CASE STUDY

Integrated Biologics

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Enabling high throughput drug discovery at Amgen with Thermo Fisher Platform for Science software

Abstract

Every day scientists are working to discover and develop new therapies and treatments to change the lives of patients suffering from serious and debilitating illnesses. Amgen Inc. has made it a priority to unlock the potential of biology to discover, develop, manufacture, and deliver innovative therapeutics to patients.

Amgen has partnered with Thermo Fisher Scientific to develop a comprehensive, highly integrated, biologics laboratory information management system (LIMS), High Throughput Biologics (HTB) to accelerate generation of breakthrough large molecule therapeutics to transform the lives of patients.

Introduction

With the increasing number of large molecules therapeutics in the pipeline, biopharmaceutical companies needed to change the way they discover and develop new treatments. Large molecule discovery and development is a complex series of interwoven cycles that span many teams within a research and development organization. This type of complex process, combined with a substantial increase in the throughput of large molecule production processes and increasing molecular complexity, the amount of data produced and analyzed has scaled at a very rapid pace, necessitating much improved LIMS.

Amgen pioneered the shift to large molecules and was on the forefront of addressing the complexity of large molecule discovery by making a commitment to informatics, as they believe that informatics is a strategic enabler and driver of innovation and business capabilities for drug discovery. Amgen has implemented Thermo Fisher's informatics system, Thermo Fisher™ Platform for Science™ software, as the underlying data management system to support High Throughput Biologics (HTB) spanning across seven Amgen locations and many external collaborator facilities. The implementation of Platform for Science software, required Amgen to take a critical look into its internal practices and develop, align, and implement best practices for all Amgen HTB locations.

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Results

The first step Amgen took in harmonizing an informatics platform was to take a detailed look into its internal practices and define biologics data management challenges. The HTB team at Amgen found it challenging to track down compound lineages due to differences in nomenclature and complex connections, to send store and collaborate on data across the seven Biologics sites, and provide a mechanism for contract organizations to directly submit data to Amgen. This review process allowed the HTB team to identify their requirements for an informatics platform. The HTB team determined that a platform that could provide sample and container registration, complex lineage tracking, definable entity transformations, flexible data capture, easy integrations with lab instruments and software, and allow for high throughput processing was needed. After a thorough review and a proof of concept implementation, Amgen selected Platform for Science software as its informatics platform.

Establishing entities and experiments to connect data

The implementation of Platform for Science software required the HTB team to look at their processes and determine areas where they could consolidate and gain efficiencies to establish a best-in-class system alongside Thermo Fisher. The HTB team first reviewed how they described entities and how they would connect those entities to experiments to ensure that they would have complete traceability. HTB system uses three data types to describe entities, sample (represents a concept, e.g. a sequence of DNA), substance (the actual material, e.g. the DNA strand), and container (storage, e.g. microtiter plates, tubes). The team determined that to connect these three entity types that it would be done via an experiment where the team could define a transformation or analysis of a molecule, establish lineages, and connect data with the transformations, entities, and processes.

This has allowed the HTB team to know exactly where a substance came from and how it is connected to other substances, what transformations or analyses were performed on the substance, along with any data that was captured on the substance. As the HTB samples, substances, and experiments are highly interconnected (see fig. 1.), the ability to easily determine the lifecycle of a substance has provided HTB with a streamlined process and the ability to make informed decisions quickly.

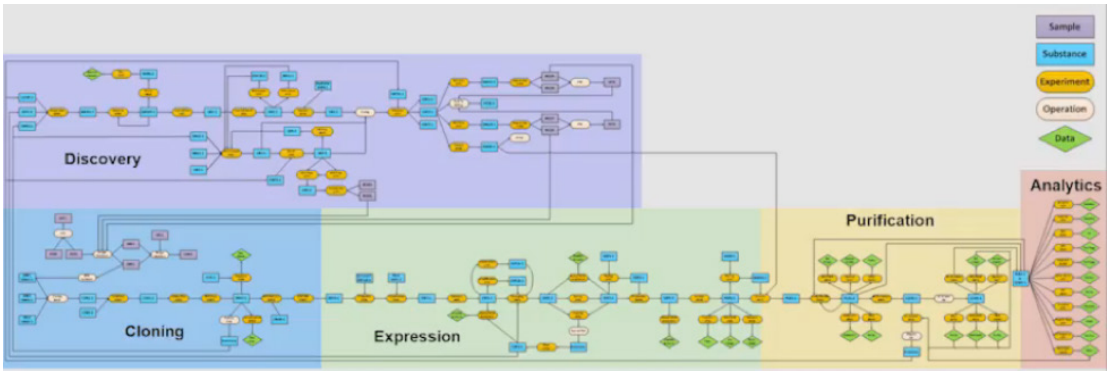

fig.1. HTB Samples, Substances, and Experiments are Highly Interconnected, Walker, Kenneth. Launch2017 Keynote Presentation: Amgen. YouTube, Thermo Fisher Scientific, 4 Nov. 2017, www.youtube.com/watch?v=zJLS1fG8zeg.

Instrumentation integration to implement automation and data capture

Within HTB, the team was supporting over different 60 instrument types (see fig.2.) with each instrument implementing its own proprietary data format. This created a challenge for the HTB team, as manually uploading the proprietary data files was not useful, and many scientists did not have access to the software package to review and analyze the data on their PC. To address this challenge, the HTB team decided to implement universal data formats. The team used two main data formats, tabular and coordinate data, with the option to also use images and reports for instruments that require that format. By implementing universal data formats, scientists within HTB always have access to the data and can perform whatever manipulations or analysis that is needed. This has streamlined processes and implemented best practices across the lab driving efficiency.

During the implementation of Platform for Science software, HTB also reviewed and consolidated instrumentation within their team. The team reviewed instruments that were performing similar types of analyses and agreed upon one common instrument rather than multiple different instruments for the same type of analysis. This resulted in a reduction of the amount of data parsers needed and also helped with group interactions, as the team could now share scripts. To reduce the burden on scientists of having to manually upload data and to eliminate transcription errors, HTB, with Thermo Fisher, also implemented automated data transfers from lab instruments into Platform for Science software.

Controlled vocabulary and integrated workflow management to drive communication

Establishing a controlled nomenclature was very important to the HTB team as the molecule types can be very complex. Amgen set out to define very controlled nomenclature to enhance communication, drive data consistency, and enable powerful query tools. As a result, Amgen implemented a very defined and controlled nomenclature for molecular classification, annotations, and targets identification.

Once the controlled nomenclature was established, the team configured integrated workflows within Platform for Science software to provide workflow management to lab managers. At the top layer of the system, the team set up a request management system, where the scientist can define what types of experiments will occur in that request, and Platform for Science software then monitors the information and materials throughout the workflow. After the workflow is complete, Platform for Science software reports back to lab managers on the process. This provides HTB lab managers with the ability to see what is actually occurring in the lab, capture metrics to identify bottlenecks, and provides the opportunity to identify inefficiencies and implement process improvements.

fig.2. HTB Instrument Integration is Central to Automation and Data Capture, Walker, Kenneth. Launch2017 Keynote Presentation: Amgen. YouTube, Thermo Fisher Scientific, 4 Nov. 2017, www.youtube.com/watch?v=zJLS1fG8zeg.

Connecting the HTB ecosystem

To create a connected ecosystem within the HTB environment, HTB team integrated 10 other software systems and instruments to Platform for Science software (see fig.3.). These integrations allow HTB to monitor molecule identities, protein engineering, inventory, external collaborations, activity assays, and capture raw data from laboratory instruments. The ability to maintain this data in one location and allow different systems to communicate seamlessly with Platform for Science software provides HTB with a more streamlined processes and shortened turnaround times on deliverables.

Return on investment

HTB has created an end-to-end Biologics informatics capability to improve operational capacity. The system was able to simplify the technology footprint and improve integrations by retiring several legacy hardware and software systems and thus saving $0.5M annually. The effort also targets to achieve the projected efficiency improvements as soft savings of $3M annually by enabling increased throughput, reducing errors through elimination of manual data processing, thus reducing material cost.

Less tangible, but of critical value to include in return on investment, is HTB enabling Researchers to readily access well-defined and integrated Biologics data from any site at any time to support advancing the discovery pipeline. In addition, the implementation of this system enables advanced queries on large molecule data, which can be utilized directly by research scientist as well as Artifical Intelligence (AI) systems to aid in the development of the next generation of breakthrough large molecule therapeutics.

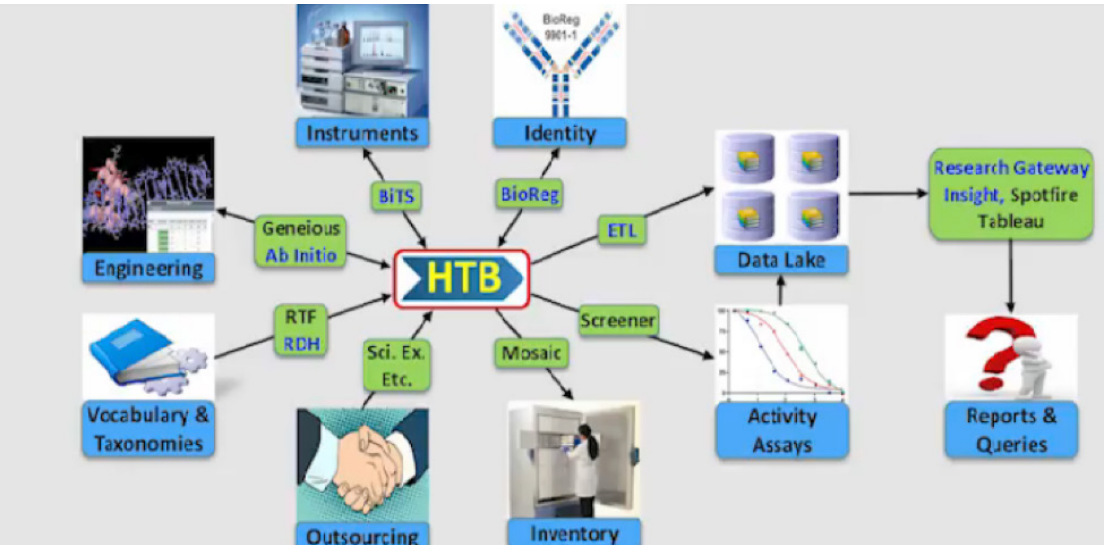

fig.3. HTB is Highly Integrated with Many Informatics Systems, Walker, Kenneth. Launch2017 Keynote Presentation: Amgen. YouTube, Thermo Fisher Scientific, 4 Nov. 2017, www.youtube.com/watch?v=zJLS1fG8zeg.

Conclusion

Enabling the next generation of breakthrough therapeutics

Together, Amgen and Thermo Fisher, have collaborated to implement a flexible and extensible laboratory informatics platform to drive High Throughput Biologics Discovery. The implementation of the Platform for Science has provided laboratory management the ability to completely track the discovery process of new molecules, protecting Amgen's intellectual property and streamlining the path to clinical filing. With complete tracking of a molecule's lifecycle and automated data capture, the HTB team can be certain that their data is of the highest integrity. In addition, the HTB team has been able to discover and reduce bottlenecks in their workflow by implementing best practices, making their team and processes more efficient.

While this implementation enables Amgen to get new therapeutics to patients more quickly, Amgen sees this implementation as enabling the next generation of breakthrough therapeutics. The ability to mine a well-defined and organized data lake facilitates the ability to use AI to derive insights. The use of AI will accelerate the Biologics team's ability to find new targets and develop new human therapeutics to treat patients with serious and debilitating illnesses.

Enabling and implementing best practices within HTB supports Thermo Fisher's mission to enable their customers to make the world healthier, cleaner and safer, and Amgen's mission to strive to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives.

References

1. Walker, Kenneth. Launch2017 Keynote Presentation: Amgen. YouTube, Thermo Fisher Scientific, 4 Nov. 2017, www.youtube.com/watch?v=zJLS1fG8zeg.

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