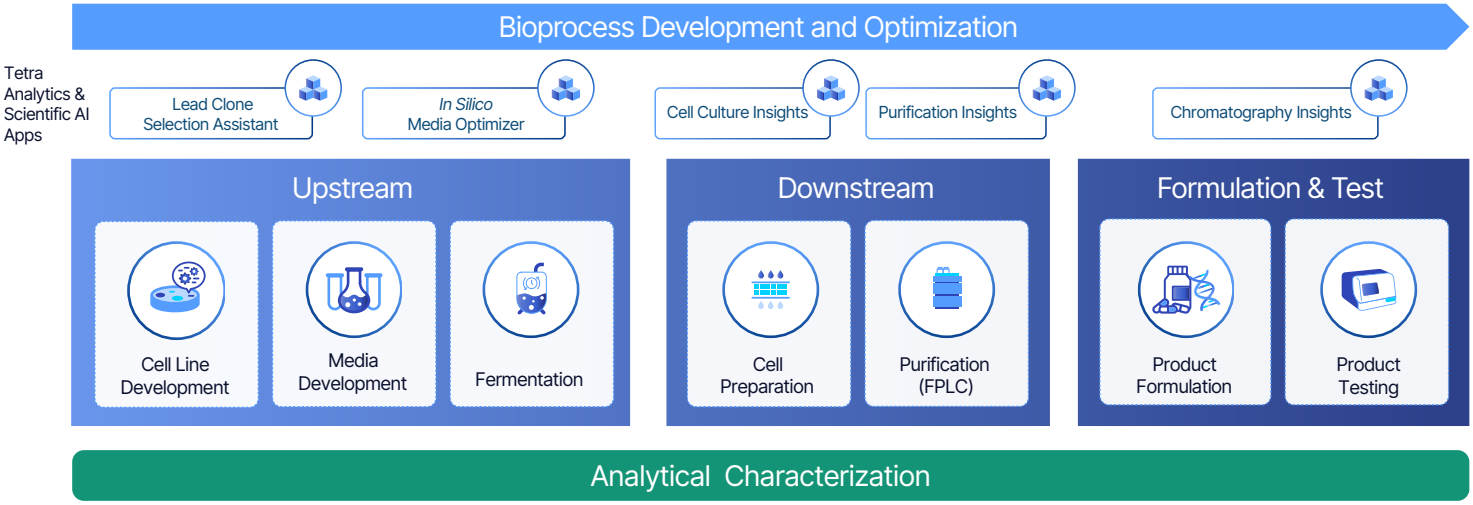

Figure 1.
Tetra Analytics and Scientific AI Apps for bioprocess development and optimization

The How: Engineering Advanced Analytics and AI-Native Data

The critical obstacle to developing AI-driven scientific use cases is the **quality and accessibility** of the underlying data. Scientific data needs to be large-scale, liquid, purpose-engineered, and compliant to fuel advanced analytics or AI/ML models. However, scientific data is often complex, multimodal, and unstructured, requiring deep taxonomies and ontologies to contextualize it effectively.

TetraScience has developed a **science-led approach** that transforms raw scientific data into **large-scale, liquid, well-engineered datasets optimized for AI and analytics** (Figure 2). Today, over **half of the world's top 25 biopharmaceutical companies** rely on TetraScience to make this possible.

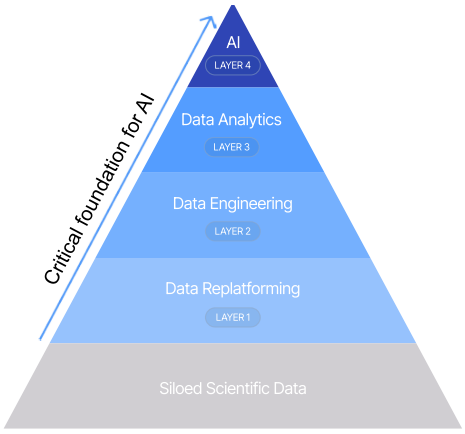

Figure 2.
Scientific data journey with Tetra Scientific Data and AI Cloud

Layer	Capabilities
1. Data Replatforming	Automatically collect data from instruments, informatics applications (e.g., ELN or LIMS), and local drives through **validated, industrialized integrations** and centralize them in the cloud. **Ready-made connectors** available to automatically **push** the final results from instruments or analysis software **into ELNs and LIMSs systems** for recordkeeping.
2. Data Engineering	Data is contextualized with relevant metadata and transformed into an open, vendor-agnostic format using a **bioprocess data model** developed through best practices from multiple customers (Figure 3). The result is AI-native **Tetra Data,** which is accessible to downstream applications like Databricks and Snowflake via API and SQL. These large-scale datasets are harmonized with scientific schemas, taxonomies, and ontologies, enabling advanced analytics and AI.
3. Data Analytics and Visualization	Scientists and data scientists can leverage Tetra Data in analytics applications, dashboards, and visualization tools. The **Tetra Data and AI Workspace** co-locates scientific data with common partner applications (e.g., FlowJo and Skyline) in the cloud, streamlining data analysis. Apps like **Chromatography Insights** and **Purification Insights** provide real-time visualization for easy decision-making.
4. AI and Predictive Modeling	**TetraScience's AI/ML models** streamline the optimization process by reducing iterations needed to achieve optimal conditions, resulting in faster and more cost-effective outcomes. These models act as **co-pilots,** providing starting points that can be adapted with your data. Apps like the **Lead Clone Selection Assistant** and ***In Silico* Media Optimizer** use advanced *in silico* models to predict the best clone and formulations for a given cell line. Customers can also **bring their own custom apps and models** into the platform.

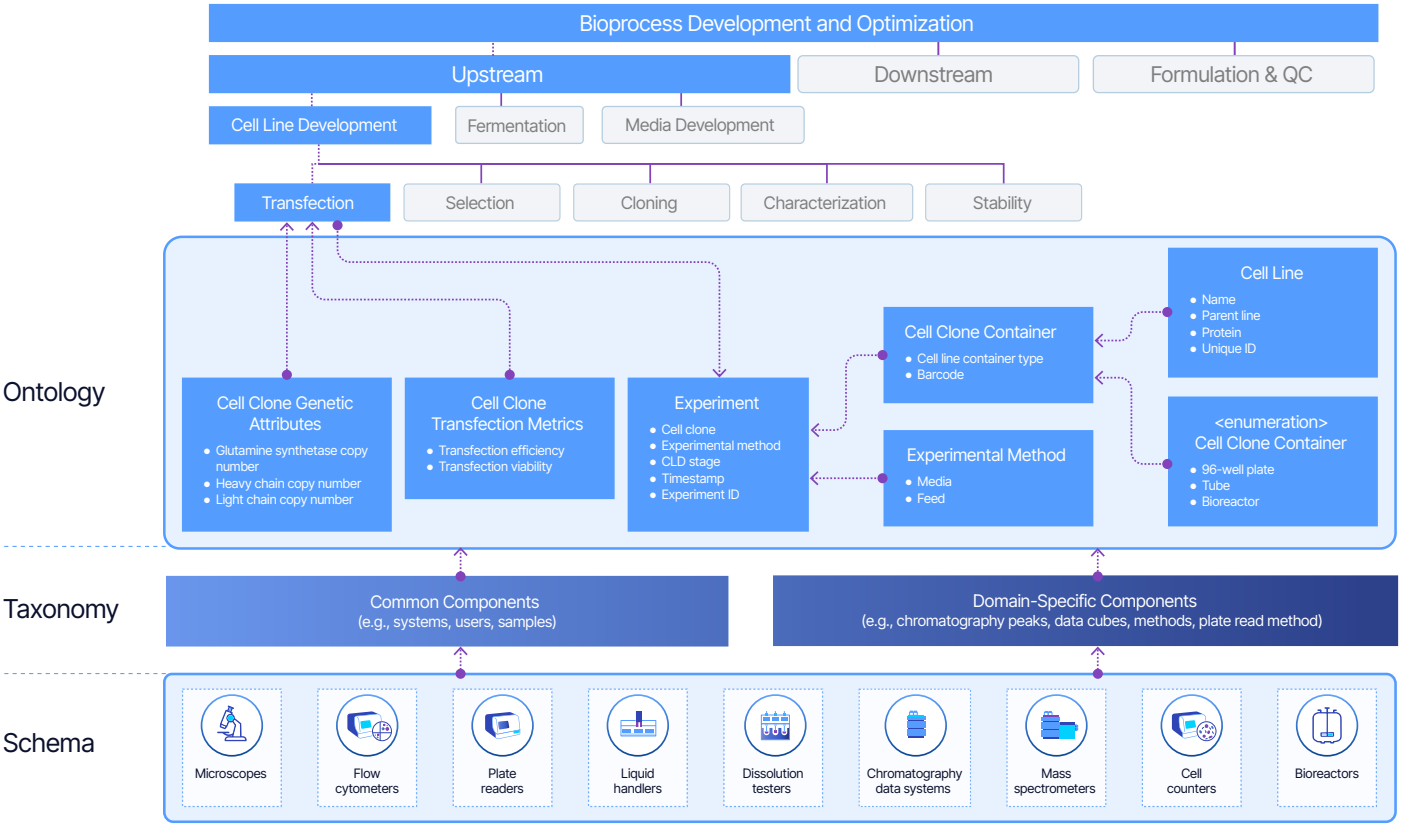

Figure 3.
Bioprocess data model highlighting one stage of cell line development

Conclusion: Revolutionizing Bioprocess Development

TetraScience is revolutionizing bioprocess development with its **end-to-end solution,** powered by the **Tetra Scientific Data and AI Cloud.** This solution accelerates milestones, enhances productivity, and makes cutting-edge optimization processes accessible and cost-effective. By leveraging TetraScience, organizations can achieve optimal conditions faster and at lower costs, ultimately enabling the creation of better, safer products for patients. Embrace the future of bioprocessing with TetraScience.

Next steps

Contact us to discuss your scientific use case