tetrascience

Accelerating bioprocessing purification at Alexion

CASE STUDY

Results*: The Tetra Scientific Data Cloud™ accelerated and enhanced bioprocessing purification at Alexion, AstraZeneca Rare Disease

- Decreased time-to-insight from **1 week to 1 day** for a fast protein liquid chromatography (FPLC) workflow
- Allows Alexion to reallocate **~5000 hours per year**
- Fully automated data migrations, improving transfer times from **2 hours to 10 minutes**, saving Alexion **80 hours per month**
- Reduced turnaround time for chromatogram merging and overlay from **1 day to 5 minutes**, saving Alexion **340 hours per month**
- **Enables increased FPLC throughput**
- Created the lab's first **centralized, searchable, cloud data store**
- **Eliminated operating costs** associated with retrieving difficult-to-find data

Challenge: Bringing automation and advanced analytics to bioprocessing purification

Alexion is a leading biopharmaceutical company with a robust pipeline dedicated to biologics for rare disease. To better serve their unique patient population, Alexion understood that speed and efficiency are imperative, as many people with rare diseases suffer from debilitating and progressive conditions with no treatment. This gives every daily, weekly, and monthly deadline at Alexion a profound meaning, as speed to market can directly impact quality of life (QoL) for patients with rare diseases.

To deliver these life-changing therapies faster, Alexion was looking to streamline bioprocessing purification and establish a novel workflow for their downstream process development labs responsible for pre-clinical research, investigational new drug (IND)-enabling, and postmarketing commitment studies.

To achieve their desired goals, the development lab needed a more effective way to evaluate and optimize chromatography strategies. To accomplish this, they needed to eliminate manual data transcription errors, improve the efficiency of data transfers, data merging, and chromatography overlays, as well as minimize data retrieval times and the risks of data loss.

*Time-saving results are estimates.

ALEXION®
AstraZeneca Rare Disease

Background

Alexion, AstraZeneca Rare Disease, was searching for a technology partner to help streamline a bioprocessing purification workflow to accelerate their goals of:

- Advancing analytics capabilities
- Improving and accelerating bioprocessing workflows
- Transforming the lives of patients with rare diseases

Customer Profile

Alexion, AstraZeneca Rare Disease is one of the top rare disease biopharmaceutical companies in the world. They currently have 5 approved medicines for 7 rare diseases distributed in 50 countries.

- 25+ years' experience developing therapies for rare disease
- Robust, advanced-stage pipeline for multiple indications
- 3000+ people employed
- $6 billion in annual revenue

Desired results

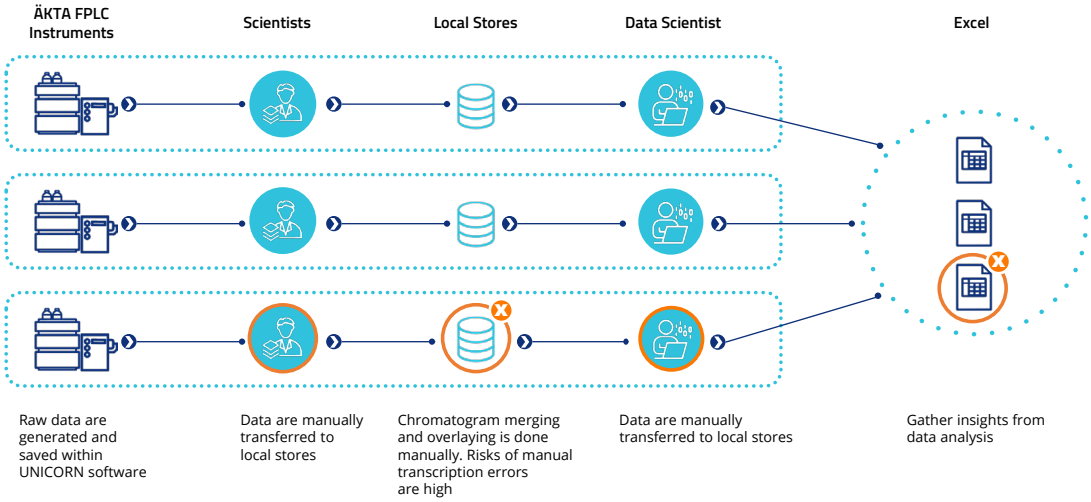
- Improved analytics capabilities
- Reduced manual data processes
- Increased data integrity
- Reduced errors
- Increased throughput in bioprocessing labs

Corporate Headquarters | 177 Huntington Avenue, Suite 1703, Boston, MA 02115

Atlanta | 8000 Avalon Boulevard Suite 247, Alpharetta, GA 30009

Alexion's existing solution involved manually transferring data files between their Cytiva UNICORN controlled ÄKTA instruments and their analysts' PCs. This process was extremely time consuming and prone to errors. Furthermore, with data being saved on multiple, independent data stores and no metadata being attributed, data retrieval became a major resource drain and the risk of data loss a real concern. And since research work, IND-filing, and pipeline advancement depend on these data, ameliorating these issues was a top priority.

FPLC workflow before TetraScience



Once chromatography results were generated, data were manually migrated for merging, overlaying, and comparing (manually) in either native chromatography software or Excel. Again, these processes were tedious, time consuming, and error prone. Alexion knew they had to create a scientific data workflow where data were easily accessible and prepared for analysis if they were going to accelerate their bioprocessing purification throughput.

If successful, their lab would help create better products, faster, for patients with no available treatment. However, if unsuccessful, inefficient data workflows and data errors would result in slow scientific progress. This would mean patients have to wait, potentially leading to increases in disease burden and loss of trust.

Trust in the rare disease space

For a producer of rare-disease products, lapses in healthcare professional and patient trust pose significant, material risk.

Rare disease treaters and patients maintain closer relationships with pharma companies compared with average consumers due to their tight-knit, well-informed population. [1-4]

From a cost analysis perspective, data quality and integrity are directly tied to company success. Advancing poor candidates into early-stage trials is extremely costly. Data from a 2020 paper suggests pharmaceutical companies spend as much as 75% of their drug development budget on failed products[5]. Furthermore, manual processes cannot scale, meaning that any increase in throughput would require significant investment and increases in costly headcount, unless their existing processes and equipment were made more efficient.

In short:

- Identifying optimal FPLC strategies was key to improving time-to-market
- Manual data transfers and data preparation were tedious, time consuming, and error prone
- Local data storage without metadata attribution made preserving, retrieving, and reusing data difficult
- Data weren't accessible and ready for analysis, quickly
- Any error carried through the workflow puts patients and the business at risk

Corporate Headquarters | 177 Huntington Avenue, Suite 1703, Boston, MA 02115

Atlanta | 8000 Avalon Boulevard Suite 247, Alpharetta, GA 30009

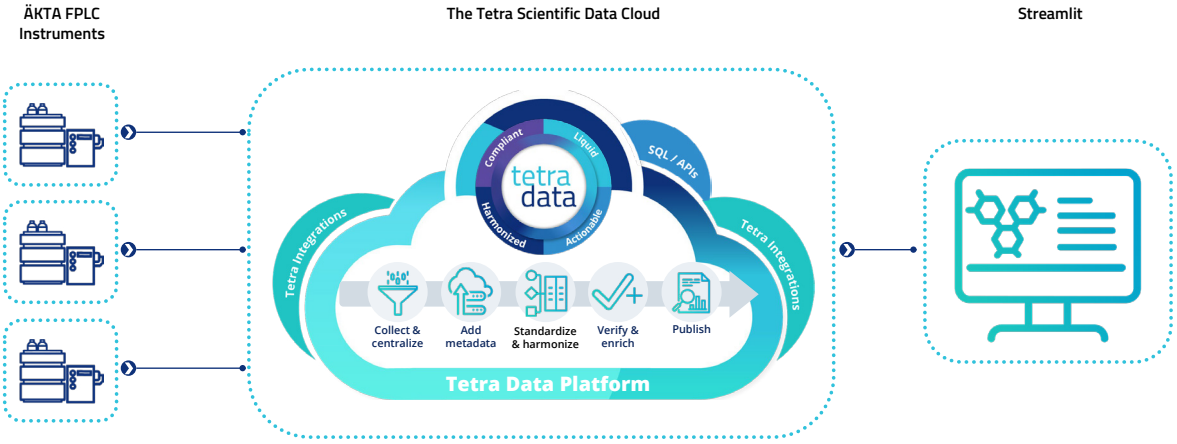
tetrascience

tetrascience.com

Solution: The Tetra Scientific Data Cloud

Partnering with TetraScience helped Alexion develop an automated, FAIR-data powered (**f**indable, **a**ccessible, **i**nteroperable, **r**eusable), analytics-enabled, FPLC workflow that significantly improves time-to-insight and throughput for their downstream laboratory.

FPLC workflow after TetraScience



Raw data are generated and uploaded to UNICORN

The Tetra Scientific Data Cloud automatically ingests, standardizes, and enriches FPLC data

The Tetra Scientific Data Cloud automatically exports FPLC data to the Streamlit data application

Integrate and automate FPLC workflows

The Tetra Scientific Data Cloud integrates with every component of the bioprocessing data workflow, from UNICORN to Alexion's analytics application in Streamlit. The Tetra Scientific Data Cloud allows users to automate their workflows, providing access to data within their analytics application 10 minutes after generation, completely eliminating the need for manual data transfers.

Centralize and find data

The Tetra Scientific Data Cloud provides Alexion with compliant and secure, cloud-based storage for all their downstream lab FPLC data. It automatically enriches FPLC data with metadata. Users can now easily search (using UI, SQL, or REST API interfaces) for their FPLC data using intuitive keywords like: date, method parameters, analyte, operator, column chemistry, system, etc., in an accessible single source of truth. Users no longer need to spend hours retrieving data through email. Additionally, the risk of data "walking out the door" when team members switch departments or leave the company has been eliminated. This means fewer repeated experiments and more durable scientific context.

Engineer data for advanced analytics

Data ingested by the Tetra Scientific Data Cloud is automatically engineered into clean, standardized, and metadata-enriched Tetra Data. Tetra Data can seamlessly flow into the Streamlit analytics application with no manual processing. As a result, users can merge and overlay chromatograms in minutes instead of an entire day.

Improve time-to-insight

The Tetra Scientific Data Cloud helps scientists and data scientists drastically reduce time spent on manual data transfers and processing for their FPLC workflow. By integrating instruments and analytics, automating data migration, centralizing storage, and standardizing and enriching FPLC data, Alexion has reduced time-to-insight from a week to a single day. This enables their downstream team to run more experiments per week, supercharging their throughput, and accelerating time-to-market for the company as a whole.

Corporate Headquarters | 177 Huntington Avenue, Suite 1703, Boston, MA 02115

Atlanta | 8000 Avalon Boulevard Suite 247, Alpharetta, GA 30009

tetrascience

tetrascience.com

Significance: Accelerating time-to-market for rare-disease therapies

Outcome	Significance*
Eliminated manual data transfers	• Automated data workflows between UNICORN and the Streamlit analytics application completely eliminate manual data transfers, providing data in **10 minutes instead of 2 hours**, saving Alexion **80 hours per month**, while substantially reducing the risk of data errors
Centralized data storage in the cloud	• Alexion now has a permanent, cloud-enabled single-source-of-truth for their **FPLC data that is centralized, searchable, and accessible**. This eliminates the operating costs of data loss, data retrieval, and poor data integrity
Enriched and engineered data	• Automated metadata attribution makes **data easy to find**. No more tedious data retrievals or repeated experiments due to lost data • Automated data engineering **standardizes and transforms data** so it can be consumed by analytics and visualization software, eliminating the need for manual data processing • Combined, these produce **future-proofed, FAIR, FPLC data**
Supercharged data science	• The combination of Tetra Data and the Streamlit analytics application reduces turnaround time for chromatogram merging and overlay from **1 day to 5 minutes**, saving Alexion **340 hours per month** • Data scientists can now **compare libraries of chromatograms** easily via API
Improved workflow performance	• The FAIR-data-powered, cloud-enabled workflow improves time-to-insight from **1 week to 1 day** • The Tetra Scientific Data Cloud **provides the tools for rapid throughput acceleration** • Automated data transfers and processing paired with cloud storage greatly increases **data integrity** and reduces the risk of errors

What's next?

By combining TetraScience data and platform technology with a modern analytics application Alexion can derive unprecedented insights from their FPLC data workflows. These insights can help drive research, optimize processes, and guide business decisions.

Furthermore, with their newfound efficiency, Alexion can run more experiments, ensure data integrity, and they can reallocate over 5000 hours per year toward their core mission—bringing life-changing therapies to patients with rare diseases.

To learn more about how TetraScience can accelerate bioprocessing purification, go to tetrascience.com/solutions/bioprocessing

*Time-saving results are estimates.

Reference:

[1] Mikami K, Sturdy S. Patient organization involvement and the challenge of securing access to treatments for rare diseases: report of a policy engagement workshop. Res Involv Engagem. 2017.

[2] Dunkle M, Pines W, Saltonstall PL. Advocacy groups and their role in rare diseases research. Adv Exp Med Biol. 2010.

[3] Stoller JK. The challenge of rare diseases. Chest. 2018.

[4] Huml RA, Dawson J, Bailey M, Nakas N, Williams J, Kolochavina M, Huml JR. Accelerating rare disease drug development: lessons learned from muscular dystrophy patient advocacy. Ther Innov Regul Sci. 2021.

[5] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*. 2020.

Corporate Headquarters | 177 Huntington Avenue, Suite 1703, Boston, MA 02115

Atlanta | 8000 Avalon Boulevard Suite 247, Alpharetta, GA 30009

tetrascience

tetrascience.com