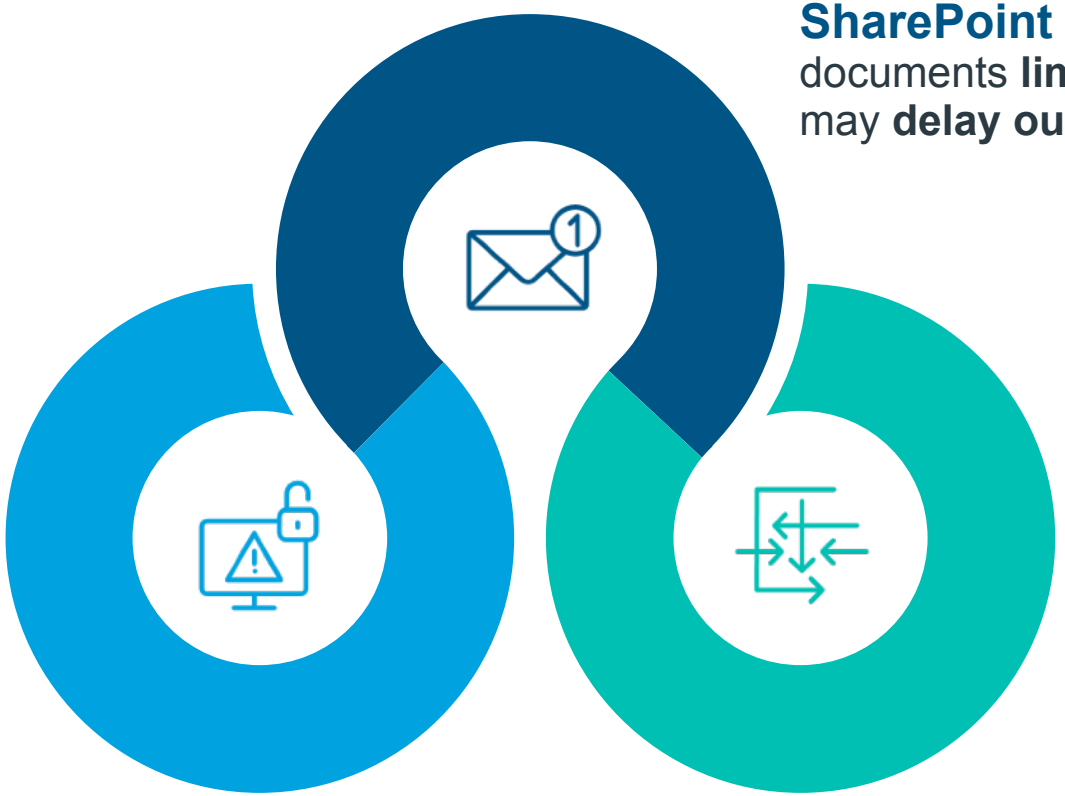
IQVIA RIM Smart Content Management

Collaboratively plan, author, review, and approve regulatory submission content

Content management challenges hinder quality of submissions

Using simple file share and SharePoint solutions to manage documents **limits collaboration** and may **delay outcomes**



Manual document management, including reconciliation of renditions and relationships, is **inefficient** and may pose **compliance risks**

Poor synergy with publishing and labeling may **duplicate efforts**, **increase costs**, and **complicate translations**

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Safe harbor statement

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RIM smart content management is a modern, cloud content management solution

Reduce costs, waste, and delays from errors in content and submission production

Foster collaboration among colleagues to create higher-quality content efficiently

Provide instant visibility into progress with submission content, enabling proactive management

Deliver peace of mind by adhering to industry standards and ensuring GXP compliance

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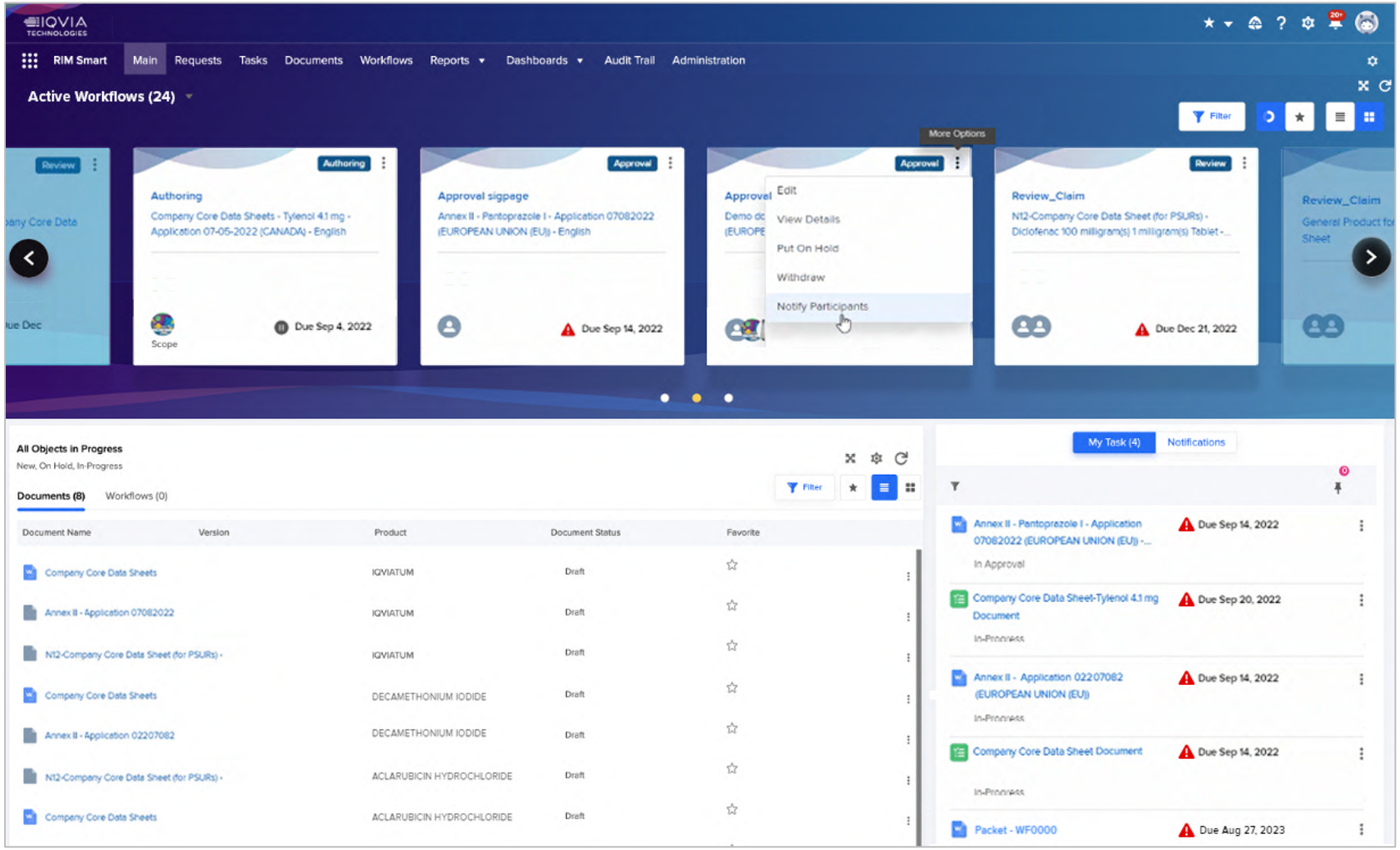
Optimize regulatory deliverables with a modular workflow management solution using IQVIA RIM Smart

Introducing IQVIA RIM smart content management



Foster collaboration on high-quality regulatory documents

Pre-built and **configurable**, **task-driven workflows** for document submissions

Improve document quality through **collaboration and transparency** among stakeholders

User-centered interface simplifies authoring, review, version control, and approval processes

Pull submission content planning upstream using structures to ensure **submission ready documents**

Includes more than **340 pre-formatted**, global authoring **templates**

Supports real-time and asynchronous collaboration among document contributors

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Content management that supports submission publishing

Improve content consistency with more than **340 pre-formatted**, authoring **templates**

Pull submission content planning upstream using **structures to plan submission content**

Auto classify documents during creation for easy alignment to a **CTD structure**

Create submission-ready PDF renditions and **Where Used Reports** to improve efficiency

Strive for greater **document re-use** across regions and for **eCTD 4.0 enablement**

Use **regulatory and product data** to simplify and automate **submission publishing**

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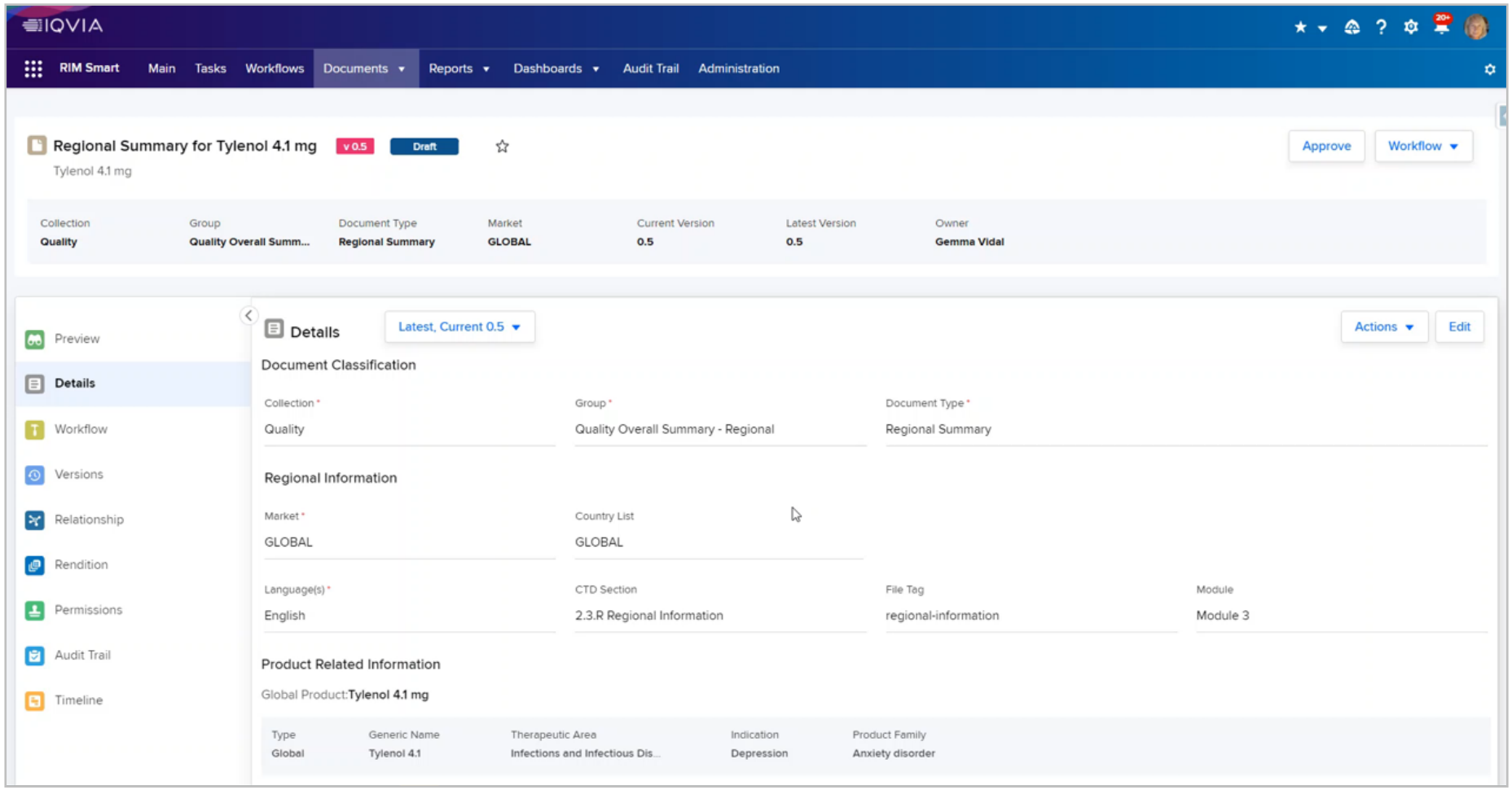
Navigate document details using an intuitive interface



Access all information about documents in one location

- Details
- Workflows
- Versions
- Relationships
- Renditions
- Permissions
- Audit trail and timeline

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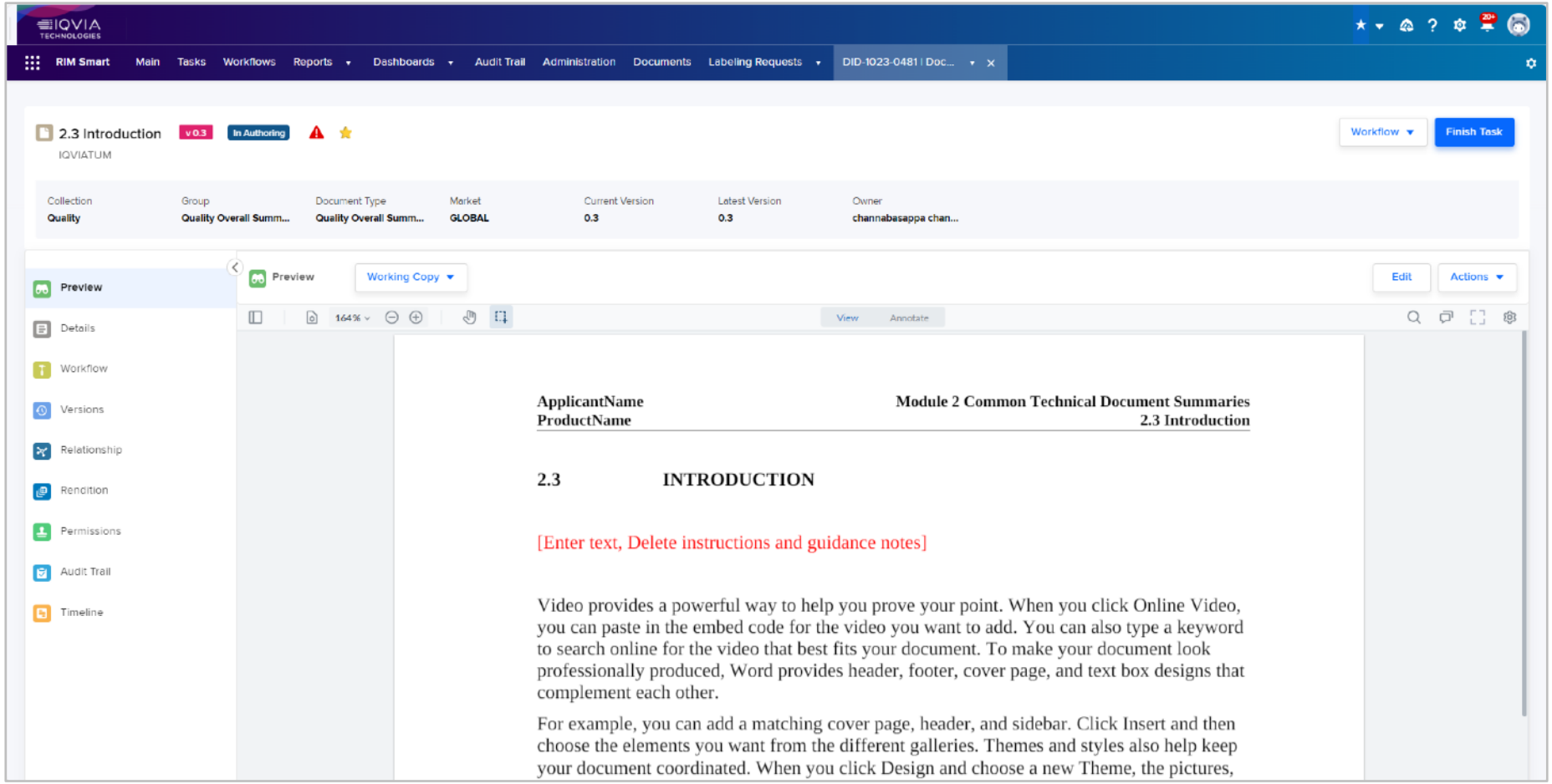
Foster real-time and synchronous document collaboration



- Present content in a feature-rich PDF viewer
- Document classification, full product metadata, and regional market info
- Predefine, create, name, and share document views
- Modify layouts and search documents to review
- Add, search for, reply to, and export annotations

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Orchestrate submission content efficiently and compliantly

Control

Manage regulatory documents across the lifecycle including timelines, relationships, permissions, and renditions

Monitor organizational usage with metrics for document production, authors and reviewers, etc.

Organize documents based on Product, Application, Composition, Study data, etc.

Compliance

Regulatory-ready with FDA's 21 CFR Part 11 requirements governing electronic records, audit trails, and digital signatures

Manage documents in accordance with industry standard CTD and eCTD content structures

Minimize the validation burden with a cloud-based solution

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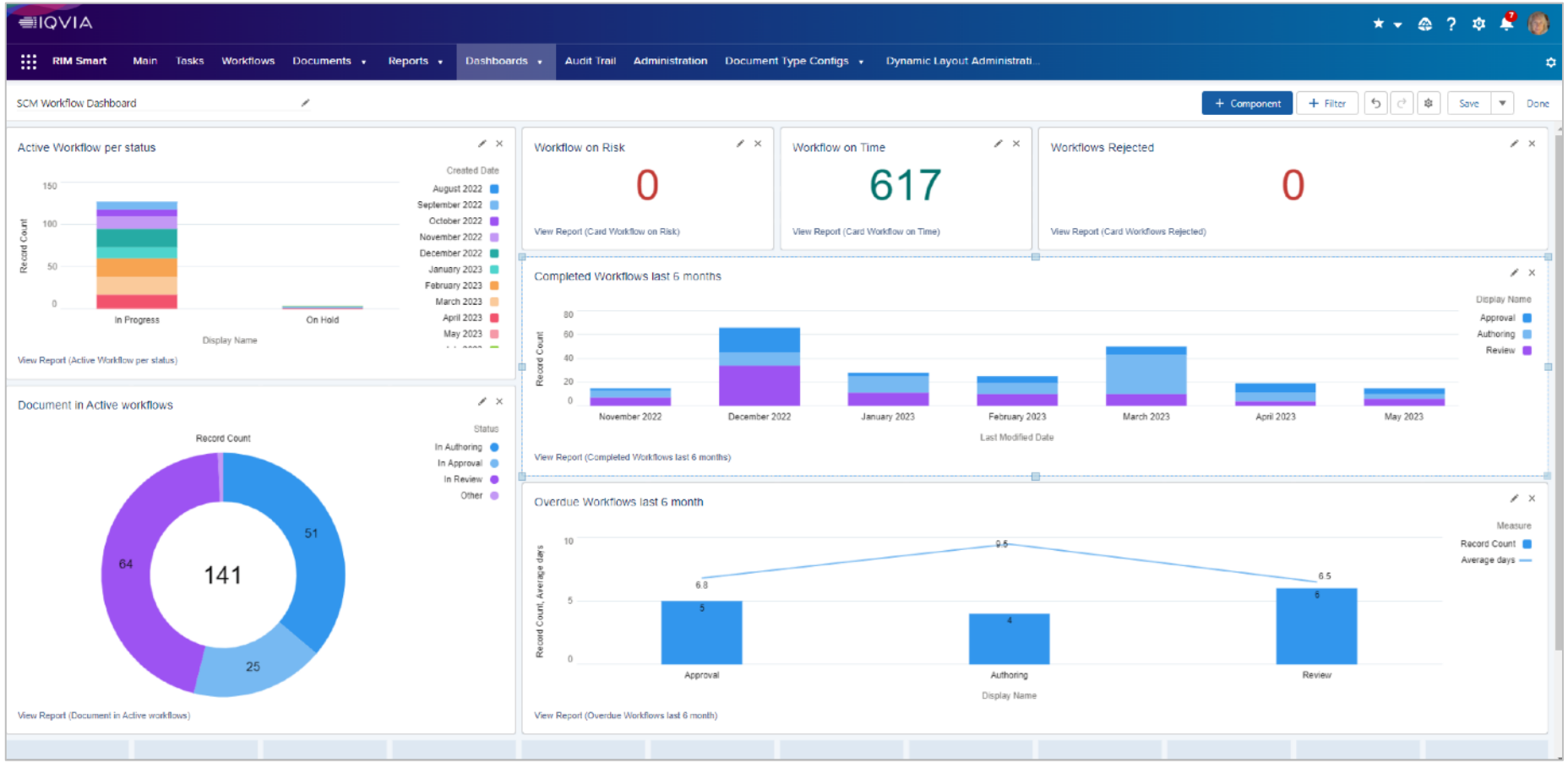
Provide teams with document oversight and traceability



- Submission by version, market, regulatory activity
- Contributors
- Task completion
- Risks to timeline

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Drive labeling and submission management in one platform

SaaS solution

Software as a service architecture manages administration and future proofs with regular new capabilities

RIM Smart platform

Built on common SalesForce platform that leverages core capabilities across the content lifecycle

Single repository

Single source of truth that eliminates risk and generates higher quality documents

Product metadata

Full relational metadata synchronized across RIM Smart including regional market and study details

Publishing and labeling

Out of the box augmented submission assembly

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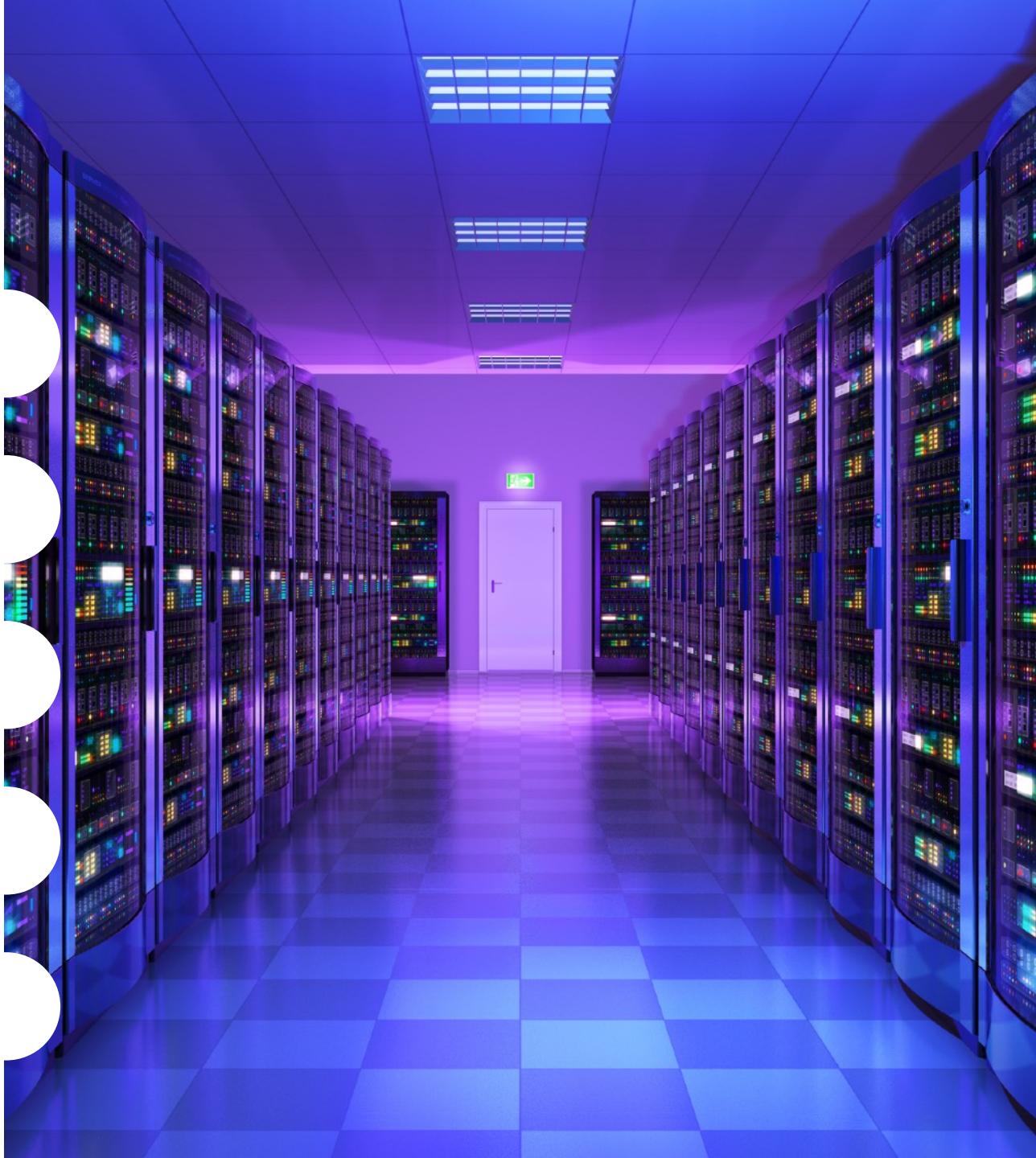
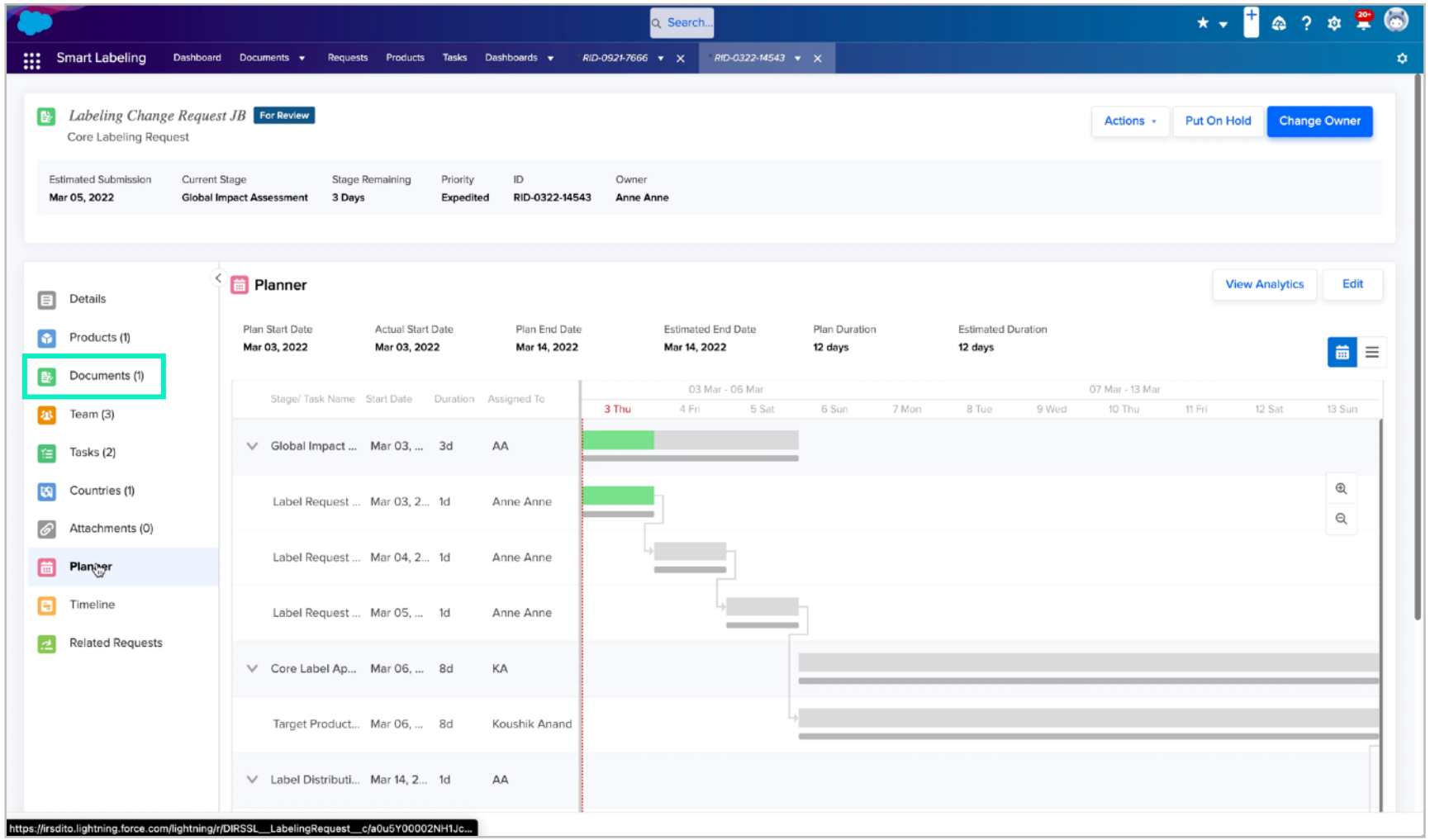
Minimize administration with a modern SaaS platform

- Three software releases per year
- Hosting services included
- Comprehensive support from IQVIA
- Scalability for large regulatory workloads
- Browser-only access for stakeholders



Support labeling and content management activities



- Monitor label and artwork activities
- Approve planned documents prior to content development
- Manage stages and tasks alongside documents
- Manage translations and relationships to original source documents
- Notify submission coordinator upon approval of label content
- Initiate change cycles upon rejection of labeling assets

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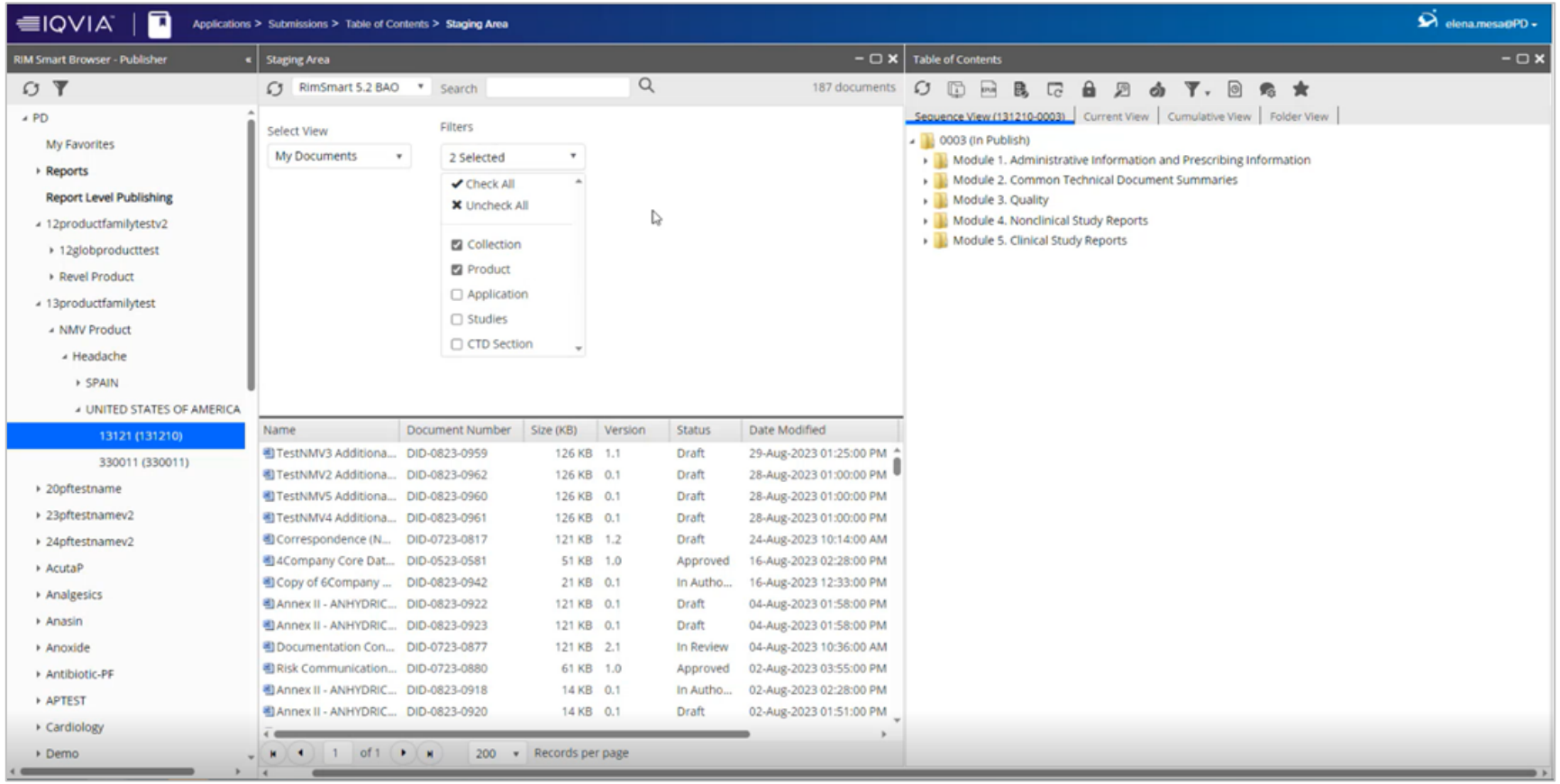
Integrate with submission content planning and publishing



- Search and filter documents in user-defined views
- Associate documents with the submission
- View reports about documents, properties, etc.
- Support hyperlink and bookmark creation documents
- Bind to specific version and rendition of a source file
- Enable and manage migration of bound documents between versions

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Advantages of RIM smart content management

- Generate **high-quality** submission content **efficiently**
- Gain **peace of mind** that regulatory content is compliant
- Simplify workflows to **accelerate time to approval**

Thank you!

(BD to insert contact info here)