

# Agatha Regulatory



Agatha Regulatory is a comprehensive, ready-to-use regulation management application that addresses the challenge of creating a unified set of submission documents from content that is often created in many locations, sometimes in many countries.

Use the application to collect, organize, and manage regulatory documents prior to submission, providing a single and authoritative source for all required content.

## Benefits

### Ready-to-Use

Cloud-based, preconfigured, validated and ready to use.

### Consistent, Complete

Based on the EDM Reference Model, it automatically identifies missing documents.

### Coordinated, Collaborative

Online review of documents with shared annotations as well as review & approval workflows.

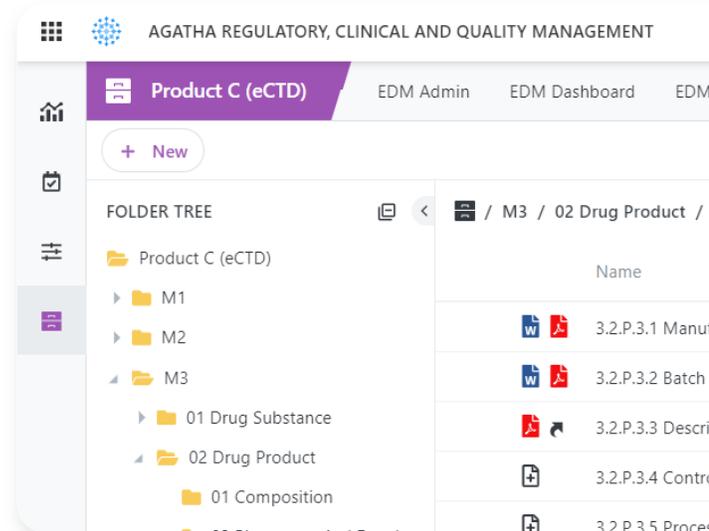
### Validated, Compliant

Fully compliant with 21 CFR Part 11, as well as EU Regulatory Requirements.

## Agatha Regulatory Features

### Preview, Edit, and Annotate

Review and edit Word, Excel, and PowerPoint documents directly in the application (does not require an Office license). Annotate PDF, Office documents, and images with a simultaneous review of documents.



## See What's Missing

Identify missing submission items automatically at any point in the process.

## Advanced Forms

Work with ready-to-use standard forms and processes, or adapt them to support your needs. Forms include rich text fields that allow the addition of images and formatted text. Use the form designer to update the look and feel of your forms.

A single multi-part form supports all steps in a process. Reviews, approvals, and assignments for actions are also built-in.

## eCTD Integration

Get all the reporting you need with built-in dashboards and reports, and export reports for external reporting requirements. Create views and reports across workspaces and export results to Excel for dashboard reports.

## Also:

### Advanced Integration Toolkit

Use Agatha's Rest API to allow applications to upload or export items from Agatha (includes documentation & sample code).

### Advanced Policy And Access Management

Manage policies, associated roles, and access controls easily.

### Secure Cloud

Agatha Applications are cloud-based, hosted in Agatha's highly secure, highly reliant, high-performance, compliant, cloud environment.

## Three Editions:

### Standard, Extended, and Premium

Some features are only available in Extended or Premium editions.

