Agatha Regulatory

A complete, centralized location for collecting, coordinating, and managing all information and documentation required for regulatory submissions.

The single most important step in bringing new drugs, devices, and therapies to market is obtaining regulatory approval. Success means patients get new options sooner, while mistakes mean delays that waste time and money.

Agatha Regulatory reduces the complexity involved in managing regulatory documents prior to submission, providing a single and authoritative source for all required content. It is a comprehensive, ready-to-use 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.

With Agatha Regulatory, regulatory and compliance professions are able to create a centralized set of documents from a decentralized process, simplifying and accelerating the submission process.

Key Capabilities

- Pre-configured with the EDM reference model to ensure complete submissions
- Includes complete review and approval workflows to enforce standard processes
- Provides immediate, online review of documents with annotations
- Provides the ability to view applicable documents across several submission sequences
-
- Integrates with eCTD submission software; includes an eCTD import capability and and a viewer

Agatha Inc.
https://agathahealth.com

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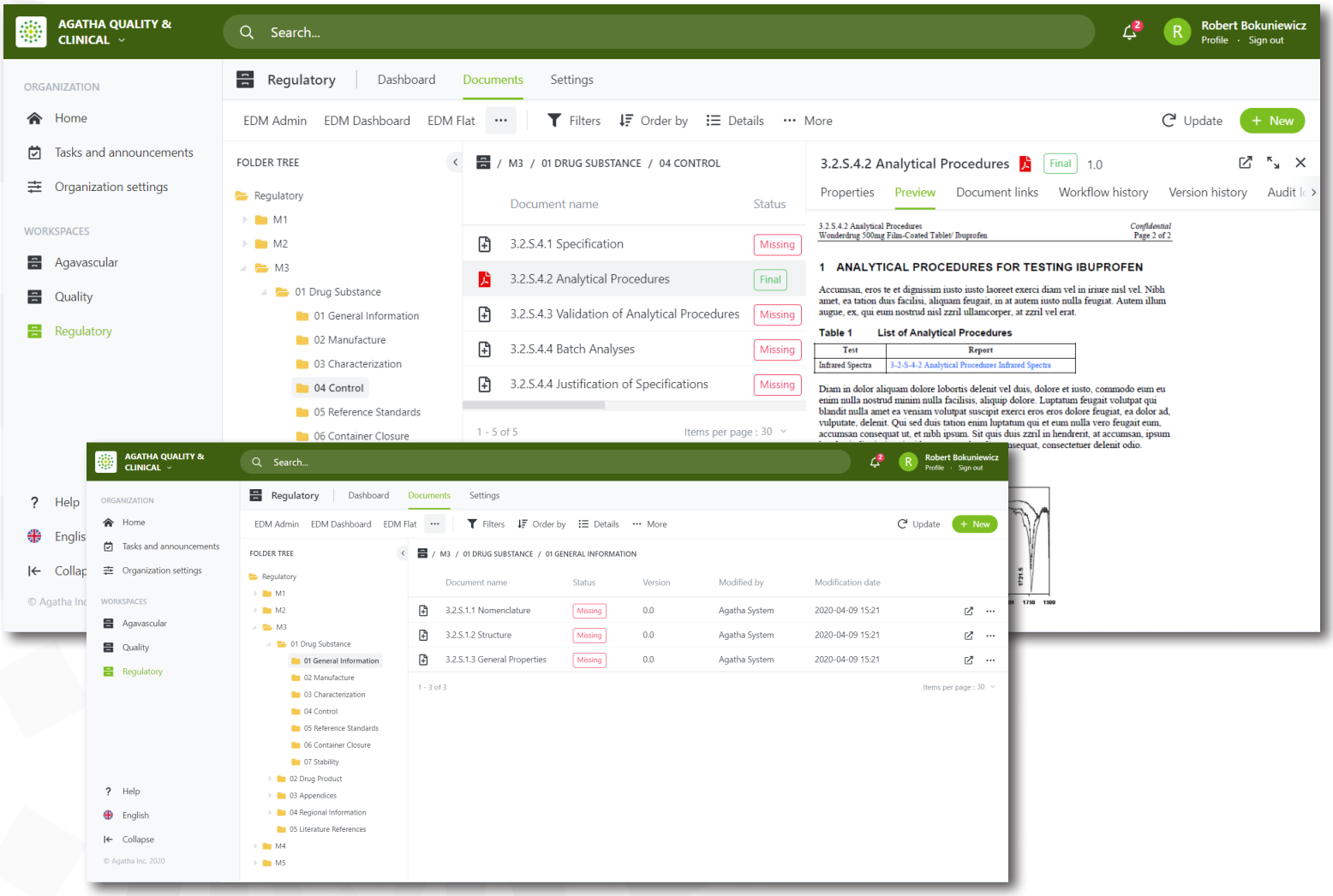
Agatha Regulatory

Benefits

- Ready-to-Use. Cloud-based, preconfigured, validated and ready to use
- Improved Coordination. Collaborate with multiple authors in multiple sites
- Consistent Content. Identify missing documents based on the EDM reference model
- Complete Records. Track regulatory applications and health authority correspondence
- Compliant. Pre-validated and fully compliant with 21 CFR Part 11



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