E-BOOK

Ideagen
Solutions for regulated industries

IMPROVING

Document Co-authoring & Review Practices

in Highly Regulated Industries

Contents

For every 100 hours spent on a document review, 65 hours are typically wasted unnecessarily on tasks that can now be either automated or eliminated.

Pharmaceutical companies generate thousands of documents while bringing new medicines to market. These documents must be correctly recorded, reviewed, and managed—meeting Big Pharma regulatory compliance is essential to ensuring that all medicines are efficient and safe.

Individual professionals and management teams play an integral role in **ensuring documents are of a high standard, meet deadlines** and **comply with industry regulations**. This is true in highly regulated industries such as pharmaceuticals, medical devices, clinical research, biotechnology, government, aerospace and defence, construction and business services. However, **document review practices** in these industries are often **complex, time-consuming, and frustrating**. This is typically because organisations' **internal processes are poorly managed and outdated**.

In this guide, we look at **how to enhance the value** and **increase the efficiency of document reviews** by using software that **automates laborious and time-consuming tasks**. We will consider how highly regulated industries– globally, can implement a simple technology solution to **reduce their document review times by 65%** and therefore **cut costs associated with the review by 35%**.

When adopting a new technology solution, time and cost savings are tangible indicators of ROI (return on investment). However, we will also explore the less tangible—but equally important—benefits of improving document review practices: the enhanced quality, focus and transparency of reviews. We will examine real-life examples of **leaders that have invested in the digital transformation of their document review practices** and explore how **you can draw on their key learnings** within your organisation.

The document owner's headache

You're working on a document with lots of other people. The deadline is fast approaching. The inquisitive eye of the auditor looms large in your mind. There is an urgency to finish, click send and meet the deadline. Yet nagging voices in your head cause you to falter and lose confidence: your neck is on the line because you're accountable for the final document's quality, compliance and accuracy.

You're not alone. Document owners frequently worry about the following things:

Version control and duplication of work

- Is this definitely the final version of the document?
- Where are we saving the final version and what is it called again?
- At least twenty people have sent me the same comment on separate versions of the same document: are we losing a colossal amount of time due to the duplication of work?

Consolidating edits from multiple people

- Did I lose or misplace any other colleagues' feedback?
- Did I incorporate all of Smith's edits? And what about Taylor's?

Tracing of document activity for audits

- Did I accurately record all the relevant changes in my report for auditors?

Managing a high volume of reviewers (internal & external)

- Most review platforms do not support more than 3-4 people working in real-time on a document without slowing down or crashing.
- Am I allowed to ask external stakeholders to review the document within this platform and, if so, will it take a long time to get them access?

Quality and accuracy of the document

- Has the text been written to a high standard? Are there any problems with spelling or grammar?
- Are we positioning the case, ideas or information in a clear, readable and persuasive manner?

Compliance with industry standards

- Has the relevant style been used and is it consistent across the document?
- Have I included all the necessary information?
- Are there any plagiarism or copyright concerns?

Getting signoffs from subject matter experts

- Has the specialist for x definitely seen this section and signed it off? Are you sure?

Disputes on comments and feedback

- Will Jones be annoyed when she realises that her comments were not incorporated? Did I explain to her why the changes were rejected—and what were they again?

Protecting your organization's sensitive data

- Has all the commercially confidential information been redacted?
- I sent an earlier version of the manuscript to external stakeholders: is my organisation's sensitive data protected?

In the following pages, we explore how leaders within highly regulated industries are using simultaneous document review software to eliminate their document headaches.

PHARMACEUTICAL, MEDICAL DEVICE AND CLINICAL RESEARCH

Drug and medical device development is document-intensive work.

There are different rulings and standards in the EU, USA, UK, and other regions that must be met when developing drugs and medical devices. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the British Medicines and Healthcare Products Regulatory Agency (MHRA), oversee these exact requirements in the respected countries.

In the US, the Food and Drug Administration (FDA) is responsible for assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.

From concept to approval and beyond, the development of pharmaceuticals and medical devices follows well-established pathways to ensure that they are safe and effective.

The FDA:

- Reviews research data and information about drugs and devices before they become available to the public.
- Monitors for drug problems once drugs and devices are available to the public.
- Monitors drug information and advertising.
- Protects drug quality.

The MHRA:

- Ensures that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- Ensures that the supply chain for medicines, medical devices and blood components is safe and secure
- Promotes international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- Helps to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- Supports innovation and research and development that's beneficial to public health
- Influences UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health

With around 1,300 employees across England, the MHRA regulates medicine, medical devices, and blood donations for transfusions in the country. It plays a vital role in protecting and maintaining public health, supporting research and development, as well as operating the Clinical Practice Research Datalink (CPRD) and the National Institute for Biological Standards and Control (NIBSC).

Review and approval processes

Each regulatory body has their own process of review and approval of newly developed medical devices or drugs. When it comes to the development of new drugs, the FDA requires an Investigational New Drug (IND) application as the first step for any pharmaceutical company on their journey to getting a new drug to market. After an IND application has been approved, and clinical trials have been completed, a formal request to market the drug must be made in the form of a New Drug Application (NDA). NDAs give the full story of a drug. Its aim is to demonstrate the efficacy of the drug and that it is safe to use in the population for which it studied.

In an NDA, the drug developer must include data from preclinical testing through Phase 3 trials. This means that all studies, data, and analyses must be reported.

Following FDA approval of a drug, the FDA works with the applicant to develop and refine prescribing information, known as 'labelling'.

It is expected that a high volume of stakeholders collaborates on the **IND**, the **NDA** and the **"labelling"**—it's arduous, **complex and time-consuming work**.

Technology and innovation is transforming the traditional and highly-regulated world of pharma and healthcare

A proven tool for life science organisations

Ideagen PleaseReview has been highly adopted by the life science sector, where it is important for document to comply with sector regulations and standards. It is trusted by companies across the world, including:

Lexicon Pharmaceuticals, Translate Bio, Pharmacyclics, uniQure, Vertex, Acorda Therapeutics, Alnylam, Galderma, Serapta Therapeutics, Prolong Pharmaceuticals and more.

While the bringing of a new drug to market **typically takes several years**, Pharmaceutical, Medical Device and Clinical Research companies are leveraging the power of technology to **streamline document reviews** and **get their market authorisation applications approved in record time**.

Keeping up with digital technologies is imperative for life science organisations as the world moves rapidly towards digitalisation.

As documentation is a vital part of quality assurance, good documentation practices are required. Documentation should be prepared, checked, verified, issued, stored, and reviewed in a systematic manner.

Implementing real-time document review software is an excellent return on investment for these organisations. Teams deliver not only higher quality documents in a shorter timescale, but also achieve significant time (and therefore cost) savings for all involved in the document review process.

Accelerating the pace of document collaboration during COVID-19

During the pandemic, the World Health Organisation used Ideagen PleaseReview, real-time document review software, to coordinate its global response. The top five COVID-19 vaccines were also brought to market in record time with the help of the software.

Key benefits of a simultaneous document review tool:

- Real-time review
- Stable review environment
- High volume of users
- Controlled external collaboration
- High user adoption
- Audit-ready report
- Comply with standards (e.g., CFR Part 11)
- Support Word, PDFs, PPT, Excel and more
- Keep sensitive data secure
- Simplify comment resolution meetings

An integrated solution

An integrated solution

The development and manufacturing of drugs require continuous cross-functional collaboration on documents in order to produce a quality product. As close collaboration between employees from various departments is a prerequisite, implementing an integrated and centralised solution allows your team to work simultaneously in one simplified workflow, making every hour count.

Ideagen PleaseReview has partnered with Veeva to offer customers the ability to collaborate on large documents with very high-volume teams—all from within Vault.

You can now use PleaseReview from within Veeva Vault to streamline document reviews into one simple workflow.

How it works:

Specify

The Review Owner specifies the document(s) to be reviewed, the deadline and the participants. They can also lock-in sections of the document for review by assigned users.

Invite

Veeva Vault participants are assigned a Vault task inviting them to the review; non Veeva Vault participants receive an email invitation (all they need is an email to log in).

Edit

Once in the review, the reviewer can see other participants' comments and proposed changes (if their permissions grant them visibility). They can then add their own edits and/or reply to others' comments.

Review

The Review Owner can reply, accept or reject comments and proposed changes.

Incorporate

All accepted changes are automatically incorporated into the document.

Check-In

Reviewed documents are then checked back into the Vault as a new version

In our experience, co-authoring in Word performs better with smaller files (less than 100 pages) and small teams (5-10 authors) [...] PleaseReview may be a better solution if you are collaborating with large groups of reviewers and looking to maintain a very high level of control over the document and the review process.

'Vault Collaborative Authoring with Microsoft Office FAQ', Veeva Systems

GOVERNMENT & PUBLIC SECTOR

In a similar manner to the Pharmaceutical, Medical Device and Clinical Research sectors, government and public service entities have embraced technology to streamline, secure and improve the way they collaborate on sensitive documents. For example, these could be policy documents, annual reports, legislation, proposals or working papers.

Simultaneous document review software for high volume teams is particularly useful for teams with multiple stakeholders that need to work on a single document at the same time—even across organisational boundaries. Specialist review platforms for high volume teams are already used by many government departments across Europe and the US because of their robust security and ability to protect confidential work from external threats.

CASE STUDY :
The International Energy Agency

The International Energy Agency (IEA) implemented Ideagen PleaseReview to help manage their extensive peer review process, which involved around 400 participants. PleaseReview enables them to collect and save comments and feedback in a structured way, ensuring nothing is lost and that each reviewer is working with the most recent version. This has saved IEA a significant amount of time and provided a much easier way of operating.

> We receive about 1200 comments for the draft report and PleaseReview's final report lets us see all the consolidated comments in less than a minute. We save a lot of time by using PleaseReview. The benefits to us have been immediate.

Heymi Bahar - Renewable Energy Markets Analyst and Project Manager, IEA

Three key benefits of document review software for the Government and Public Sector -

1. Version control

Several people can work on the same document at the same time in PleaseReview without feedback being lost or overwritten. Everyone works on a single version of the document, thus giving you a single source of the truth. Because conversations are brought away from email and into the platform itself, the document owner spends much less time on chasing contributions and consolidating different versions of a document.

2. Automatically capture all activity for audits

If your documents are typically scrutinised by senior figures, regulators or auditors, document review software can help you feel more in control and confident about your activities. The document owner has full visibility of all activity that takes places within a document preparation cycle, including who has edited what and when. This can be captured and displayed in a detailed reconciliation report within minutes. If the document owner receives questions from an auditor or regulator about the content of a completed document, the report allows them to see quickly who made what contribution and when, as well as review any in-document conversations that were had about the queried content.

3. Collaborate securely with third parties.

When collaborating with people outside of your organisation, they can easily be added to your project in PleaseReview. The document owner can control which documents they can access, how much of the document they can see and what they can do within it. This makes it a highly secure environment when working on sensitive information.

AEROSPACE AND DEFENCE

Save time on sensitive, time-critical documents.

A significant challenge facing Aerospace and Defence organisations is facilitating collaboration across geographically dispersed teams and complying with regulations. Document collaboration in this industry can require a lot of resource and take many weeks to complete. These include areas like intelligence, operations, logistics and planning.

CASE STUDY : The US Navy

The Challenge

Navy Doctrine Library System (NDLS) found themselves needing a better tool to develop and revise Navy doctrine. Frustrated by reading through lengthy emails searching for relevant comments amid the background clutter of administrative remarks, NDLS needed an off-the-shelf collaboration process to increase productivity and save time.

NDLS had the capability for uploading Word documents for online review and commenting. The system was designed to maximize collaboration during the review process, but the document import process was clunky and labor-intensive requiring multiple manual entries and many steps that took days to complete.

Benefits of adopting simultaneous document review software

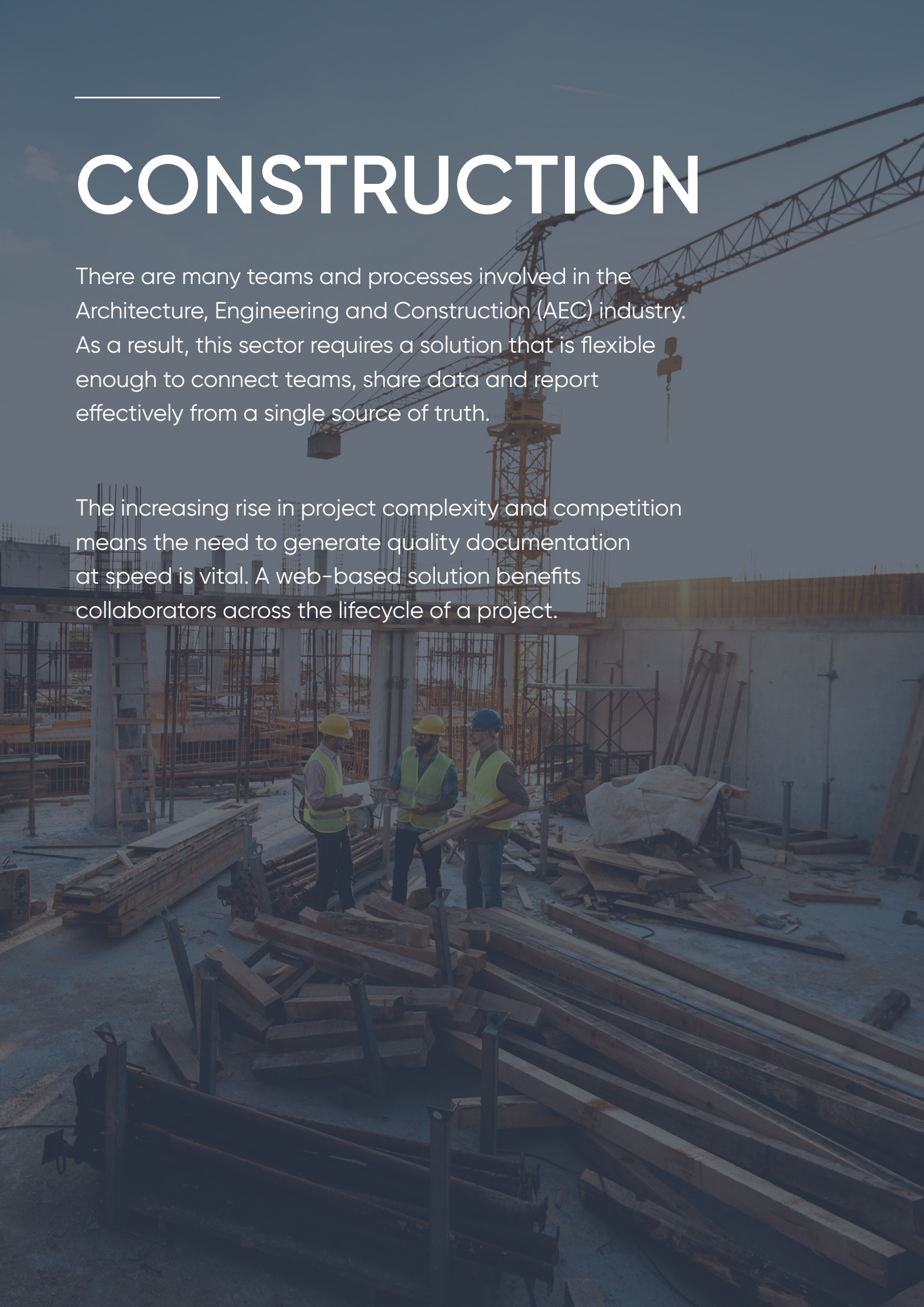
- Increases productivity with reviewers working on the same document at the same time.
- Improves transparency by letting reviewers see and respond to each other.
- Removes bottlenecks with a complete record of all comments and changes.
- Cut timelines for the review process in half to between one to three weeks and has cut the operating costs of the previous system in half.

> Now stakeholders can work on the same document simultaneously which increases productivity and saves time.
>
> **Roger Webster** - Program Manager NWDC Navy Doctrine Library

CONSTRUCTION

There are many teams and processes involved in the Architecture, Engineering and Construction (AEC) industry. As a result, this sector requires a solution that is flexible enough to connect teams, share data and report effectively from a single source of truth.

The increasing rise in project complexity and competition means the need to generate quality documentation at speed is vital. A web-based solution benefits collaborators across the lifecycle of a project.



How Construction firms have transformed their document review practices

1. Version control and high-volume teams

When files are downloaded via email or FTP (file transfer protocol), they are not live documents. This can lead to confusion as contributors are unsure if they are working on the most up-to-date version of a file. This can lead to work being duplicated or lost, while also causing workers to lose motivation if they feel that their feedback might be overlooked.

Document review software fit for highly regulated industries, such as Ideagen PleaseReview, enables teams to come together in a secure workspace to collaborate on a single version of a document. This means they can ensure everyone is working on the latest and greatest version of a file and not miss anyone's changes.

2. Collaboration with third parties

Within AEC, workers can typically waste 4-5 hours on waiting to get the right access to a document, such as a bid or proposal manuscript, an RFP, a tenant dossier or property maintenance file. If time is lost waiting for the right person to have the right access, this means that work is delayed—and this can impact the quality of your finished document.

With a web-based, real-time document review solution, the end user is in control and can access the right document in seconds. This means that teams can give access to whoever needs it within seconds. All that is needed is the contact's email address.

3. Bids and proposals

Ideagen PleaseReview makes it easy to have in-document conversations about concerns, questions for the customer, recommendations and guidance. You can review the RFP (Request for Proposals) with all stakeholders in one place and ensure everyone is aligned on business-winning actions.

- Everyone reviews in their own time, anywhere
- Contributions are not lost or overwritten
- In-document conversations enhance creativity
- Makes it easy to gather stakeholder input and collaborate

- Everyone's comments captured and displayed with equal importance
- Visibility of comments leads to better quality contributions
- Manage conflicting feedback more easily
- Helps you justify why edits were accepted or rejected

A leading proposal manager has reduced her admin time by 95%

> Simultaneous document review software "saves me so much time by automating manual preparation and improves document control. It also makes it much easier for multiple people to review a document and helps me track who has started the review and what comments are being made. It would be hard to go back to "old school" proposal reviews..."

Carrie Ratcliff - Managing Director, 21rw.

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PleaseReview

Reimagine document reviews with Ideagen PleaseReview

Real-time document review, co-authoring and redaction software for highly regulated industries. Proven to **streamline review times by 65%** and **cut costs by 35%** with a **full audit trail**.

G2 highlight - **4.7 out of 5**

Read our reviews on

> State-of-the-art review tool. The real-time collaborative aspect, transparency, and ease of use for audits...It will change your life.
>
> **G2 reviewer** - Biotechnology company, <1000 employees

A proven cost-effective solution

Ideagen PleaseReview is a proven cost-effective solution for the document review and co-authoring process, providing an excellent return on investment.

Organisations deliver not only higher quality documents in a shorter timescale, but also achieve significant time (and therefore cost) savings for all involved in the document review process.

Ideagen

PleaseReview

Loved by highly regulated industries

PleaseReview has been highly adopted in the Life Sciences industry, along with Military, Government, Utilities, Energy, Technology and other market sectors where maintaining document compliance and other regulatory requirements is of importance.

Used by:

85% of the top 25 global pharma companies	4/5 4 out of the top 5 CROs
4/5 4 out of the top 5 medical device companies	4/5 4 out of the top 5 defense contractors

Request a demo

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Solutions for regulated industries

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