Hybrid Agile Delivery Methodology – How Pfizer Meets Quality Document Compliance in a Highly Regulated Environment

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Pfizer

Agenda

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2. Overview of QDoC Modules
3. Benefits
4. DMS Process Flow
5. QDoC Innovations
6. QC Metrics
7. Demonstration
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8. Questions

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Submission Quality at Pfizer

Our purpose is grounded in our commitment to fund programs that provide public benefit, advance medical care and improve patient outcomes. Our belief is that all people deserve to live healthy lives. This drives our desire to provide access to medicines that are safe, effective, and affordable.

Document Quality and Compliance

- Performs Quality Control activities for all submissions to regulatory agencies (e.g. FDA)
- Reviews more than 1500 submission documents per year
- Provides detailed metrics for process quality improvement

QDoC Overview

QDoC is a global business platform management tool used across quality organizations. It addresses the overall quality process for the following groups:

Safety & Regulatory Quality (SRQ)
- Quality Reporting and Analytics - Individual Case Safety Report (ICSR) Quality
- Document Quality and Compliance

Vaccines Quality Control and Medical Writing Quality Team

Medical Quality Assurance (MQA) and Global Clinical Submission Quality (GCSQ)
- Reports for Submission Quality Planning
- Identification of Submissions for Audit

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Overview of QDoC Modules

QDoC has two modules:

Document Management System

The Document Review Management System (DMS) supports quality review of regulatory submission documents.

Case Management System

The Case Management System (CMS) supports quality review of Individual Case Safety Reports (ICSRs) from Pfizer's safety database.

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Benefits

Compliance - Timely support of audit and inspection request for evidence of QC

Productivity - Quality metrics reporting will be reduced from 3 weeks to 1-2 days; integrated tracking of workload/resource allocation worldwide

Function-agnostic - Supportive of business reorganizations, 2-way communication with QC target users

Technical - Flexibility to support business process changes over time; Easily extended for use by other QC groups

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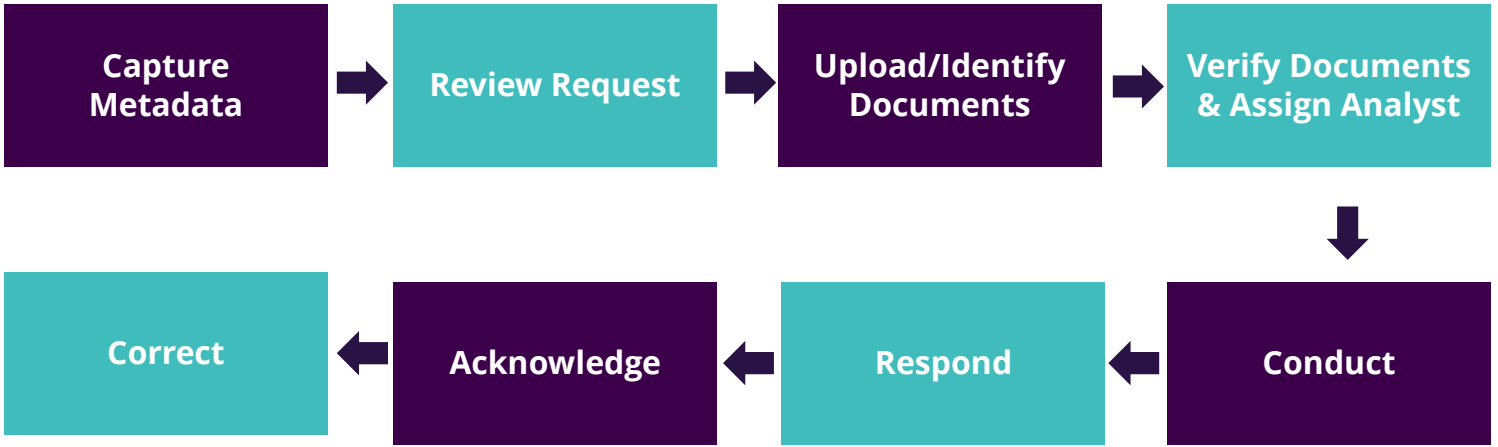
DMS Process Flow

The quality review of the regulatory submission documents is performed in eight stages.



Document Authors, Document Coordinators, Quality Analysts, and Business Admin perform various activities in each stage.

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QDoC Innovations

General Purpose Document QC

- QC Observation Categories configurable
- Supports multiple QC groups and documents
- Supports review of MS Word, Excel, PDF, and Powerpoint

Documentum Integration

- Documents for QC identified in Documentum
- QDoC uploads document directly from Documentum to PleaseReview

PleaseReview Integration

- Integrates with PleaseReview to automate creation of reviews
- Automates extraction of QC Observations and Responses
- Automates creation of QC Report

ANSI/ASQ Z1.4 Sampling

- ANSI/ASQ sampling methodology implemented in Pega
- Automated switching logic for sampling methodology

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PleaseReview

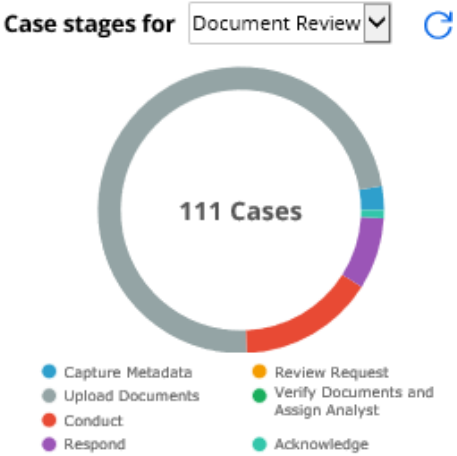
Ideagen PleaseReview is a leading in-document document review, co-authoring and redaction software application that provides:

- MS Word track changes-like interface for review and observations on Word, Excel, PowerPoint, and PDF documents.
- Ability to schedule, assign, and conduct document reviews.
- Record and store details of the review including observations, comments, and responses.

https://www.ideagen.com/products/pleasereview

Available QC Metrics

- Efficiency Metrics
  - Reviews Completed by Analyst
  - Pages Reviewed per Hour by Analyst
  - Observation Accuracy
- Document Quality Metrics
  - Observation Rate (per page) by Author
  - Observation Rate by Category
- Trending Metrics
  - Observation Category



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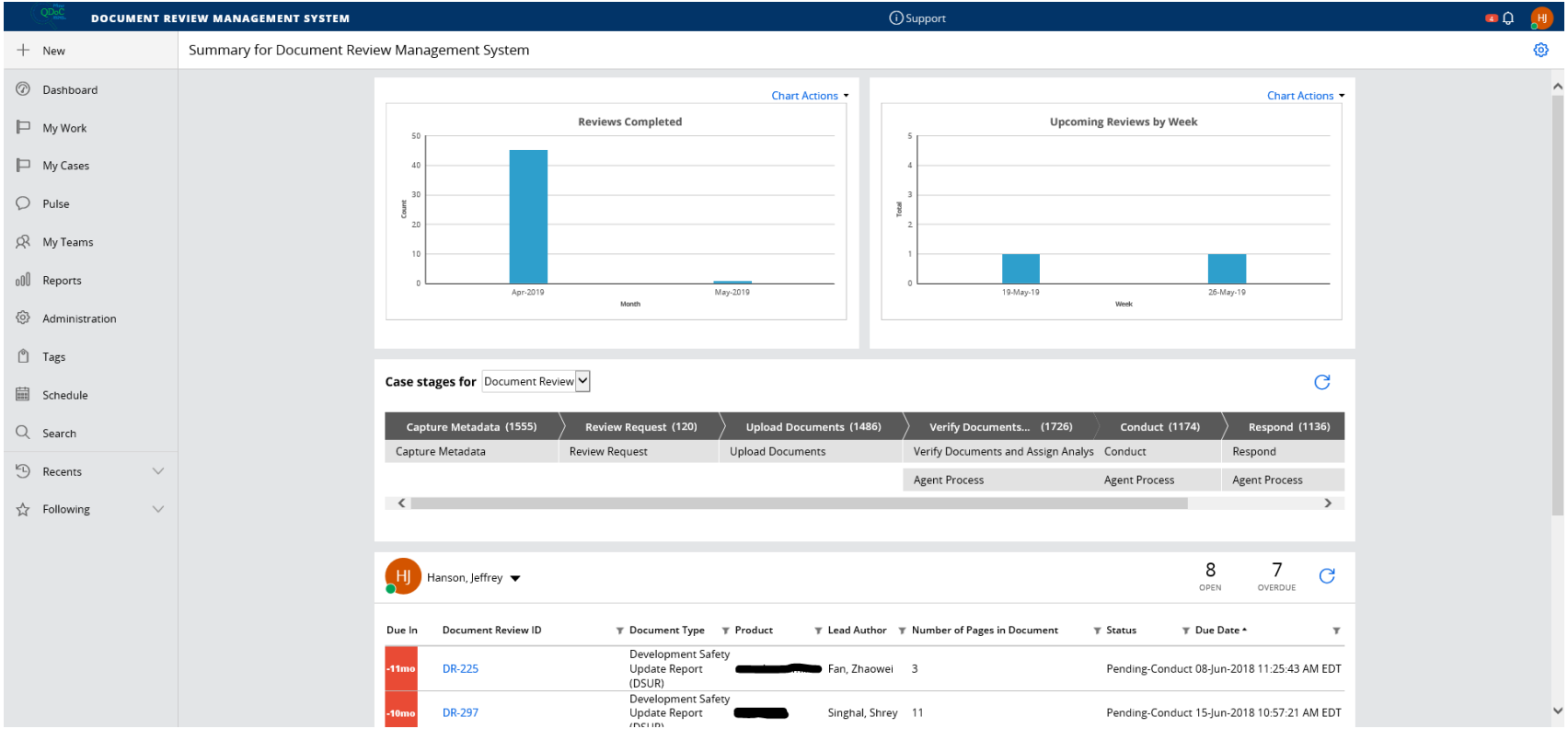
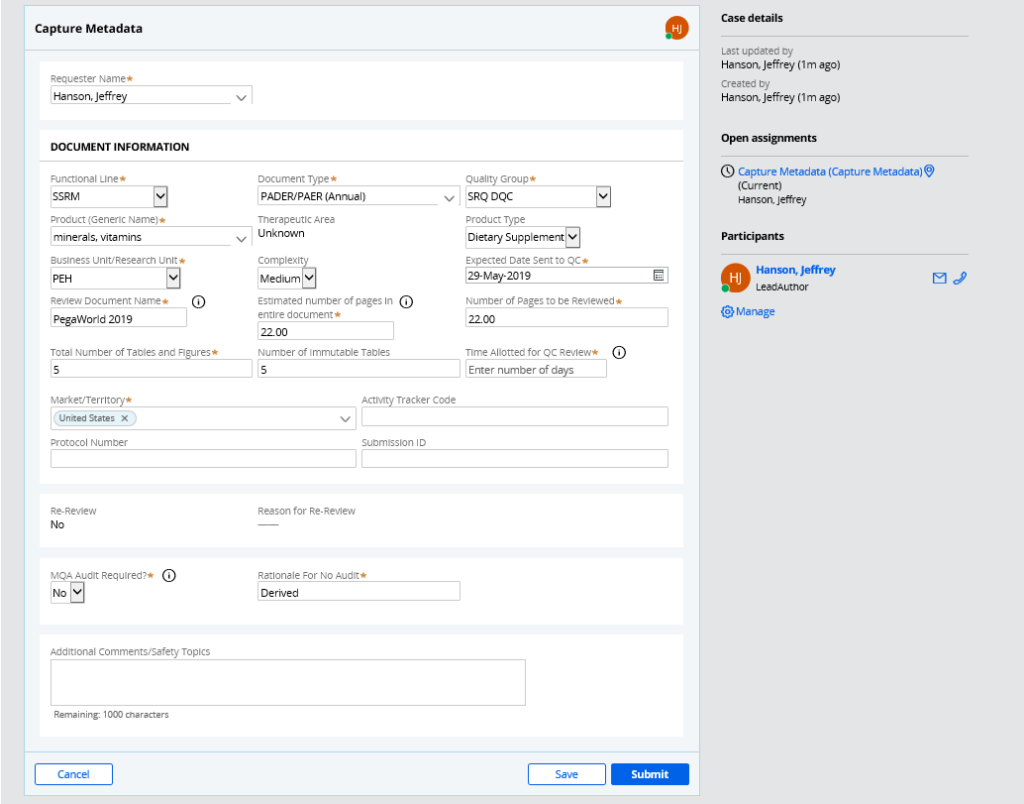
DEMONSTRATION

Slides 12 to 23 are backup slides instead of live demo in case of issues

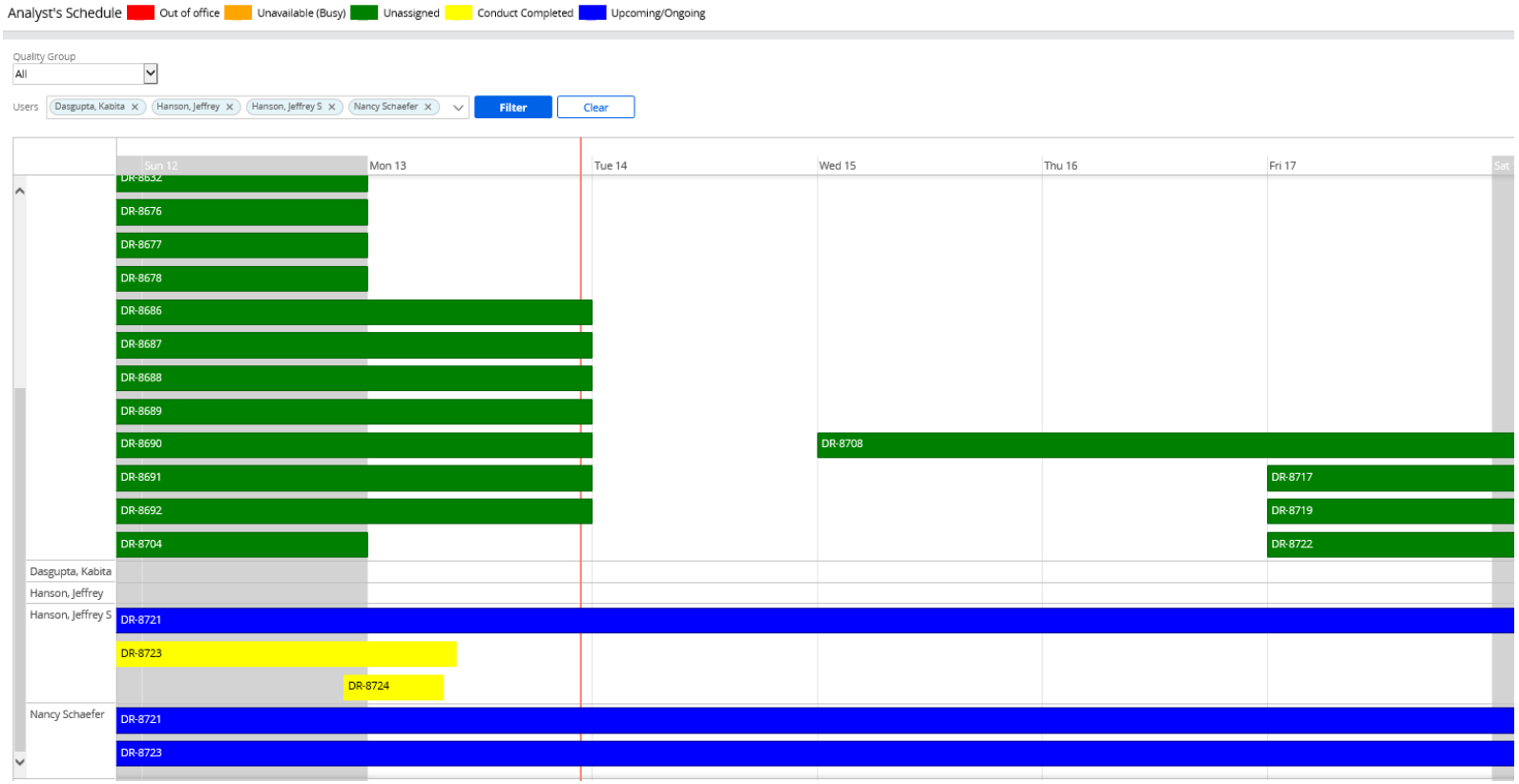
QDoC Landing Page - Dashboards



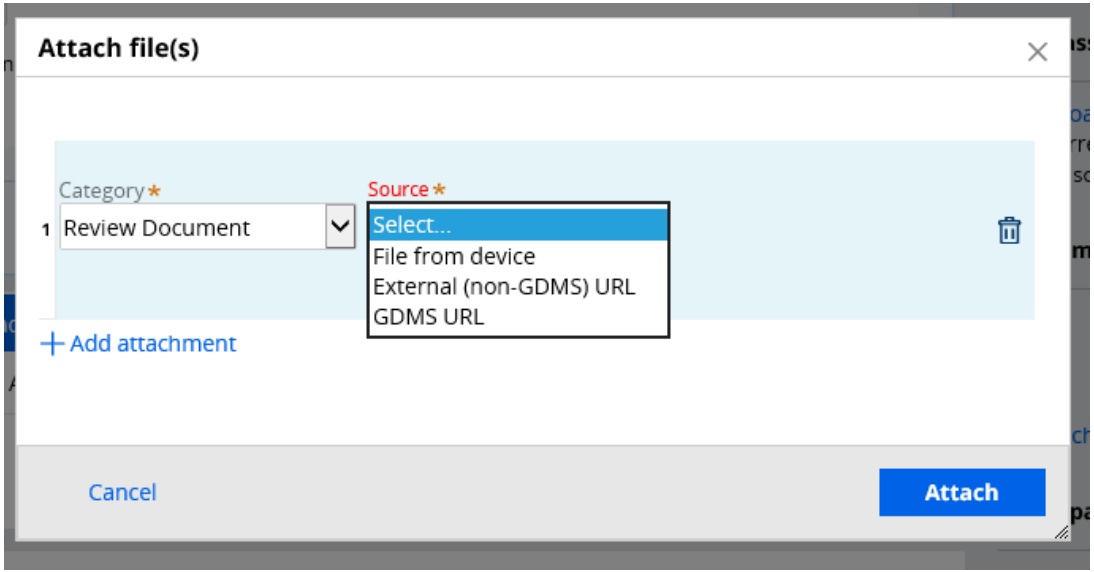
Create New Document Review Request



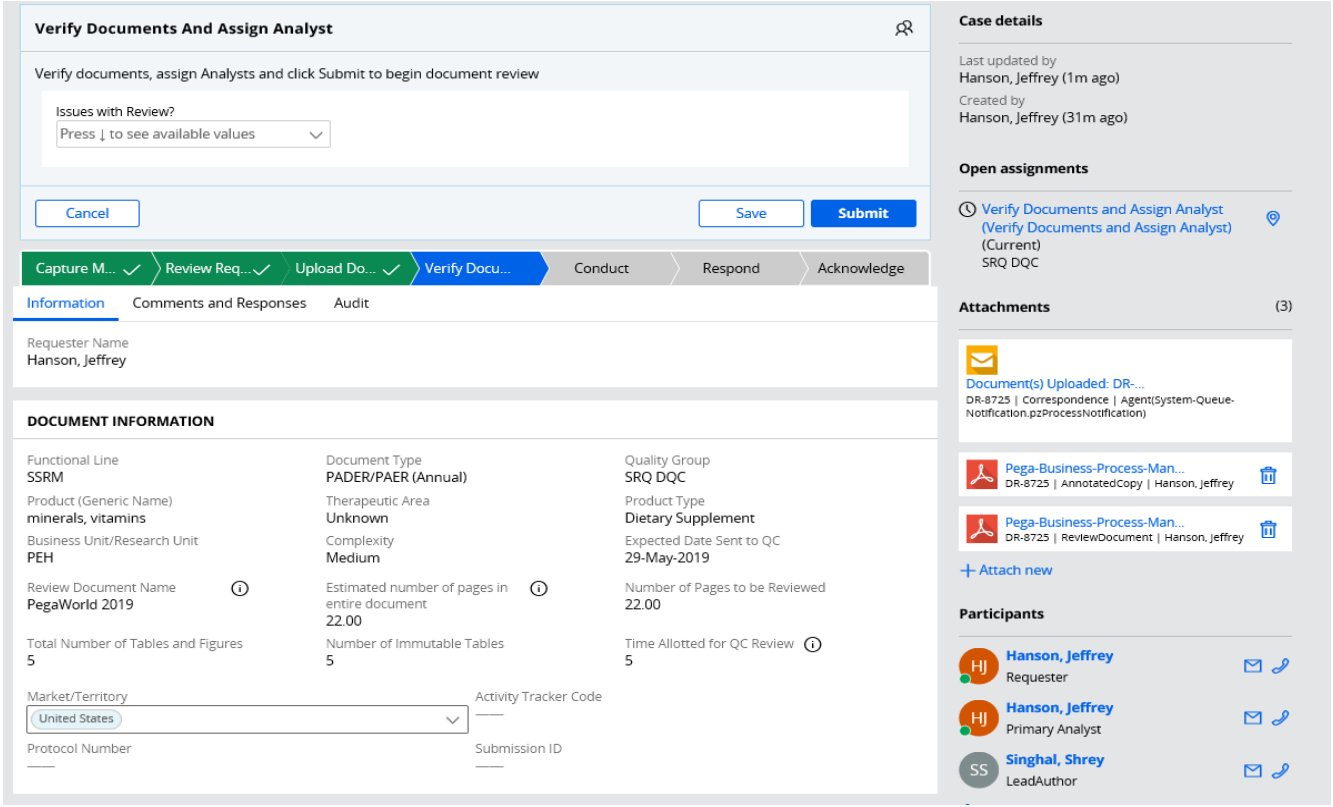
QDoC Schedule View



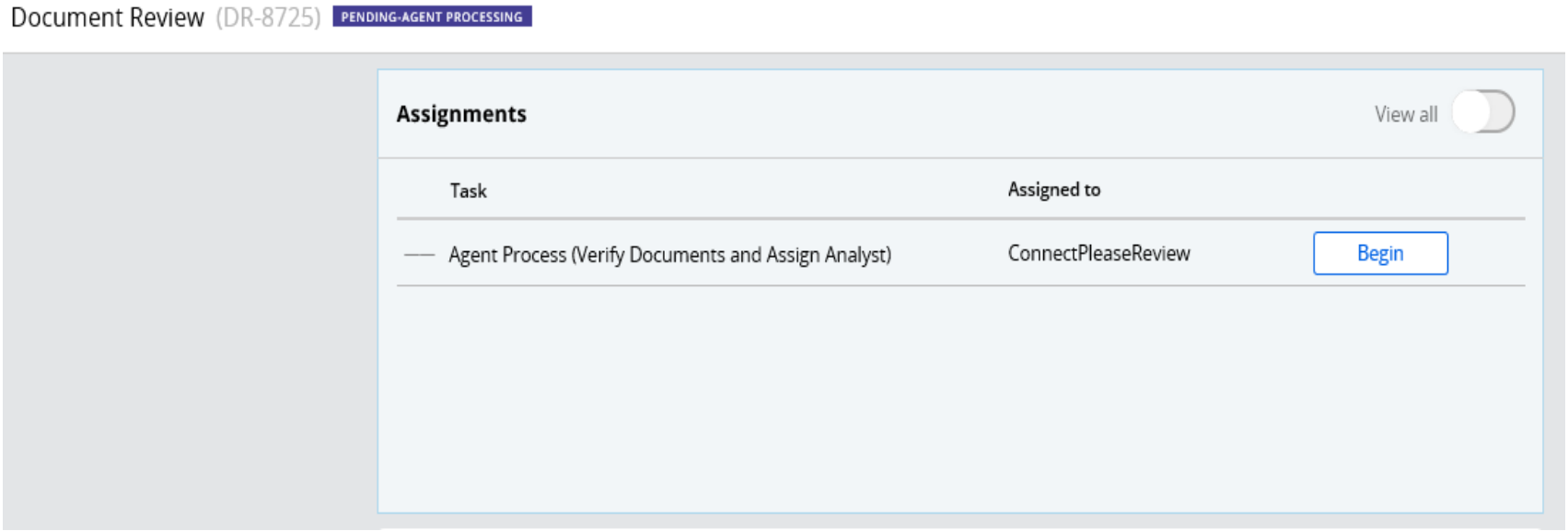
QDoC – Upload Documents



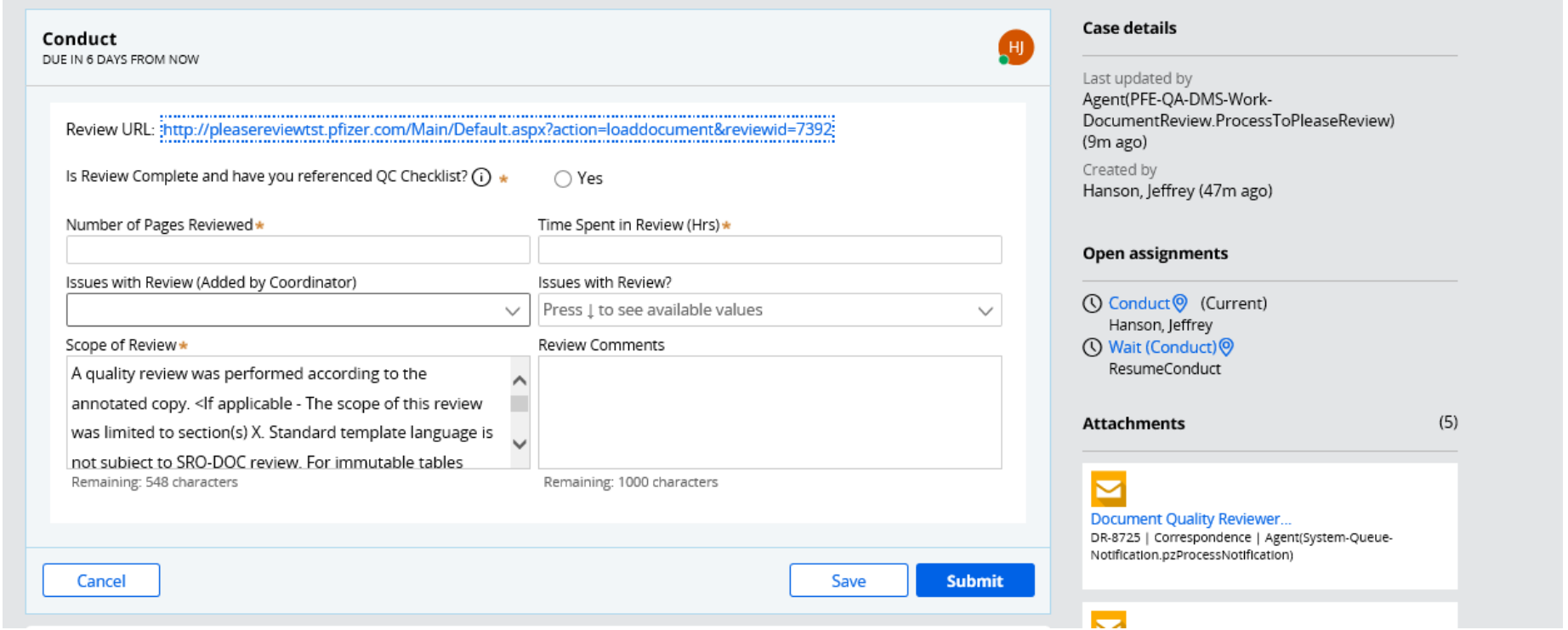
QDoC – PleaseReview Integration



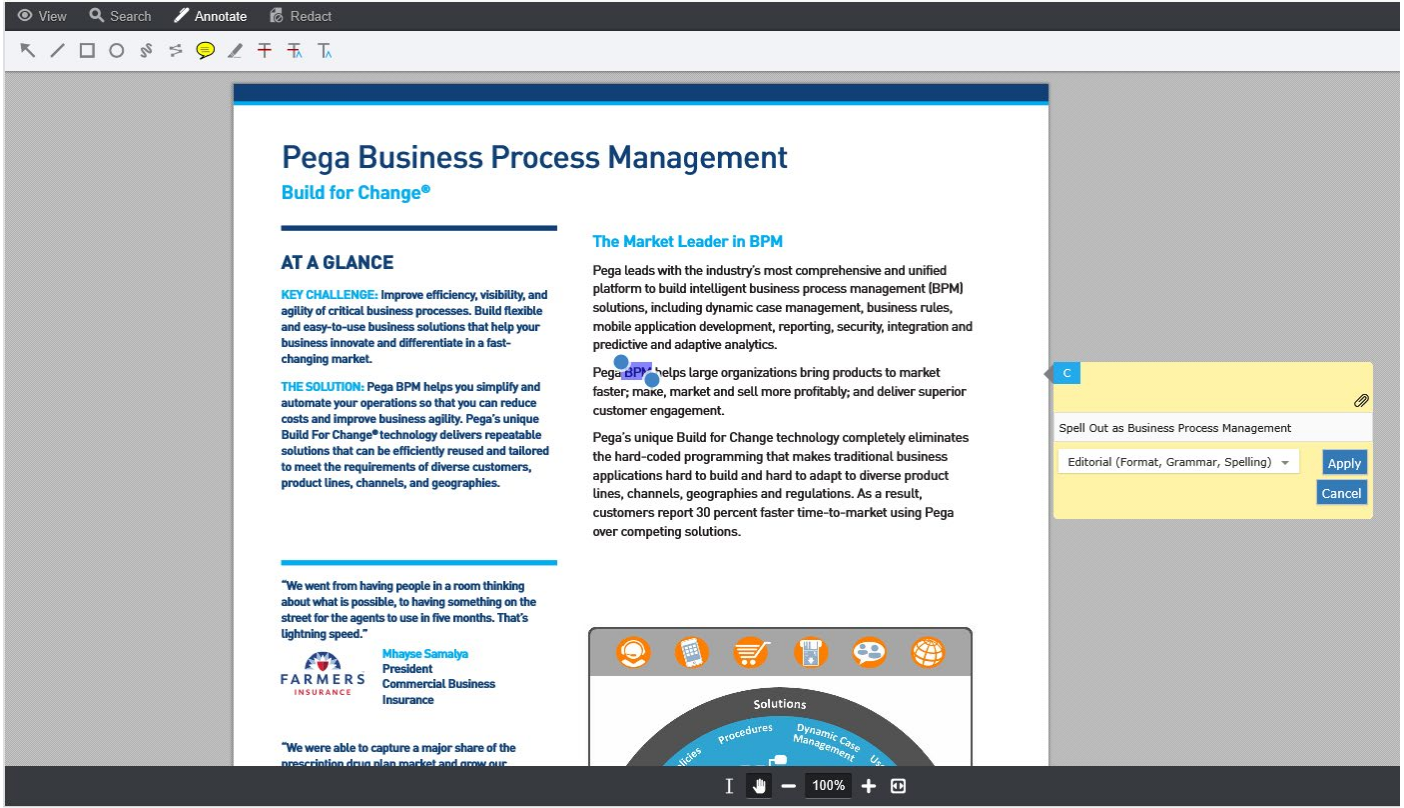
QDoC – PleaseReview Integration



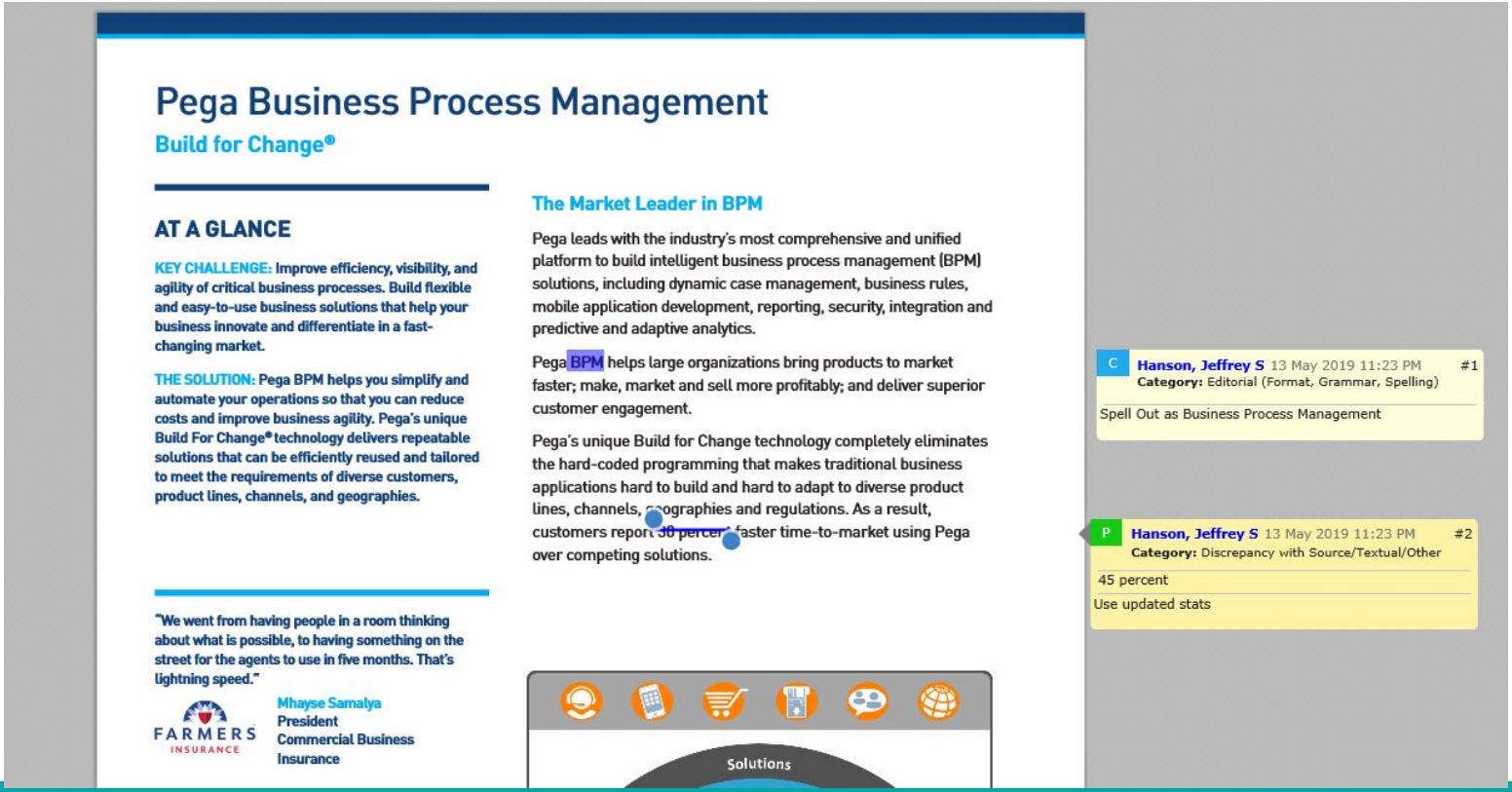
QDoC – PleaseReview Integration



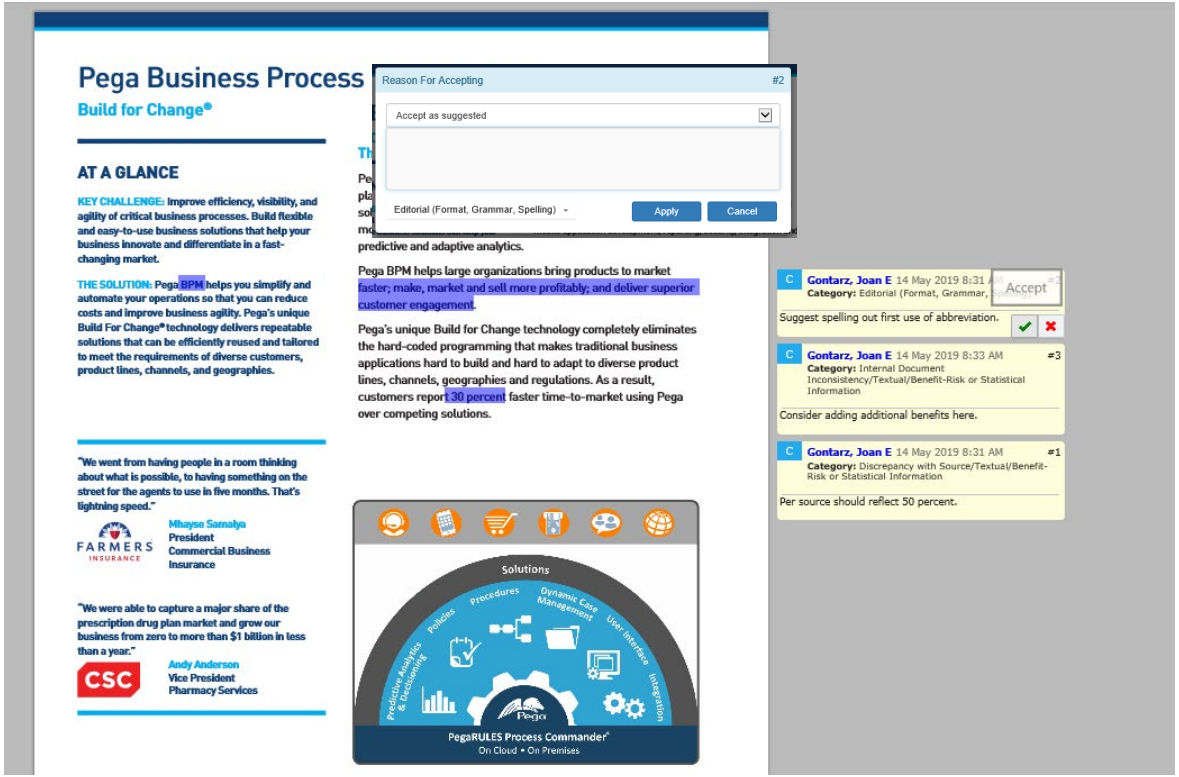
PleaseReview Interface - Comment



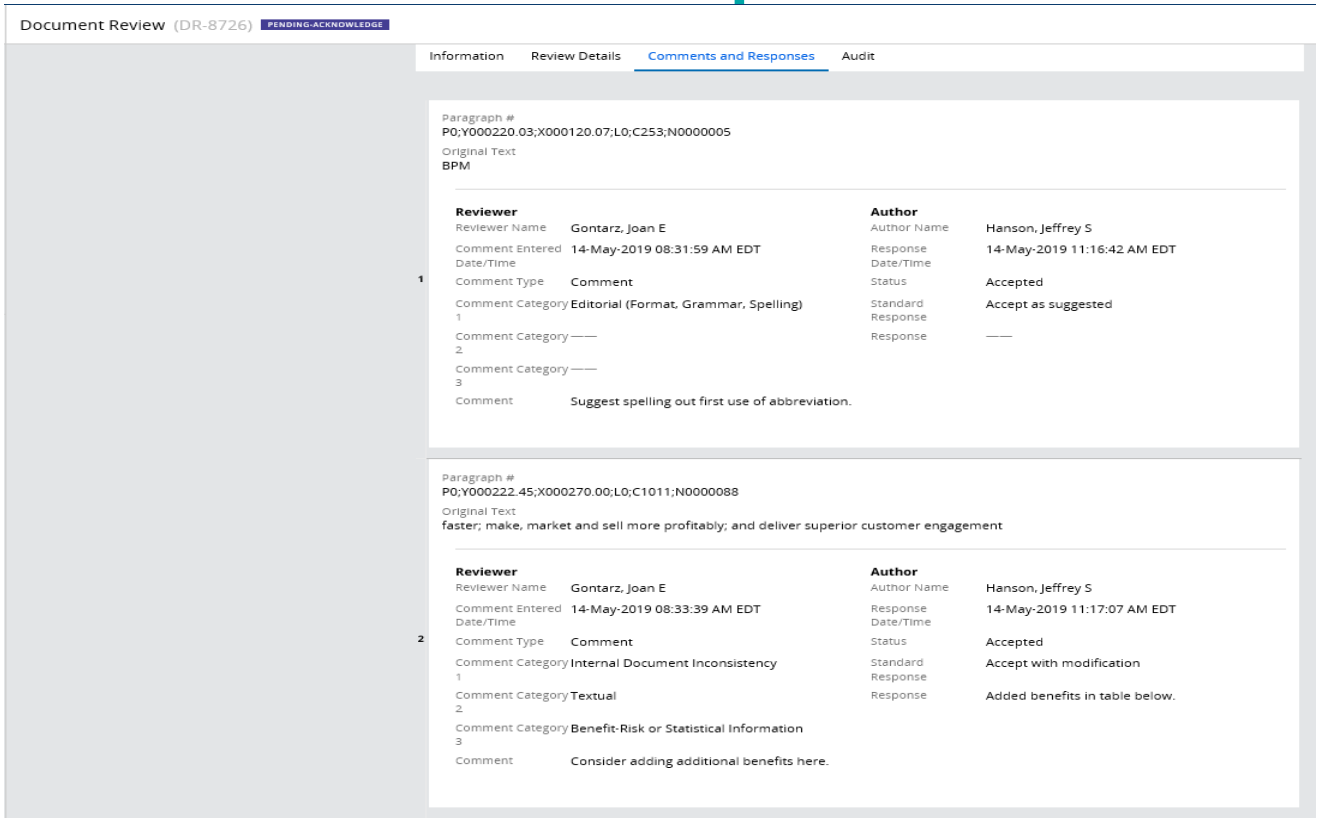
PleaseReview Interface – Proposed Change



PleaseReview Interface - Respond



PleaseReview Interface – Import Observations



Sample Metrics Report

Filtered by: **Review Completion Date = Previous month** and **Any Functional Line** and **Any Document Type** and **Quality Group = SRQ DQC**

Collapse all group headings

Functional Line	Document Type	Total Documents	Re-Review/Related Review	Total Unique Docs	Total Number of Pages Reviewed	Accepted (excluding Editorial and Source not Provided)	Not Accepted (excluding Editorial and Source not Provided)	Total (excluding Editorial and Source not Provided)	Total Hours	Accepted (Editorial)	Not Accepted (Editorial)	Total Editorial	Accepted (Source not Provided)	Not Accepted (Source not Provided)	Total Source not Provided
⌄ALL		45	4	41	179	17	9	26	182	8	8	16	9	8	17
⌄Epidemiology		6	0	6	57	2	1	3	62	1	2	3	3	0	3
	3/4 Month Safe...	4	0	4	48	2	1	3	38	0	1	1	2	0	2
	Clinical Overvie...	1	0	1	5	0	0	0	20	1	1	2	0	0	0
	PADER (Annual)	1	0	1	4	0	0	0	4	0	0	0	1	0	1
⌄PSSR		24	4	20	46	14	8	22	36	7	5	12	6	8	14
	3/4 Month Safe...	4	0	4	8	3	3	6	2	2	2	4	2	2	4
	Bridging Docu...	8	3	5	10	4	3	7	5.5	4	1	5	2	2	4
	Briefing Docum...	7	1	6	10	6	0	6	8	0	1	1	2	1	3
	Clinical Overvie...	2	0	2	12	1	1	2	13	1	0	1	0	1	1
	PADER (Annual)	2	0	2	4	0	1	1	5	0	1	1	0	1	1
	PADER/PAER (A...	1	0	1	2	0	0	0	2.5	0	0	0	0	1	1
⌄SSRM		15	0	15	76	1	0	1	84	0	1	1	0	0	0
	Briefing Docum...	1	0	1	1	1	0	1	1	0	1	1	0	0	0
	Clinical Overvie...	12	0	12	65	0	0	0	61	0	0	0	0	0	0
	Clinical Study R...	2	0	2	10	0	0	0	22	0	0	0	0	0	0

Future QDoC Enhancements

- Integration with Pega-Based application for regulatory document triggering and authoring (COMPASS)
- AI-Based automated Quality Control:
  - Automated QC Checks of tabular data in documents against sources
  - Automated QC Checks of textual narratives against source data
  - Automated creation of textual narratives using source data
- Further integration with document repository (Documentum)
- Integration with Pfizer's Quality Management System (QMS)

Why choose Pega?

Flexibility and ability to address change

Life Sciences Framework - Provides built-in, robust audit trail

Past implementation success at Pfizer

Integration Capabilities

Hybrid Agile approach to development

- Allows for adjustment through development process
- Reduces development time

Process-centric approach to implementation

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Questions


PEGA®
Build for Change®