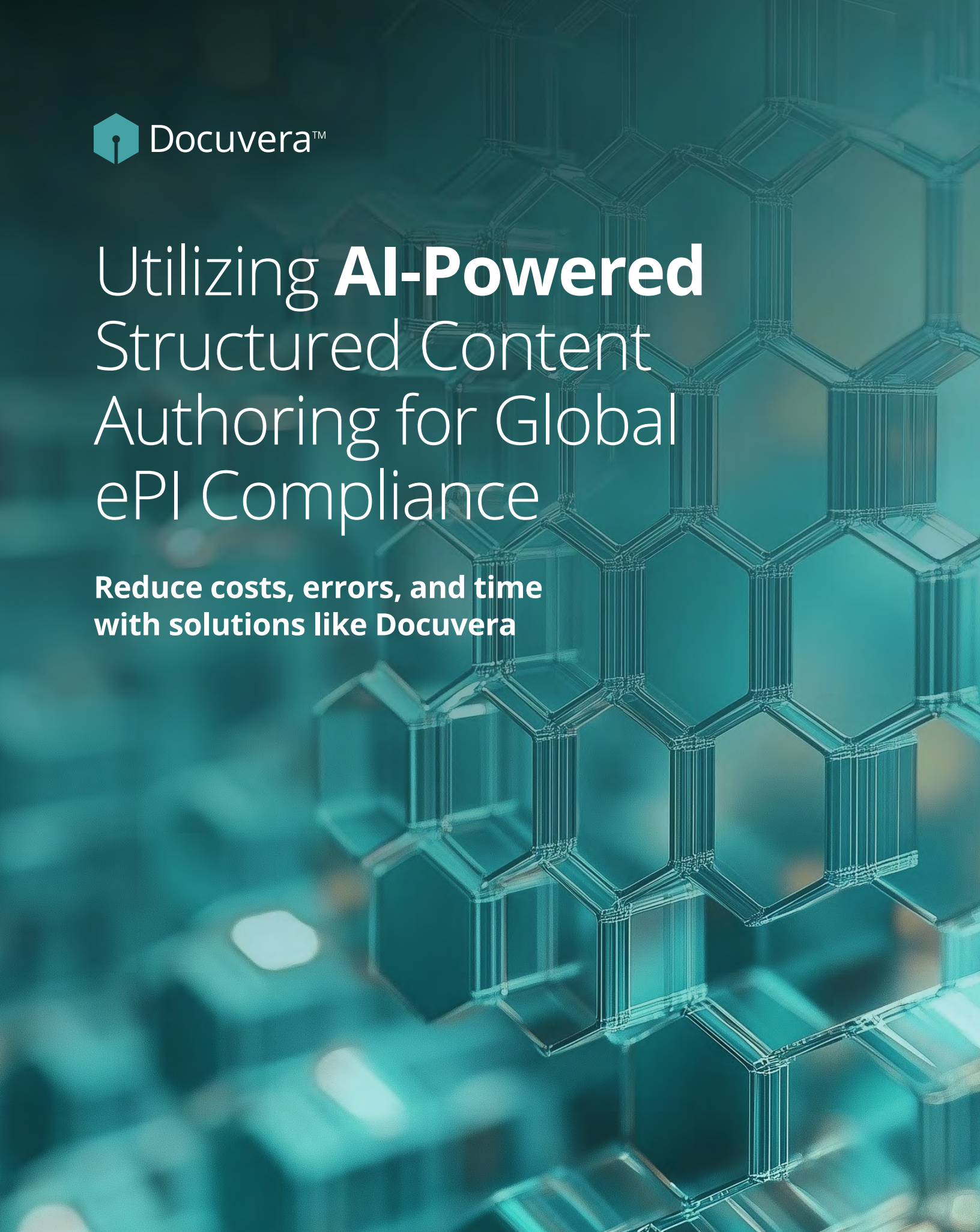
Docuvera™
Utilizing AI-Powered Structured Content Authoring for Global ePI Compliance
Reduce costs, errors, and time with solutions like Docuvera

Executive summary

Around the globe, health authorities are shifting to electronic product information (ePI) requirements to streamline pharma information management processes, improve patient safety, and leverage reporting capabilities on a level that is only possible with wide-scale digital transformation.

Recent pilot programs have demonstrated that ePI can cut costs while reducing errors and risks to the industry's companies.

As this momentum grows, a common goal for all entities involved is to develop an international standard for market authorization and access. Implementing ePI through structured content authoring (SCA) offers great potential as it's inherently machine-readable and aligns with universally accepted standards for greater accuracy, accessibility, and compliance.

As more companies migrate away from word processing and portable document format (PDF) tools, solutions like Docuvera offer significant, cost-effective advantages to ePI implementation over traditional, manual solutions by streamlining and automating global compliance requirements.

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The next step in pharma digital transformation

The evolving and expanding pharma compliance challenges, coupled with the speed and simultaneous nature of global submissions, are now acting as the key accelerant to industry digital transformation.

For companies working to implement ePI, challenges such as the growing complexity of global requirements (i.e., conforming to different schemas and applications for the same standards), an inability to meet digital submission requirements (metadata, tagging, etc.), a lack of content audit and traceability (regulatory compliance), and a lack of cross-functional collaboration (across functions and regions) all act as critical roadblocks. While structured content authoring (SCA) has been available for several years, AI-powered SCA continues to gain traction due to its ability to drive efficiencies in content analysis, drafting, and reuse. Successful implementation of ePI depends on adopting a deeper level of digital transformation—starting with AI-powered SCA.

The emergence of more broadly implemented ePI

Electronic product information (ePI) is driven by standards such as the Fast Healthcare Interoperability Resources (FHIR) standard, which is widely used in health information technology. ePI is structured, machine-readable, and designed for seamless integration into healthcare systems. This agility ensures faster, more reliable product information updates. In addition, through projects like the EMA DADI initiative (digital application dataset integration), the industry as a whole is shifting away from PDFs to more effectively meet digital health standards.

The broadening implementation of ePI regulations represents the next major step for pharmaceutical companies in utilizing this technology as a safeguard to both compliance and margins. This lays the groundwork for the not-so-distant-future industry state of end-to-end structured content, real-time data exchanges, and digital-first regulatory operations.

Regulatory evolution and adoption

Unlike traditional PDFs, which often require manual searching, scrolling, zooming, and lack usability in mobile formats, ePI is easily searchable, filterable, navigable, and web browser-friendly. Even more importantly, ePI already aligns with globally accepted regulatory frameworks from leading authorities and organizations, such as:

FDA SPL
(Structured Product Labeling)

EMA ePI
(European Medicines Agency's ePI standard)

FHIR
(Fast Healthcare Interoperability Resources)

National agency frameworks,
such as the Jordan FDA (JFDA) and Health Canada initiatives

The investment in ePI is two-fold: standard submission for Market Authorization and pre-configuration for next-generation patient access and support. The 'smarter' file format enables machines to utilize the encapsulated content in various ways that grow month over month.

By transitioning to structured ePI formats like XML and JSON, regulatory bodies and pharmaceutical companies are able to ensure greater accessibility, accuracy, and compliance with evolving digital health standards while avoiding the cost of manual solutions.

> ***"Fortunately, leading structured content authoring solutions (SCAs) such as Docuvera, are already equipped to enable this digital transition by supporting both manual/legacy and new processes. The result is an easier and greatly accelerated ePI implementation and compliance curve."***

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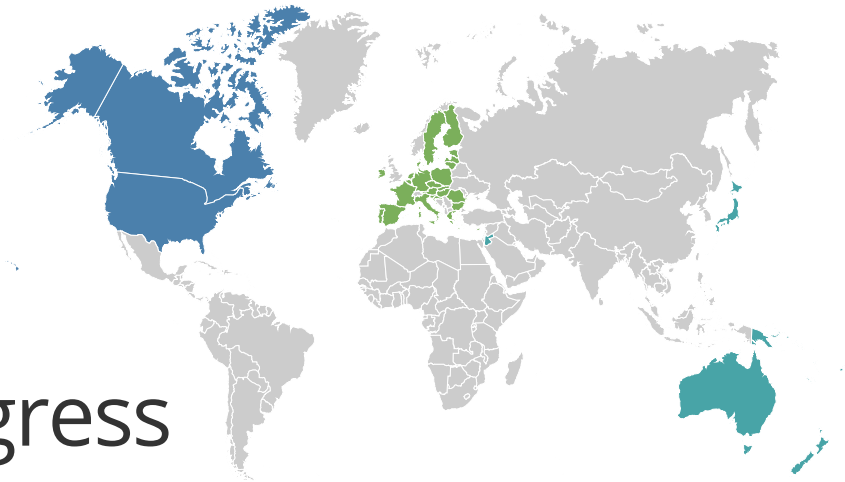

Snapshot:
Global ePI progress

2022	2023	2024	2025	Future

European Union

Most active and forward-thinking with ePI; methodically provides global insights and guidance.

2022
- ePI Common Standard adopted
- HL7 standards developed
- Interoperability goal from start

2023

2024
- Voluntary ePI pilots in **Spain+Denmark, Netherlands, Sweden**
- Published findings and recommendations

2025
- Voluntary ePI pilot participation continues
- SPOR Master data integrated
- Portal and infrastructure support

Future
- New MAAs may be mandated as ePI
- Mandatory FHIR ePI for centralized procedure
- Integration into HER systems
- Paperless medicine strategy

North America

U.S. has been slow to start; Canada has made significant progress.

2022

2023

2024

Canada
- Voluntary SPM pilots
- SPOR-like data models

United States
- SPL-to-FHIR initiative with pilots

2025

Canada
- Monograph in XML accepted
- SPM mandatory for new submissions (PDF still included)

United States
- FHIR pilots continue

Future

Canada
- SPM requirements planned
- Cross-border FHIR harmonization planned

United States
- FHIR native updates to DailyMed
- IDMP-like structure to support global alignment

Asia-Pacific

Aggressive adoption focused on patient access.

2022

2023

Japan, Australia, Jordan
- Evaluations of FHIR started
- Patient access first approach

2024

2025

Japan
- ePI Mandatory with GS1 code

Australia
- Optional ePI or Traditional Label submission with QR code

Jordan
- ePI Mandated by Nov 2025

Future
- Region leads way in adoption and implementation
- APEC and ASEAN forums drive convergence
- Pilots and movement toward ePI in **Singapore, Republic of Korea, China, Indonesia**

How AI-Powered SCA mitigates the challenges of ePI

ePI brings with it three material challenges: Global Regulatory Complexity, Technology Readiness, and Change Management. Approaching these challenges with careful preparation, initiative, and the right technology solution is key to a smooth implementation and future agility.

Health authorities prioritize different elements

There are already multiple interpretations and applications of ePI: HL7 FHIR-Based ePI; SPL (Structured Product Labeling) XML; proprietary XML formats (region-specific, such as Japan, Taiwan, South Korea); and now hybrid-pilot formats in Saudi Arabia, Australia, and Jordan. If current behavior persists, health authorities will continue this trend, creating an even larger and more complex ePI compliance matrix.

Technology readiness

Companies are recognizing that the use of manual tools and processes is increasingly untenable as the industry continues its shift toward machine-readable standards. While new processes that start with ePI are optimally positioned for automation, transition strategies for existing processes will vary based on the level of manual inputs and flows. As a result of these variances—which can be present across multiple content use cases—careful planning is required to ensure analog processes are converted into structured components and there is a fixed point in time to align and standardize content.

AI-powered SCA solutions, such as Docuvera, are ideally positioned to both simplify and facilitate this transition as well as equip pharma companies with the agility to develop native ePI processes and adapt to new or evolving requirements.

TechAccelerating change management

Successful ePI adoption involves cross-functional change that spans data governance, regulatory workflows, likely IT modernization, cultural mindset shifts, vendor alignment, safety integration, and compliance control. In organizations with siloed teams and outdated workflows, it can present operational friction—especially with the need to modularize, tag, and validate content across global markets and standards.

Fortunately, SCA solutions such as Docuvera serve as both a catalyst and a stabilizer in the complex transformation to ePI. By embedding structure and intelligence into every phase of the content lifecycle—from authoring and review to submission and reuse—data quality is increased, cross-functional collaboration is enhanced through expanded accessibility and reduced review friction, a greater level of global consistency is achieved, and pre-submission compliance and regulatory readiness improve.

SCA/AI-Powered SCA removes the Blind Spots of Incremental ePI Transformation

Many digital transformation efforts fail not from lack of effort, but from relying on incremental strategies that dilute impact and prolong inefficiency. While ePI adoption introduces real challenges, clinging to manual processes, outdated tools, or slow-moving change initiatives is routinely riskier—and more costly. Key risks include:

- **Inconsistent Regulatory Priorities:**
  Health authorities prioritize different requirements, such as auditability, version tracking, multilingual support, or digital distribution. Without a centralized, flexible solution, organizations face mounting complexity and inefficiency when trying to meet divergent global needs.

- **Persistence of Legacy Outputs:**
  Even as structured ePI becomes mandatory, legacy formats like PDFs are still required for some markets. Business units often respond with region-specific solutions, but this fragmented approach leads to redundancy, increased error risk, and diminished overall agility.

- **Parallel Systems with Limited ROI:**
  Many companies choose "slow and steady" transitions, maintaining parallel technology stacks and manual processes to minimize disruption. However, this duplicative model increases operational costs, complicates compliance management, and rarely delivers the anticipated efficiencies or speed.

- **Fragmented Solutions and Content Silos:**
  Layering new tools onto outdated workflows can seem safer in the short term—but it creates siloed content repositories, fragmented collaboration across functions and geographies, and additional rework. These inefficiencies undermine both compliance and responsiveness.

- **Fear of Disruption Leading to Stagnation:**
  Internal resistance to change, combined with apprehension over regulatory complexity, often causes delays in critical technology investments. What is intended to reduce short-term friction instead results in long-term stagnation, missed opportunities, and rising operational risk.

True digital transformation requires more than incremental upgrades. It demands a strategic shift in how content is created, structured, and shared, enabled by purpose-built tools—such as Docuvera—that bridge the gap between legacy processes and future standards.

The digital path forward to ePI and beyond

Pharmaceutical companies have been cautious about digital transformation due to the industry's strict regulatory requirements. However, global health authorities are now pushing for digital innovation, making digital transformation a necessity. Regulations like the European Medicines Agency's ePI and IDMP compliance and the FDA's structured product labeling demand accurate, accessible product information quickly. Traditional modes such as PDFs are no longer tenable due to the time and error-prone process of manual document creation, which also exposes companies to ongoing risks.

AI-powered SCA offers the ideal solution. Unlike traditional workflows, SCA and AI-powered SCA allow pharma teams to create modular content that's tagged, versioned, in compliance, and reusable. This means updates can be made once and published across multiple formats and languages, improving accuracy, accelerating review cycles, and driving greater agility. SCA also supports broader digital transformation, enabling better collaboration, AI-driven compliance tools, and adherence to emerging standards like HL7 FHIR and SPL. Embracing digital transformation through SCA is no longer just about compliance; it's about working smarter, faster, and more adaptively. In today's market, this isn't just an advantage—it's essential.

Docuvera: AI-powered SCA with a "compliance-first" mindset

Not all structured content platforms are designed for compliance. Docuvera stands out by future-proofing content for new frameworks and mandates with its native JSON storage, separation of content from styling, and structured component authoring. Unlike other tools, Docuvera's data-centric approach adapts easily to evolving schemas. Built specifically for the pharma industry, Docuvera ensures compliance by design.

How Docuvera facilitates and accelerates ePI compliance

Docuvera's structured content authoring solution provides key advantages such as:

Ensuring consistency and compliance

- Maintains uniformity across regulatory submissions, reducing errors
- Adapts seamlessly to new compliance standards such as FHIR-based ePI
- Streamlines secure data exchanges while maintaining content integrity

Improving content reusability and adaptability

- Enables repurposing of product information across multiple platforms, including electronic health records, mobile apps, and regulatory portals
- Ensures fidelity of content through what has historically been a transformative process
- Facilitates easy updates without disrupting other content components

Enhancing machine-readability and automation

- Supports advanced metadata tagging, meeting critical Identification of Medicinal Product (IDMP) and other data-rich regulations
- Highly indexable, improving searchability and retrieval

Supporting global compliance and interoperability

- Aligns with international ePI frameworks for seamless regulatory adoption
- Ensures product information is accessible and structured for healthcare professionals, patients, and regulators worldwide

Business Benefits of Implementing Docuvera

Docuvera is a global leader in AI-powered structured content authoring for the pharmaceutical industry and serves as a platform for companies to further digital transformation initiatives. For over a decade, our solutions have enhanced worldwide regulatory compliance, improved content standardization, and accelerated both approval submissions and time to market.

Efficiency and Automation

Docuvera automates creation, formatting, and maintenance of product information with templates, content reuse, and version control. This reduces oversight, accelerates approvals, ensures consistency, and minimizes risks through automated formatting.

Risk Mitigation and Compliance

Docuvera's architecture includes validation tools, automated checks, and metadata tagging to minimize errors and ensure accurate submissions. Audit trails provide proof of regulatory adherence, improving compliance interactions with health authorities.

Cost and Resource Optimization

Docuvera centralizes content management and simplifies updates across regions or frameworks, reducing duplicative efforts. Enhanced submission quality translates to fewer rejections or delays, accelerating time-to-market and lowering operational costs.

Future-Proofing

Docuvera's adaptable platform supports continued growth and compliance excellence. By aligning with evolving ePI guidelines, companies can maintain compliance as standards change and adapt to future requirements and technological advancements. Docuvera addresses key pharmaceutical compliance and content management challenges, offering measurable advantages.

Let's Talk

Docuvera helps organizations address today's challenges in regulatory compliance and multi-format publishing. Pharma companies can now future-proof their content and streamline ePI compliance and publishing.

To learn more, contact us at **epi@docuvera.com** to speak with an SCA consultant or visit our website to explore Docuvera for comprehensive ePI management and broader digital transformation initiatives.

Docuvera is a cloud-based structured component authoring (SCA) platform that empowers pharmaceutical and life sciences organizations to modernize regulatory content creation and management. Developed by Docuvera Software Corporation, a global leader in structured content solutions, the platform combines intuitive interfaces with embedded AI to drive consistency, accelerate approvals, and ensure compliance at scale. Trusted worldwide for over a decade, Docuvera plays a critical role in advancing digital transformation by enabling smarter content reuse, stronger governance, and faster time to market. Visit docuvera.com to learn more.

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