Biotechnology company paves the way for DNA medicine with AX for Pharma 365

EXECUTIVE SUMMARY

INOVIO creates DNA-based medicines and smart delivery devices that have the potential to treat and prevent infectious diseases and cancer. With products in clinical phase trials, the biotechnology company wanted to update its Enterprise Resource Planning (ERP) solution to include go-to-market activities. It chose AX for Pharma 365 built on Microsoft Dynamics 365, the only life sciences manufacturing platform that combines clinical and commercial activities. AX for Pharma 365 makes it fast and easy for INOVIO to innovate.

After decades of relying on inactivated or live-attenuated vaccines to teach the body how to fight infection, breakthroughs in Messenger RNA (mRNA) technology have set the stage for INOVIO's DNA-based medicine, which has the potential to treat and prevent infectious diseases and cancer. In addition to creating highly effective and highly stable DNA-based vaccines, the publicly traded biotechnology company, also externally funded by organizations such as the United States Department of Defense, Bill and Melinda Gates Foundation, and CEPI, develops DNA medicines for cancer and HPV as well as the smart delivery devices needed to administer them. Getting these products to market is a long journey that involves years of clinical research before reaching commercial viability. With several of its products moving successfully through clinical phase trials, INOVIO needed to update its Enterprise Resource Planning (ERP) system to prepare for the production and commercialization of its products. The company wanted a 21st Century technology that would a support the seamless roll out of its 21st Century medicine.

ANTIQUATED ERP SYSTEM POSES CHALLENGES WITH GETTING LIFE-SAVINGS MEDICINES TO MARKET

INOVIO approached AX for Pharma 365 for help updating its on-premises ERP solution that only handled clinical tasks. The company knew it wanted a cloud-based solution that would seamlessly bridge the clinical-commercial divide and enable a future of unbounded growth. INOVIO searched for a partner that knew the industry intimately and could deliver the high-quality products and services needed to improve patient outcomes. Furthermore, the company needed to complete the migration in a compressed timeframe in order to meet an important milestone—and it all needed to be done remotely due to the COVID-19 pandemic.

Logistics aside, this request was a tall order to fill for several reasons. First and foremost, traditional ERP systems are not designed to meet the stringent regulations and unique requirements of combo (drug/device) development companies that INOVIO needed. Standard systems must be heavily customized if they're to be used. Second, solutions pre-configured for the industry tend to focus on only clinical or only commercial processes. Bringing them together requires more investment and customization. Lastly, companies that operate in this industry have zero margin for error. Even processes deemed basic in other industries, such as controls for manufacturing product, product configuration, and the warehouse must be perfect in FDA-regulated products, where patient safety is paramount.

THE ONLY COMPREHENSIVE SOLUTION IN THE LIFE SCIENCES INDUSTRY

AX for Pharma 365 specializes in helping pharma, biotech, and medical device organizations efficiently develop, test, and bring products to market through a unique combination of platform services and deep industry expertise. It offers the only clinical and commercial life sciences manufacturing platform available in the market, and it is built on Microsoft Dynamics 365, which delivers maximum flexibility and functionality for customers.

MODULAR COMPONENTS MAKE IT EASY TO ADD CAPABILITIES AND GROW

The platform's comprehensive life-sciences capabilities makes it easy for companies to bring new features online and integrate with third-party sources as needed. This is a stark change from the standard approach of needing to install fully loaded ERP systems on day one, and it's crucial for startup companies like INOVIO. "Having that flexibility and that functionality available if we need it, considering our potentially unlimited opportunities for expansion, was very attractive," explained Matt Coultas, Associate Director of Operations for INOVIO.

"WE CHOSE AX FOR PHARMA 365 BECAUSE WE NEEDED A SYSTEM THAT WAS FULLY VETTED AND WOULD ALLOW US TO QUICKLY TURN ON INDIVIDUAL FUNCTIONALITY AS WE NEEDED THEM, SO THAT WE COULD KEEP PACE WITH THE SCIENCE THAT WE'RE DOING."

- Matt Coultas, Associate Director of Operations, INOVIO

AXP365
Powered by TO INCREASE ⊕

Intelligent Manufacturing Operations and Optimized Production Performance

Finance, Operations, and Business Intelligence

GxP FastTrack™

LIMS, Weighing/ Dispensing, Quality Control, EAM

www.axforpharma.com

INTEGRATION WITH MICROSOFT 365 OPENS A WORLD OF NEW POSSIBILITIES

By extending Dynamics 365 modules instead of building line of business applications from scratch, AX for Pharma 365 makes it possible for customers to unify their ERP with the rest of their business. "One of the things I absolutely love about AX for Pharma 365 and the Dynamics 365 platform on which it sits, is the intuitive nature of the software," said Dan Jordan, Senior Vice President of Device Manufacturing for INOVIO. "At INOVIO, we utilize Microsoft Office 365 for everything internally, and this platform made the move intuitive and simple to use for our users while providing the functionality we need to move forward as a business."

QUALITY AND SERVICE DELIVERED WITH A PATIENT-FIRST MENTALITY

AX for Pharma 365 extends the capabilities of the Dynamics 365 modules to make them highly relevant for industry needs. The platform is ready to use out of the box without customizations, and a team of experts continually validates the software against each release from Microsoft, so customers don't have to worry about whether or not a version update will impact their business. "We chose AX for Pharma 365 because we needed a system that was fully vetted and would allow us to quickly turn on individual functionality as we needed them, so that we could keep pace with the science that we're doing," explained Matt Coultas.

GOLD STANDARD SOLUTION DELIVERED UNDER TIME AND UNDER BUDGET

The project scope included implementing nearly a dozen modules and achieving manufacturing and FDA validation in the cloud. AX for Pharma 365 used its GxP Fast Track™ rapid implementation methodology to complete the migration remotely in six months and six days—putting it under time and under budget. Furthermore, by partnering with AX for Pharma 365 to run on fully managed infrastructure backed by Microsoft, INOVIO's team feels more confident than ever before in the reliability of its data. "With AX for Pharma, we are more confident than ever that we have reliable data because it's the "DNA" standard for our data," said Dan Jordan. "We're excited about all the capabilities this new solution provides our team to help us explore new advancements in our platform—from anywhere."

"ONE OF THE THINGS I ABSOLUTELY LOVE ABOUT AX FOR PHARMA 365 AND THE DYNAMICS 365 PLATFORM ON WHICH IT SITS, IS THE INTUITIVE NATURE OF THE SOFTWARE."

- Dan Jordan, Senior Vice President of Device Manufacturing, INOVIO

AX for Pharma North America	**AX for Pharma Europe**	**AX for Pharma Australia PTY LTD**	info@AXforPharma.com
100 S. Ashley Drive	Centro Direzionale Milano Due	Level 1	www.AXforPharma.com
Suite 600	Palazzo Bernini, 701-704	6-10 O'Connell Street	US: +1 (813) 365-9576
Tampa, FL 33602	20090 Segrate (Milan)	SYDNEY NSW 2000	Europe: +45 80 25 41 81
United States	Italy	Australia	Australia: +61 2 9052 0872

AXP365
Powered by TO INCREASE ⊕