

Catalent

Customer Background

Catalent, a contract development manufacturing organization (CDMO), is the global leader in enabling pharma, biotech, and consumer

Company Profile

Name Catalent Industry Life Sciences Headquarters Somerset, NJ USA Website www.catalent.com

health partners to optimize product development, launch, and full life-cycle supply for patients around the world. Its flexible manufacturing platforms at over 50 global sites supply more than 70 billion doses of nearly 7,000 products to over 1,000 customers annually.

Process development (PD) laboratories present a unique challenge as the equipment can be highly varied and they often have poorly supported data connectors. Commercial laboratory data platforms offering pre-built connectors to lab equipment were too cost prohibitive and did not align with the company's unified namespace (UNS) strategy. On the other hand, modeling thousands of machine tags for all the PD assets using IIoT platforms proved inefficient and time consuming. In 2023, Catalent turned to HighByte to help scale this process.

Chris and the team at Catalent are thought leaders in applying the Unified Namespace concept to pharmaceutical manufacturing. Even in a challenging, highly regulated industry, they have been able to put a digital foundation in place that will allow them to scale, improve operations, and quickly accomplish new digitalization projects with limited resources. **??**

CHALLENGE

- High throughput labs with 48+ bioreactor platforms, each with hundreds of tags stored locally with no regular backup.
- At-line equipment including cell counters and metabolite analyzers required expensive third-party connectors to extract data.

APPROACH

- Leverage HighByte Intelligence Hub to create a bioreactor data model that can be deployed to any number of sites in about an hour.
- Use HighByte SQL connector to extract data from at-line equipment without the need for off-the-shelf connectors.
- Use HighByte Intelligence Hub to curate, orchestrate, and model data at the edge before publishing into HiveMQ.
- Build towards a highly scalable UNS using the Intelligence Hub as the abstraction layer and HiveMQ as the enterprise broker.

BENEFITS

- Bioreactor data is easily contextualized and available for analytics and remote monitoring.
- Teams save hundreds of hours by eliminating manual tasks like transcribing digital HMI data.
- PD labs can easily curate data by customer and share insights with them in real time.

John Harrington Chief Product Officer at HighByte

Catalent Reference Architecture





L To stay ahead of the ever-changing contract manufacturing landscape, Catalent is significantly investing in Pharma 4.0, including technology updates, training, and digital transformation leadership. Digital transformation is no longer a 'nice to have' but a 'must have' as we work to speed time to market while maintaining the highest levels of quality.

HighByte Intelligence Hub forms a key part of our digital architecture because it enables a small team with limited resources to scale out faster than any other connectivity tool. For instruments that have existing data models, we can start to model and publish data at a new site within minutes. Connections to new instruments only takes a few hours even for the most complicated equipment and can often be performed by the equipment subject matter expert through the simple drag-and-drop interface.

Chris Demers Global Lead for Plant Data and Analytics at Catalent

WHAT'S NEXT

 Leverage HighByte Intelligence Hub as an abstraction layer for Good Manufacturing Practices (GMP) assets to land data in both an enterprise historian and data lake.

Learn more about Catalent's digital transformation journey from Chris Demers in **Bioprocess Online**.

About HighByte

HighByte is an industrial software company in Portland, Maine USA building solutions that address the data architecture and integration challenges created by Industry 4.0. HighByte Intelligence Hub, the company's award-winning Industrial DataOps software, provides modeled, ready-to-use data to the Cloud using a codeless interface to speed integration time and accelerate analytics. Learn more at https://highbyte.com.

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