



Agatha

Mablink Bioscience Manages Regulatory Compliance with Agatha

Mablink specializes in the development of a new class of cancer drugs, Antibody Drug Conjugates (ADCs). ADCs are highly targeted biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with highly potent anti-cancer agents. Mablink wants to leverage ADCs in the fight against cancer because they have the promise to be quick, efficient, and cost-effective.

Mablink is a young company with a young team that is just getting started with clinical trials. Today, they are in the discovery phase, and they wanted to put in place the right practices, processes, and systems for managing clinical trials from the beginning.

With a regulatory preclinical phase scheduled for late 2021, Mablink adopted Agatha to help them prepare for both the preclinical and clinical development phases. Agatha enables Mablink to capture the data needed through documents and forms that will support them as they move through each phase of the clinical trial process.

Agatha Clinical TMF enables them to compile and track all scientific and administrative documentation to ensure compliance with regulatory requirements, and Agatha Quality ensures they have the desired guarantee of quality for Mablink both from a scientific point of view and in terms of protecting their investments.

Mablink has three sites: two laboratories and an office. Agatha is a cloud-application, making it easy to connect the sites and work efficiently. With all documentation archived properly, it's very easy to share information with investors and with regulators.

Before Agatha: The Challenges

- No way to capture and track documents through clinical trial phases
- Issues related to finding the correct documents
- Inability to easily supply information to investors

With Agatha: The Benefits

- Easily track all scientific and administrative documentation
- Provide access to VCs during fundraising to get information quickly
- Syncs with Mablink's ERP system
- Cloud-based solution to support all offices

“Agatha is very efficient and simple to use. It’s a good way for us to create the right structure in Mablink.”

We have a second fundraiser scheduled for September 2021, and to manage the growth of the company it’s essential to have a good structure in place. We have Agatha for documents and ERP for financial data and managing the project. Both systems work well together and help us greatly.”

Jean-Guillaume Lafay, CEO Mablink

About Mablink Bioscience

Mablink Bioscience is a French-based biotechnology company founded in 2018, specializing in the development of a new class of cancer drugs, called Antibody Drug Conjugate (ADCs). Mablink leverages its expertise in chemistry, pharmacology, and immuno-oncology to design 3rd generation ADCs that are less toxic, show better efficacy, and are easy to manufacture.

About Agatha

Agatha, Inc. is a leading strategic software solutions provider to the healthcare and life sciences industry. With offices in the US, Europe and Japan, Agatha is dedicated to helping the world’s hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their quality, regulatory and clinical documentation and processes.