

# IT SUCCESS STORY: MID-ATLANTIC BIOTECH



**MELE Associates, Inc.**  
Translating Vision into Reality

## OVERVIEW

To realize the company's mission, advance its innovative cell therapies targeting cancer and inflammatory diseases, and grow the organization, a well-regarded Mid-Atlantic biotech (The Biotech) company needed a partner that could manage daily IT operations and help the company meet the IT regulatory and compliance requirements of the U.S. Food and Drug Administration (FDA).

MELE's work with The Biotech began in 2018 and initially focused on the company's IT network at their Rockville, Maryland Center of Excellence. The scope of work included building out the network infrastructure, including installing the wiring/cabling, setting up the physical and virtual environment (servers/hardware/Local Area Network), and standing up voice-over internet protocol (VoIP), the wireless network, and the company's Internet Service Provider (ISP).

In addition, the MELE team deployed advanced firewall protection and end point security for added network protection from external threats and internal risks. The team also led The Biotech's network disaster prevention program, including data center power protection planning.

When the company outgrew its first-floor space, MELE expanded the network to accommodate its

new upper floor offices. As the relationship deepened, MELE continued to operate as the company's onsite IT department, maintaining the network, monitoring performance, overseeing network security, and performing other key tasks in coordination with their parent company IT counterparts.

The MELE team and its IT counterparts at the parent organization had significantly improved The Biotech's IT ecosystem and approach by 2023. However, the advent of new FDA IT regulations required additional enhancements that would not only comply with the FDA but would also improve the company's operational and business development results. In 2023, momentum built within The Biotech to invest in improving its IT network across multiple areas.

"We have a strong partnership. Our team provides the one-on-one responsive service that was particularly important during this massive IT transformation. Despite opportunities to choose another partner, they've stuck with us, and we deeply appreciate that loyalty. We feel like members of their team and look forward to our continued collaboration."

**RON COLBERT, MELE'S CTO**

## THE CHALLENGE

Early in 2023, The Biotech and its parent company decided to transform the company's IT approach, including building out an IT infrastructure that better aligned with FDA regulations. This meant upgrading its hardware, software, and tools to operate seamlessly within the FDA regulated biotechnology compliance environment. The successful transition to an augmented and compliant IT enterprise infrastructure was critical not only to empower more efficient operations, but also for securing new life science company partnerships while advancing its pipeline through the FDA regulatory process.

MELE worked closely with The Biotech and its parent company counterparts to lay the groundwork for the impending IT transformation.



# THE IT TRANSFORMATION

The MELE team now had a major IT overhaul to deliver while continuing to manage The Biotech's day-to-day IT operations. MELE faced myriad challenges like a language barrier among teams, different time zones, and acute discrepancies in IT protocols and regulatory systems. This was an IT transition and translation project on multiple fronts, including overhauling the company's domain and IT toolbox.

"For example, they were limited to using Skype with its older IT setup. We were able to move them to Teams, which is more widely used in the life sciences world. Their email domain also had to change because their existing firewall hindered their ability to operate," stated Mac del Rosario, MELE's Systems Administrator. "The Biotech was also part of the parent company's domain, making the company one tree in a giant domain forest. Creating a standalone domain and IT environment independent from their parent company was a crucial step in removing bottlenecks stunting their growth."

*During this critical time, MELE delivered a host of key projects in addition to the new domain, including:*

- Ongoing IT management and oversight, including IT onboarding of new employees
- A detailed and actionable IT transformation plan
- Key network data to underpin the creation of the company's FDA compliance policy
- Robust Public Key Infrastructure (PKI) and encryption capabilities
- The installation of video conferencing and upgraded security software
- FDA-compliant hardware procurement and installation
- A seamless data migration to Microsoft 365

"This IT transformation and our ongoing work with our long-term biotech partners has helped the company advance its pipeline, remain FDA-compliant, and secure strategic partnerships with major life science companies," said Ron Colbert, MELE's Chief Technology Officer.

## THE OUTCOMES

The Biotech has increased its IT capabilities, enhanced its network security, and retained a trusted IT partner to proactively manage all aspects of its IT infrastructure.



- The company has successfully transformed its IT system to an FDA compliant, more efficient IT environment that now includes its own domain and market compatible software products and tools.



- The Biotech removed major drug development and new business opportunity bottlenecks because it is now fully compliant with FDA and U.S. regulations.



- The Biotech now has an agile, compliant, and scalable IT ecosystem that is empowering its scientists and corporate teams with better data and stronger enterprise communications tools.



- The company continues to grow rapidly and has secured new partnerships with several leading multinational life sciences companies.



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