A New Generation of Online Apps for **Life Sciences Businesses**

CLINICAL | SOP | QUALITY | REGULATORY

Biotechnology, pharmaceutical, and medical device companies develop highly complex products. For these organizations, accuracy, consistency, efficiency, and quality are not goals; they are imperatives because the medicines, therapies, and devices they make can enhance and save human lives.

Agatha provides cloud-based SaaS applications that address the imperatives for core business processes like managing clinical trials, tracking quality processes, and organizing regulatory submissions.

Agatha Apps are:

Faster. Ready-to-use, robust, and easy to adapt, unlike prior generations of document management platforms. By eliminating long planning, preparation, and validation processes, you can use Agatha Apps within days.

Smarter. Comprehensive functionality with a parameter-based configuration allows easy and incremental adjustments to business processes. That means the system adapts to its users, not the other way around.

Better. Designed for business users. Robust, compliant apps that are available immediately, adopted by users faster and cost less. You get better results. And higher value.

That's our commitment and our promise.

When it comes to software for life sciences companies, no one delivers better value than Agatha.

A Complete Suite of Validated Applications in Agatha's Secure Cloud

Agatha's business apps for life sciences are cloud-based, ready-to-use applications. Core processes are already in place, and we have done the heavy lifting on validation.

Easy Configuration

- Easily adjust Agatha applications to your specific requirements without re-validation using parameter configuration.

The Agatha Cloud

Agatha offers a highly secure, reliant, high performance, compliant, cloud service.

- True multi-tenant cloud, hosted on AWS (Agatha is an AWS partner).
- End-to-end data encryption during transit and at rest.
- Separation of non-production and production environments through Private Networks (VPNs).
- Agatha Cloud satisfies the requirements of our most security-sensitive customers.

With Agatha Apps, you have a faster start-up, lower costs and highly flexible solution to meet your requirements.

Compliant Apps that Reduce Regulatory Risk

Every Agatha App is designed around regulatory requirements.

- Compliant with FDA CFR 21 Part 11.
- ISO 27001 certified.
- Validated follow ing GAMP 5 guidelines.
- Fully equipped with all the functions necessary to manage GxP documents such as:
  - Audit log: Every action is documented in a complete audit trail, so you are always inspection-ready.
  - Electronic signatures
  - PDF rendition: A large range of parameters are available to make the PDF rendition suit your regulatory needs.
  - Quality Control: Final documents can be sent to quality control (based on document criteria such as document type or location).
- Users receive training using video clips, and acknowledge their training when they start using Agatha.

We know the regulations, and our solutions ensure compliance.

Agatha Clinical

An eTMF management app that ensures every essential document is accounted for.

The Trial Master File plays the central role in every clinical trial, documenting processes, and ensuring compliance with protocols. With multiple sites, often across many countries, tracing every item in the TMF is a challenge.

Agatha Clinical is a complete eTMF solution, ensuring that the set of essential documents for every site and study is present and ready for inspection.

- Complete set of placeholder documents created for every study and site
- Automate review and approval workflow processes
- Automatic checking for all required documents, with notifications
- Combine documents and forms to accelerate study processes
- Aligns with the TMF reference model

Agatha SOP

An application for managing Standard Operating Procedures (SOP) and related training documents.

Managing SOPs and Employee Records requires a robust system that controls the authoring process, manages versions, executes approval processes, and tracks related training documents.

Agatha SOP is a comprehensive system that tracks every activity, collects every signature, and ensures every process is completed. The result is a complete set of documents and records, ready for audit at any time.

- Create SOPs from your own templates - or ours
- Generate Employee Records for target groups based on approved SOPs
- Manage SOPs through multiple states, from draft to effective

- Drive every SOP and related document through review, approval and signature processes
- Require successful completion of quizzes to ensure new processes are understood
- Ensure that paper based copies are managed properly with Controlled Print
- Automatically trigger review workflows on documents when they are close to their expiry

Agatha Quality

A complete, closed-loop system for managing Corrective and Preventative Actions (CAPA), Audits, documenting Deviations, and coordinating Change Control activities.

Managing the corrective and preventive action process is at the center of the continuous quality improvement process.

Agatha Quality is a complete solution for capturing complaints and deviations, documenting corrective and preventive actions, and managing change control processes. Every action is connected, from the initial issue to the new process, and every step documented, reviewed, and approved.

- Complete, closed-loop process captured in an expanding form, from initial issue to preventative action
- Automated distributions for review, approval, and notification
- Complete records with signatures and audit trails, ready for inspection
- Ready-to-use with standard forms and processes, but easy to adapt and tailor to current procedures

Agatha Regulatory

A complete, centralized location for managing all regulatory documents and information.

Tracking and managing regulatory documents is challenging; managing them across offices and countries makes it even more difficult. Duplicate content and a lack of visibility into regulatory activities increase the risk of non-compliance.

Agatha Regulatory reduces the complexity involved in managing regulatory documents prior to submission, providing a consolidated and authoritative source for regulatory submission content.

- Collaboration with external partners
- Management of expected documents per product (as per the EDM Reference Model)
- Online review of documents with annotations
- View applicable documents across several submission sequences
- Integration with eCTD submission software, including eCTD import, and viewer with link remap
- EDM Reference module provided in standard

Agatha also provides a central location to track regulatory applications and health authority correspondence.

Ready to Learn More?

Reach out to learn more about Agatha's applications for Life Sciences.

Sign up for a Trial:

https://www.agathahealth.com

Send us an email:

US us_sales@agathalife.com

EU sales@agathalife.com

Japan sales@agathalife.com

Agatha

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. With lower costs and faster on-boarding, Agatha delivers the best ROI on business applications for life sciences that are ready to use and easy to adopt. Agatha, Inc. is a strategic software solutions provider to the healthcare and life sciences industry, providing SaaS-based business applications for managing SOP, regulatory documents, and clinical trial master file records. .