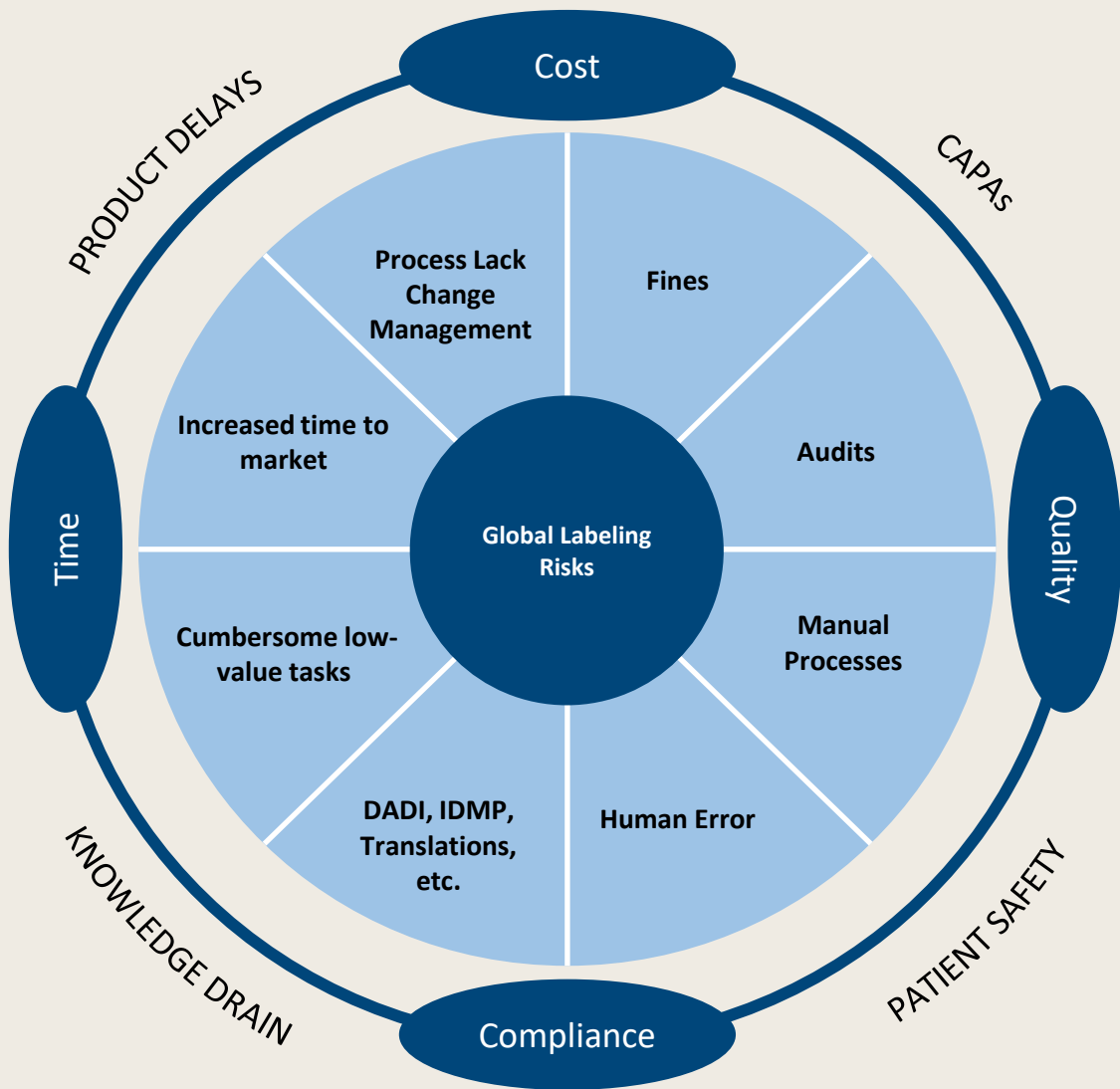# Glemser

Global Labeling
PLAYBOOK

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Founder & Chairman of Glemser Technologies
" *www.Glemser.com*

Impact of Current Global Labeling Processes and Systems

Labeling challenges are manifesting downstream as much larger issues. These issues put every organization at risk of increased costs, decreased quality, non-compliance, and wasted time.

Quantifying Global Labeling Challenges

Labeling challenges result in wasted time, increased costs, decreased quality, and non-compliance. All of which erode the financial stability and impede the ability to get life saving drugs in the hands of patients.

TIME

- Label changes number in the tens of thousands (30K+) over the course of a year
- Complex label changes require 12+ months
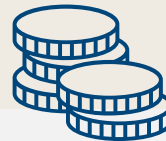
COST

- Violations exceeded over $50 billion USD since 2000 and the cost of non-compliance has grown by 43% since 2013

QUALITY

- Increasing regulatory oversight (DADI, IDMP, etc.) that require electronic applications and tools to fulfill requirements

COMPLIANCE

- Volume of data and changes in documents requires an automated process to keep labels current and compliant

Process Improvements are Needed to Modernize the Labeling Workflows and Systems

Why?

- Plans in place to satisfy regulatory requirements
- Ability to scale through mergers, acquisitions, and divestitures

Who?

- Alignment between Quality, Regulatory, and IT departments
- Automated submissions to Heath Authorities

What?

- Life-sciences enabled end-to-end labeling solution
- Quality and efficiency focused labeling processes and system

How?

- Advancements in artificial intelligence, machine learning, and natural language generation
- Staff retention via high-value work

How to Solve Your Current Labeling Challenges

Labeling challenges across people, process, and technology require modern technology to meet current and evolving global requirements.

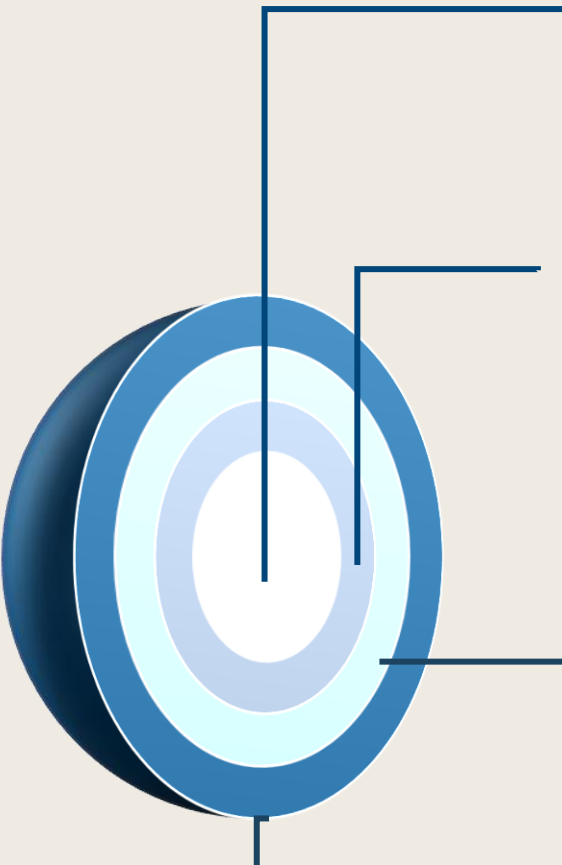| Required Features |
|---|
| Systemically analyze multiple data sources and create easily finable content |
| Maintain compliance by storing data in an agency-neutral format that can scale to current and future global and local regulatory requirements |
| Generate label submissions in required company or regulatory formats, fulfilling all regulatory rules |
| Outputs (FHIR/HL7, Pharma Ledger, country specific formats) |
| Evolving client mandatory minimums. Partner with key stakeholders to drive enhanced experience and new functionality |
| Enhanced reporting and dashboards |
| Overlay existing RIM systems and data repositories |

![Glemser logo]

ComplianceAuthor Solutions™ Design Principles

ComplianceAuthor™ uses an inside out approach, designed to easily scale and generate any required document type or output.

Proven Core
- Harmonize agency-neutral content with meta-data / attributes / properties for controlled compliant components and data driven documents

Engineering Approach
- Generate any output or document type
- Using proven industry best practices with 30+ pre-configured available document types with all industry relationships mapped, populated picklists, available drop-down menus

End-to-End Ecosystem
- Support ecosystem of health authorities and local operation business interactions for improved time to market

Scalable Transformation
- Perpetually sustained compliance via Natural Language Processing
- CFR Part 11 and EU Annex 11 compliant with audit trail and e-signature capabilities out-of-the-box

Glemser Background

Glemser's rich history with Life Science, pharmaceutical, and other regulated industries uniquely positions us to understand challenges, deliver value, and allow your business to support your mission in human healthcare.

Key Business Drivers

- Increase data supply chain efficiency
- Sustain compliance
- Enhanced end-user experience and productivity
- Return on investment model and metrics

Centralized Repository

Authoring in Word

Content Reuse

Renditions

Pre-configured Labels
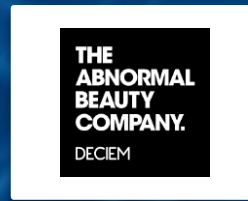
Label Tracking

Translation Management

User-Friendly Workflow

eSignatures

Glemser is a Trusted Partner and Global Leader In Structured Product Labeling

Summary of Features & Functions

ComplianceAuthor Solutions™ provides best practices that are unmatched in today's market.

| Out-of-the-Box Functionality	Compliance Author™	Competitor 1	Competitor 2	Competitor 3
Sustained Compliance & Change Management	✔	✔	✔	✔
Audit Trail with Electronic Signatures	✔	✔	✔	✔
XML/SPL (Structured Content Made Easy)	✔	✔	✘	✘
Translation Approach	✔	✔	✘	✔
Integrates to Other Solutions (Veeva, DCTM, SP)	✔	✘	✔	✘
Natural Language Generation (NLG)	✔	✘	✘	✘
Natural Language Processing (NLP)	✔	✘	✘	✘
Content Authoring with MS-Word Using XML Author Plug-in	✔	✘	✘	✘
Agency Neutral Format (Controlled Compliant Components) Allows Scaling for Current & Future Outputs	✔	✘	✘	✘
Document Management (Versioning & Branching)	✔	✘	✘	✘

Benefits of ComplianceAuthor™

Technology advancements have come of age for the industry and ComplianceAuthor Solutions™ adds value across four dimensions

TIME

- Reduce non-productive administrative work
- Streamline workflows with process automation
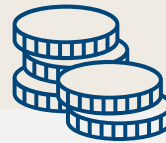
COST

- Self funded implementation
- Reduced employee turnover, overtime, recruiting costs

QUALITY

- Improved visibility and utilization of resources
- Improved therapeutic area knowledge and throughputs

COMPLIANCE

- Sustains compliance over change management
- Manages Health Authorities interactions and audit trails

What's Next?

Schedule an introductory call with **Our ComplianceAuthor Solutions™ Team**

- Step 1: Understand your current infrastructure and goals

- Step 2: We delivery a fully customized ROI analysis

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