An Agatha Customer Story

Mediscience Planning Selects Agatha for Flexible, Compliant TMF Management

Mediscience Planning needed to address the increasing demand to provide trial master file management (TMF) services. Agatha's Clinical TMF solution helped them.

Mediscience Planning is a CRO with a history of over 30 years, offering clients one-stop services including regulatory consulting; monitoring; DM/statistical analysis; and post-marketing surveys and analysis. About 70% of its monitoring projects are focused on global clinical studies.

To address the increasing demand from their customers to provide trial master file (TMF) management services, Mediscience decided it needed to deploy an electronic TMF system (eTMF), which would allow them to increase the efficiency and scale of their service. They were concerned, however, that the systems available seemed too cumbersome to use, expensive, and time-consuming to set up and maintain.

Mediscience wanted a solution that was cost-effective and user friendly, one that could support both the DIA TMF Reference Model or its Japanese version (where Japanese clinical documents designated by Japan Pharmaceutical Manufacturers Association are mapped to DIA TMF Reference Module).

Ultimately, their search led them to Agatha's Clinical TMF solution.

Before Agatha: The Challenges

- Increasing eTMF compliance requirements with Japanese regulations
- Increasing requests from customers to have access to an eTMF solution
- Need to scale their TMF services with a system that could be available quickly and which would scale easily

With Agatha: The Benefits

- Ease of use in managing and storing eTMF documents
- Configurable workflows for review and approval
- Flexible document list and folder structure
- Compliant with key industry and legal regulations
- Complete audit trail and e-signatures

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Customer Story:
Mediscience Planning

"Agatha makes editing Word documents within the TMF and rendering them as PDFs simple and easy, and logs every transaction on the system in the Audit Trails. Electronic signature and version control are also available. Agatha is compliant with MHLW's ER/ES guidelines and FDA 21 CFR Part 11. It is also fully compliant with the rigorous security requirements of healthcare and life sciences companies, as it's built on Amazon Web Service.

With Agatha, you have visibility into documents uploaded to the eTMF off-site. This makes monitoring highly efficient, and enhances quality control, as you can detect high-risk sites and processes by central monitoring at an early stage.

Agatha is growing as our document management platform, as we're now using Agatha for our internal SOPs, in addition to our clients' essential documents."

- Mr. Fujisaki, Information System Department, Business Administration Headquarters; Mr. Horii, Document Group, Development Promotion Department; Mr. Tasaka, International Communication and Clinical System.

About Mediscience Planning

Founded in 1982, Mediscience Planning, Inc. has a long and successful history, as a leading Japanese CRO with an outstanding global profile and a high ratio of international companies among its clients. Involved in the formation of the Japan CRO association, Mediscience has a great deal of knowledge related to all aspects of global clinical trials. As a CRO, Mediscience Planning offers integrated services from Phase 1, Phase 2, Phase 3 Studies, Post-Marketing Trials, to In-Country Clinical Care-taker.

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.

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