

Accelerating Innovation in the Allergy Market – Two Products in 2.5yrs

The Starting Point

The global allergy diagnostics and therapeutics market size was valued at USD 32.06 billion in 2018 and is anticipated to expand further at a strong CAGR of 6.3%. These numbers are driven by a higher demand for IVD blood tests as a result of increasing incidences of allergic diseases. In the US alone more than 50 million people have experienced various types of allergies each year¹ and the number keeps growing. One of the companies shaping the global allergy market and providing better solutions for the end-users is [Macro Array Diagnostics GmbH \(MADX\)](#), a Vienna-based MedTech company. MADX partnered with BIT in 2017 to develop the first IVD multiplex allergy diagnostic device with an allergen panel close to 300 allergen extracts and molecular allergens. This portfolio aims to cover over 99% of all routine diagnostic needs. This IVD product received CE mark clearance and entered the market successfully in Q4 2017. At the time of launch, BIT and MADX already started work on the next generation instrument: a fully automated diagnostic device platform. We expect to see this on the market early in 2020.

The MADX Challenges Faced

- Create Higher Throughput with Consistent and Accurate Results**
 The goal was to achieve an automated allergy testing platform that required minimum operator intervention while delivering high quality repeatable results.
- Aggressive Launch Goals**
 Time to market was the most critical component that directly affected revenue and consequently defined the success of MADX. A rapid launch was key in generating early market share and revenue. The tight timelines could only be met by outsourcing the project to BIT instead of designing, developing and manufacturing in-house and acquiring resources at great cost.
- Decreasing Manufacturing Costs and Accelerating Manufacturing Transfer Time**
 The challenge was to decrease manufacturing costs and transfer the product rapidly into manufacturing. This required a price point achievable in the market by MADX's customers for the product and a fast time to market to capture early market share and to ensure their innovations reach consumers quickly.

The Results



¹ CDC, Gateway to Health Communication and Social Marketing Practice. Allergies. <https://www.cdc.gov/healthcommunication/toolstemplates/entertainment/tips/Allergies.html> (March 14, 2018)

BIT's Solutions

With MADX being based in Austria, BIT leveraged its European presence to manage the project locally through our Germany offices. Consequently, the processes could be streamlined and managed more efficiently. The main reason for the success of the project was the rapid development (in less than three months) of the ImageXplorer, a manual cartridge-based imaging solution, which allowed MADX an earlier market entrance to gain share and create an initial base of customers. This increased their brand awareness and generated revenue while MADX and BIT developed the 2nd generation fully automated diagnostic device.

- Leveraging Automation Expertise**

The main way to obtain high throughput while having repeatable and consistent test results is to automate. BIT leveraged pre-developed solutions (e.g. robotics, sample carousel, fluidic components) to create fully automated workflows which reduce operator hands-on time and provide a machine based full-chain-of-custody sample management that lowers chances of operator errors.

- Cost and Design Approach**

In order to achieve completion of the project under budget and within the required timelines – planning was key. BIT utilized an extended Phase 0 planning phase with heavy client involvement to ensure success. Part of this planning allowed BIT to work with the client to implement pre-developed sub-assemblies and systems to ensure success without reducing the device capabilities.

- Focus on Manufacturability through Close Collaboration of Development and Operation Departments**

BIT was able to decrease the manufacturing costs for MADX by 15% through a close and early collaboration between the design, industrial engineering, supply chain, quality and production departments. By applying a mixture of verified off-the-shelf technologies, pre-developed sub-assemblies and alternative materials instead of costly injection molding, cost per goods were cut significantly. These combined efforts supported the smooth transition into manufacturing and helped to streamline assembly processes leading to a shortened time to market. Overall, by using in-house solutions, effective planning and strong communication internally and with the client, BIT was able to deliver the project with reduced manufacturing cost, which resulted in a commercially successful product for MADX.



Why BIT?

- 150 Engineers and Scientists Holding over 30 Internal Patents** - Systems, Software, Electronics and Mechanic Engineers with a vast knowledge in a broad variety of technologies receive continuous updated training in spaces like market regulatory requirements, risk management and design processes to ensure they are leaders in their space. Our patents can be utilized by clients to accelerate time to market and to add additional beneficial features to their products.
- 43 Years of Excellence with More Than 190,000 Instruments on the Market** - Our competency is evident in our long-term manufacturing relationships with industry leaders like Siemens, Abbott, Beckman Coulter.
- We Speak Regulatory** - With an in-house regulatory team and all BIT manufacturing facilities operating under ISO 13485 and FDA certifications we ensure our customers are planning and achieving all relevant regulatory requirements.
- Long-lasting Team Collaboration** - We have over 95% full-time employee's with low turnover rates and long work relationships in our engineering and manufacturing department. This allows working together with a stable and consistent project team throughout development and manufacturing.