

“From the first day to now this has been an outstanding experience. I could not recommend them highly enough.”

Andrew Rooney – Product Lifecycle System Coordinator at Allergan (Acquired By AbbVie Inc.)

Maly deliver Innovative Process Control via The Hub

The AbbVie logo is displayed in a dark blue, lowercase, sans-serif font. The letters are bold and rounded, with a consistent weight throughout. The 'v' is slightly taller than the other letters, and the 'ie' at the end are connected.

About AbbVie Inc.

Based in the US, and founded in 2013, AbbVie is a biopharmaceutical company. It brings together the stability, global scale, resources and commercial capabilities of a pharmaceutical company with the focus and culture of a biotech. AbbVie’s mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. With over 47,000 employees around the world, AbbVie focuses on delivering transformational medicines and therapies that offer significant patient benefits. Allergan Aesthetics is part of the AbbVie portfolio, and was Maly’s first client in 2010.

The Challenge

As with all American pharmaceutical enterprises, AbbVie is subject to the Good Manufacturing/Distribution/Laboratory Practice of GxP, where x denotes the specialist field. Quality assurance is essential and all software is stringently verified ahead of going into production. Allergan approached Maly in 2010 and while the initial challenge was looking at sales operations, taking data from multiple sources and producing reports to support the frontline sales teams, it became apparent that the systems in place across the business could be significantly improved by taking a more holistic view of the regulatory and process requirements. Maly were asked to look at all the business processes, map the different systems and establish clear objectives for each. Rules and steps for each process were

required so responsibilities could be assigned and progress tracked. Specifically, one of the initial challenges was a disconnect between the Regulatory Authority(RA) department and the Artworks department. Between the two they were responsible for the highly complex and regulated labelling process, with Artworks responsible for the design of the labelling, packaging and messaging to support each product and RA responsible for the adherence to the strict regulations and laws as dictated by each country's Ministry of Health. By not using a common process or supporting system, the two departments were not working together effectively, leading to significant risks of incorrect labels or packaging. If errors of this kind made it to the shop shelf, there was the risk of harm to consumers, potential stock recalls, brand damage and fines.

The Solution

Having worked with Allergan and then AbbVie for over 10 years, Maly was best placed to understand the complexity of the processes involved and be able to design new software and enhance existing software to ensure appropriate security, availability, accessibility and integration, as well as compliance with the regulatory constraints placed upon the business. The initial solution was to design an Artworks Project Management system, including an electronic form for the RA department to complete, progress could be shared automatically, streamlining the process and putting in place the rigorous standards of data and system security required. With so much of the artwork itself outsourced to a third party, the internal project management capability of the new system ensured the Artworks Department could accurately track and flag nearing deadlines and milestones, manage timelines and record performance metrics.

The Artworks Project Management System was the first solution in a series of innovative software tools designed and deployed by Maly. Subsequent systems included a Score Carding system for the Quality team, where Maly integrated data from multiple systems to provide team performance scores against quality targets; a Workflow Management System that can be used for a variety of processes, prompting action at appropriate times; and a Temperature Excursion tracking system for the transportation of temperature sensitive drugs.

Collectively these systems became known as The Hub, a flexible, highly configurable, centrally managed set of process management tools with intuitive dashboards, making them easy to use. Maly's flexible, innovative solutions have streamlined a number of manual, fragmented and iterative processes, saving AbbVie both time and money.

The Results

Maly understood the level of process control required for a global pharmaceutical enterprise. They developed and deployed a number of fully integrated systems that solve many different process control and project management scenarios that vary from a shared electronic form between highly regulated departments, to vital temperature tracking software, ensuring the integrity of temperature sensitive drugs.

AbbVie now has a process control Hub that is designed for the way they work and is accessible, flexible and cost effective.

From a quality perspective, The Hub means that during internal and external audits there is less exposure to non-conformity, and when issues do occur AbbVie can respond quickly,

putting corrective measures in place. This efficient, seamless, highly configurable and resilient solution has revolutionised process control within AbbVie.

Business Benefits

- Flexible, configurable system that can be used in many process control scenarios
- Increased visibility and control over all processes
- Reduced exposure to non-conformity
- Exception management, they can respond quickly and put changes in place to resolve
- More efficient communication between siloed departments
- Seamless integration with existing systems
- Improved performance reporting and management
- Better business insight with easier access to business data