# How AI will shape the future of Quality & Compliance

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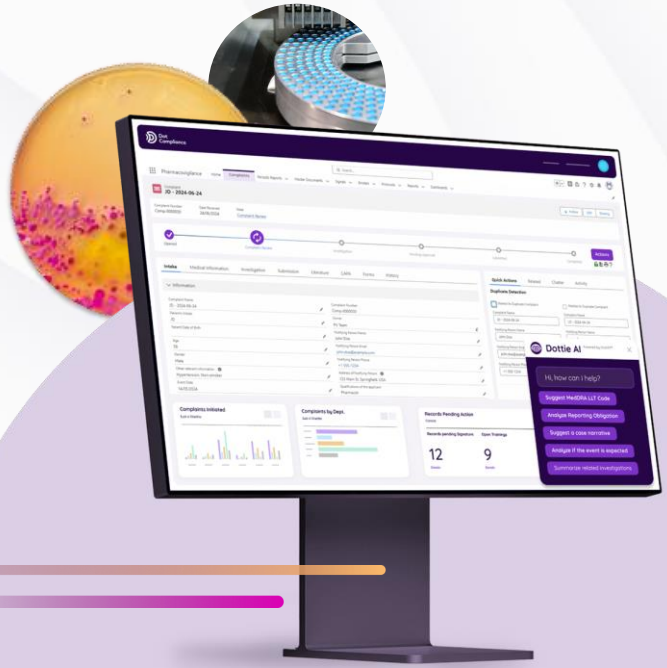
# Who we are.
# What we do.

Dot Compliance **empowers** life-sciences organizations to deliver life-saving, innovative products **faster, safer,** and more **efficiently,** by providing them with **AI Powered ready-to-use** and **end-to-end** solution to manage their entire quality and compliance needs



# In Numbers


25+
Countries

150+
Employees

500+
Customers

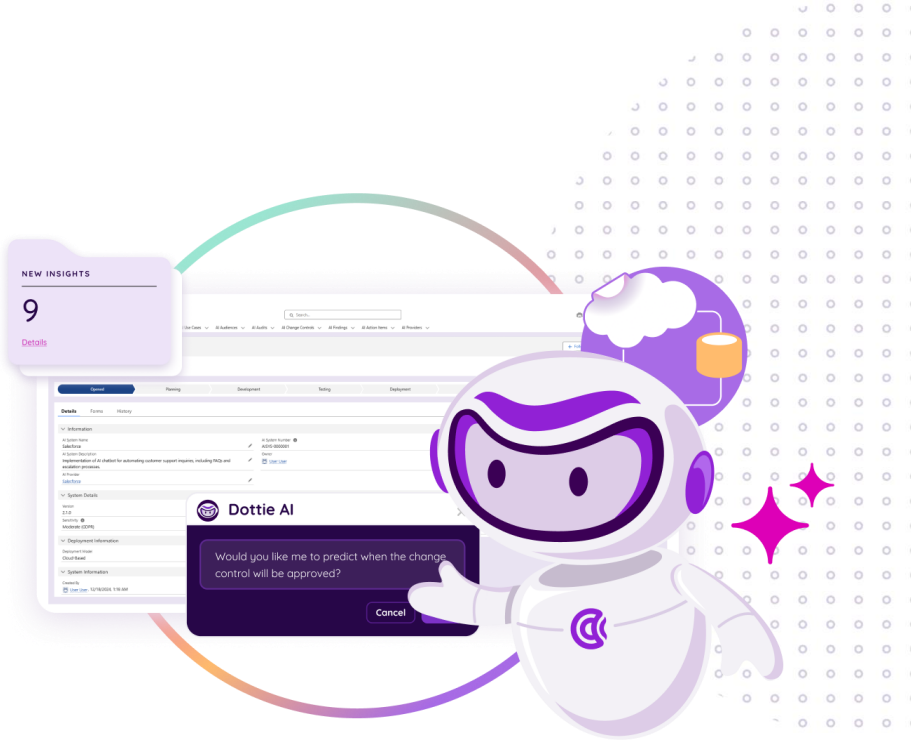
95%
Pharma, Biotech,
Med Device, Healthcare

# Meet Dottie: Vertical AI for Life Sciences

Dottie AI is a vertical AI platform for life sciences and based on an AI data pipeline, built specifically to support industry use cases. The AI data pipeline serves Dottie AI Agents, which leverages **Predictive AI and Generative AI** capabilities.

100+

**Dottie AI Customers**



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# How is AI evolving ?

- What is the expected technolgical cpabilities?
- Can it replace Knolwodege workers?
- Can it replace phisical human labor?
- When this will happen?
- How will this affect quality and compliance professionals?

# Progression of Generative AI LLM

- **Launch of ChatGPT (Nov 2022):** OpenAI introduced ChatGPT, a conversational AI model capable of generating human-like text, marking a significant milestone in AI development
- **Rapid User Adoption**: Within 2 months, ChatGPT amassed over 100 million users, becoming the fastest-growing consumer application at that time
- **Catalyst for AI Advancements**: The success of ChatGPT spurred the development of competing AI models, including:
  - Google's Gemini, Anthropic's Claude
  - Meta's Llama
  - Deepseek
- Integration into Daily Life: AI-powered tools have been integrated into various applications, enhancing productivity and user experience across multiple sectors




## חוקרים נתנו לבינה מלאכותית מבחן עם שאלות שגם סטודנטים לתואר שני יתקשו לפתור ■ יש הסבורים כי בעתיד הבינה המלאכותית תענה על שאלות שהאנושות עדיין לא יודעת עליהן את התשובה — אבל איך נמדוד את היכולות שלה אם הרגע הזה יגיע?

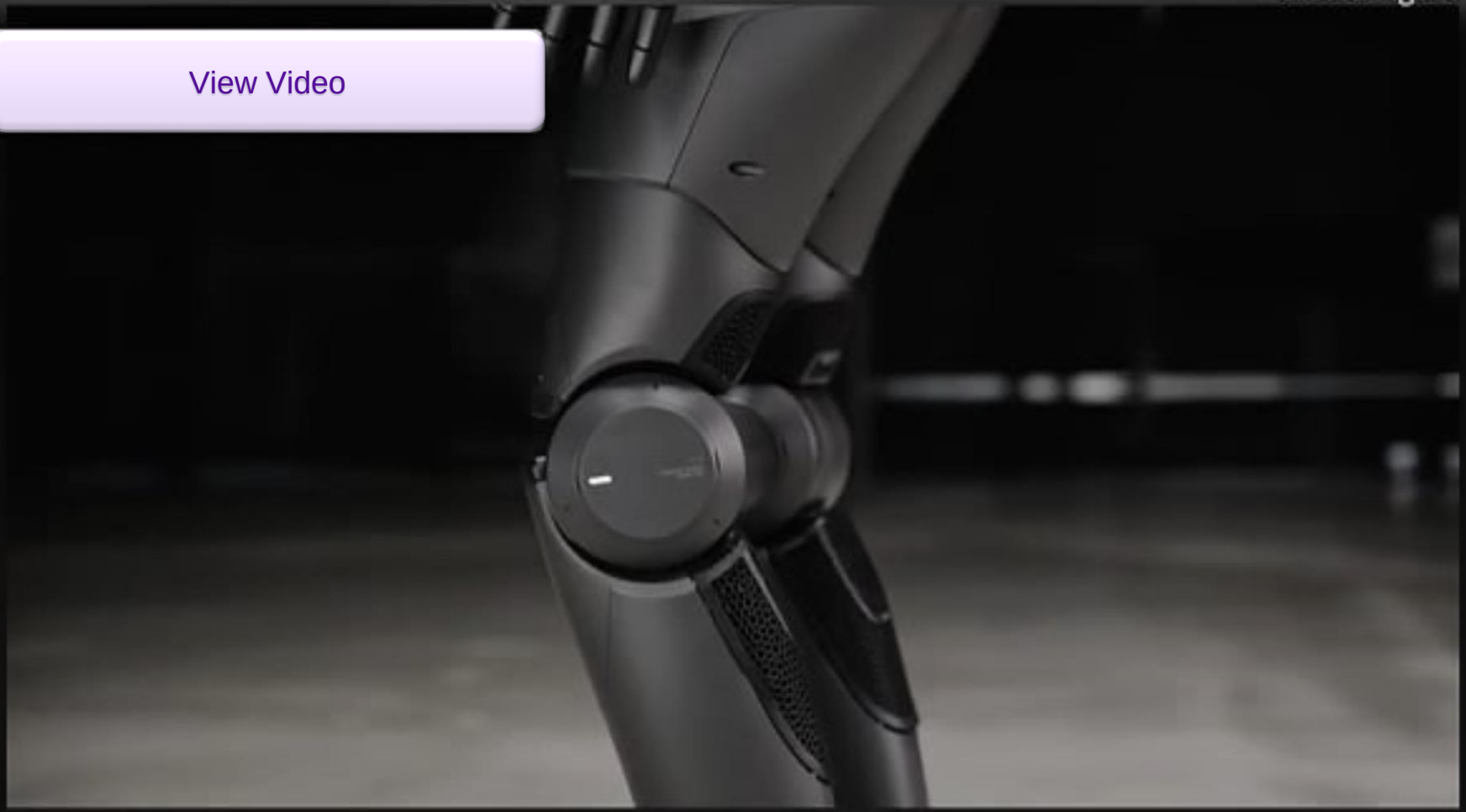
**ניו יורק טיימס** • קווין רוס

03 בפברואר 2025

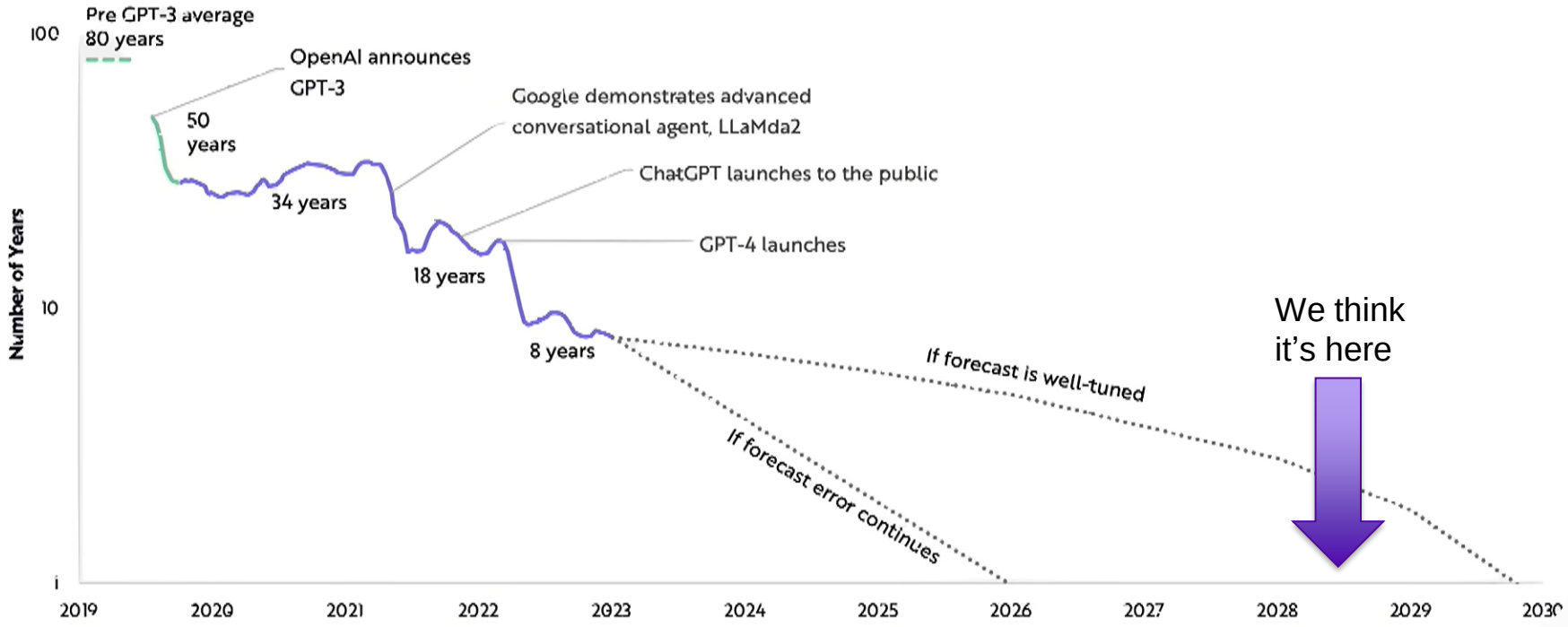
**תקציר הכתבה ב-71 מילים**

האם מערכות בינה מלאכותית הופכות לחכמות מכדי שנמדוד אותן? חוקרים הציגו מבחן חדש שנקרא "המבחן האחרון של האנושות", שהם טוענים כי הוא המבחן הקשה ביותר שניתן לבינה מלאכותית. המבחן כולל כ-3,000 שאלות ברמת קושי גבוהה במיוחד. התוצאות הראשונות מפתיעות: אפילו המודלים המתקדמים ביותר נכשלו. ואולם המומחים צופים שעד סוף השנה המודלים כבר ישיגו ציונים טובים בהרבה — מה שיעורר שאלות חדשות על הדרך למדוד את יכולות ה-AI.

**Humanity's Last Exam** https://lastexam.ai/

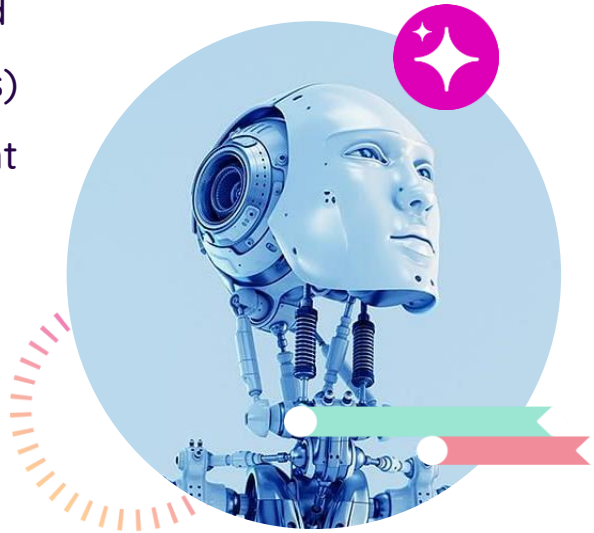

View Video
Credit: Figure

# Timeline predictions for Artificial General Intelligence



# Outlook

- AI and Robots are likely to replace significant percent of human job positions in this generation (or even sooner)
- **Knowledge workers** as well as **physical labor** jobs will be impacted
- Ability to work in **Hybrid mode** (human and AI) will be needed
- In Pharma changes will take more time (Risk and Regulations)
- The changes will impact quality and compliance management



# Quality leaders need new tools to take control.

The quality and compliance role must pivot to proactivity as the pace of innovation increases. **Reactive behaviour is now seen as "too little, too late".**

Yesterday

## Messenger

Manually managing processes and routing documents.
→ **Siloed systems.**

Today

## Air traffic controller

The big picture of quality and identifying trends.
→ **Digitization.**

Tomorrow

## CIA analyst

Anticipating and proactively remediating quality issues.
→**Holistic end-to-end view.**

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# Where to start?

- What are the capabilities available today (Feb 2025)?
- Examples of AI agents
- How to build your AI adoption strategy?
- What a are the applicable

# But how does it make your life better?

## Improve Data Quality

- Contextually organize & visualize quality records and documents
- Standardize quality professional language
- Data entry validation recommendations when filling forms
- Identify duplicate and conflicting quality documents and recommend changes
- Summarize cases, complaints, investigations

## Make Better Decisions

- Detect impactful data changes and launch tasks for review & decision making
- Detect Deviations/OOS and recommend immediate actions
- Predict record state transition timing
  - Determine timeline risk
  - Recommend route changes
- Root Cause Analysis
  - Return Product Analysis
  - Regulatory Reportability Analysis
- Product Troubleshooting

## Improve Productivity

- Identify and leverage similar and related quality records
  * Deviations, CAPAs, Change Controls, Complaints
- Suggest and launch processes
  * Risk Assessments, Regulatory, Audits, etc.
- Generate communication / correspondence letters and emails
- Production Optimization
  - Predictive Maintenance
- Predictive Shelf-Life and Survivorship

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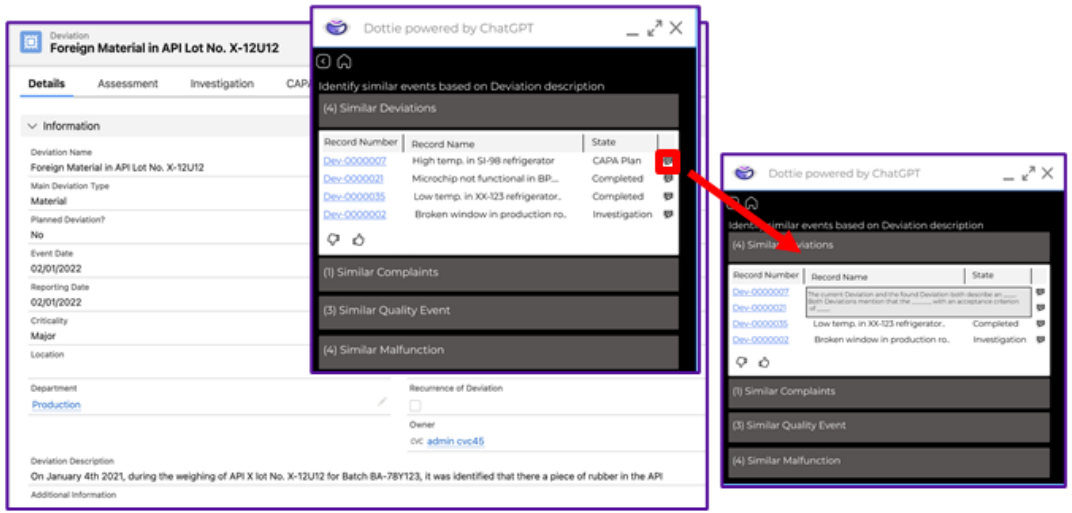
# Introducing Dottie AI 3.0

# Similarity and Explainability Agent




## 1. What

Semantically similar event search engine

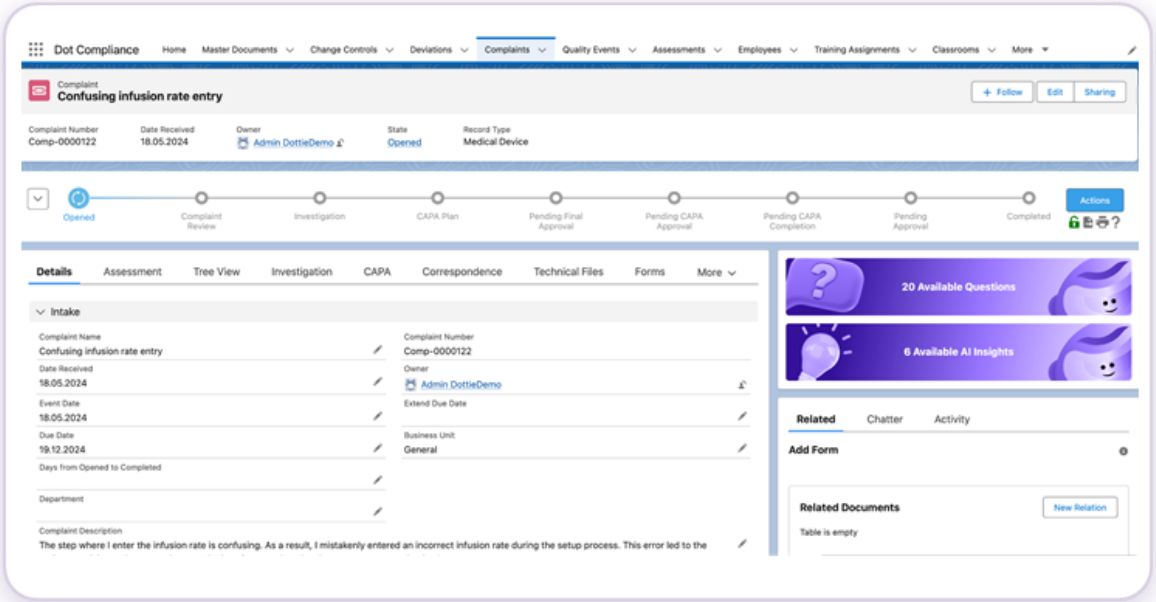
## 2. Pain Alleviated

Saves time and money of endless document review and tedious search for relevant and similar events

## 3. Under the AI hood

QMS-tuned Retrieval Augmented Generation (RAG) with Explainable AI capabilities via semantic data grouping and hybrid search

# Complaint Triage Agent




## 1. What

AI-driven complaint reportability classification

## 2. Pain Alleviated

Efficiently eliminates the need for time-consuming manual tasks

## 3. Under the AI hood

Combine regulatory authority guidance documents and complaint data to predict reportability, providing AI-generated explanations

# Clustering Visualization Agent


## 1. What

Similarity clustering of QMS and documents textual data

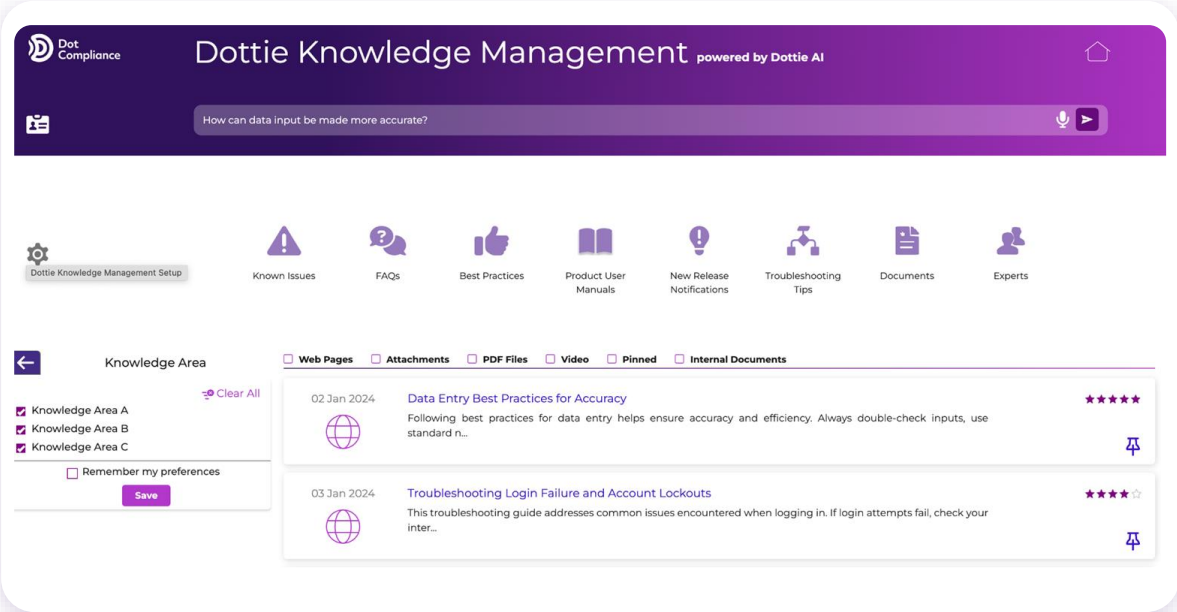
## 2. Pain Alleviated

Easy and quick inspection of all QMS data in one place

## 3. Under the AI hood

Bird's/Worm's-eye view in a single plot, showing QMS agglomerative and divisive hierarchical clusters and outliers via embedding and dimension reduction

# Knowledge Management Agent




## 1. What

The first AI-powered knowledge management and QMS system for the Life Sciences

## 2. Pain Alleviated

Query and retrieve organization-wide knowledge in an instant

## 3. Under the AI hood

Knowledge-tuned Retrieval Augmented Generation (RAG) via hybrid search and re-ranking algorithms

# AI compliance and governance - **A CHALLENGE**

Rapid AI adoption without proper controls creates significant **operational and reputational risks**

Traditional software governance frameworks don't work for AI's **probabilistic nature** and emergent behaviors

**Complex regulatory landscape** with rapid evolution (EU AI Act, state-level regulations, industry standards)

Lack of standardized approaches for **AI risk assessment and validation**

Challenge of maintaining visibility across various AI systems (i**nternal, third-party, embedded**)

Difficulty in maintaining consistent performance and preventing **model drift**

Need for **specialized audit trails** and documentation for AI decisions

# And specifically for Pharma organizations

Direct impact on patient safety and **health outcomes**

**Strict regulatory frameworks** (FDA, HIPAA, GxP) requiring validated systems and complete audit trails

**High stakes of AI failures** in medical applications (diagnosis, treatment recommendations, drug discovery)

Complex **integration** with existing quality management systems

Handling of **sensitive patient data** requiring enhanced security and privacy controls

Need for transparent, **explainable AI decisions** in medical contexts

**Higher burden of proof** for AI system **validation** and monitoring

# Regulatory Frameworks Addressing AI Risks

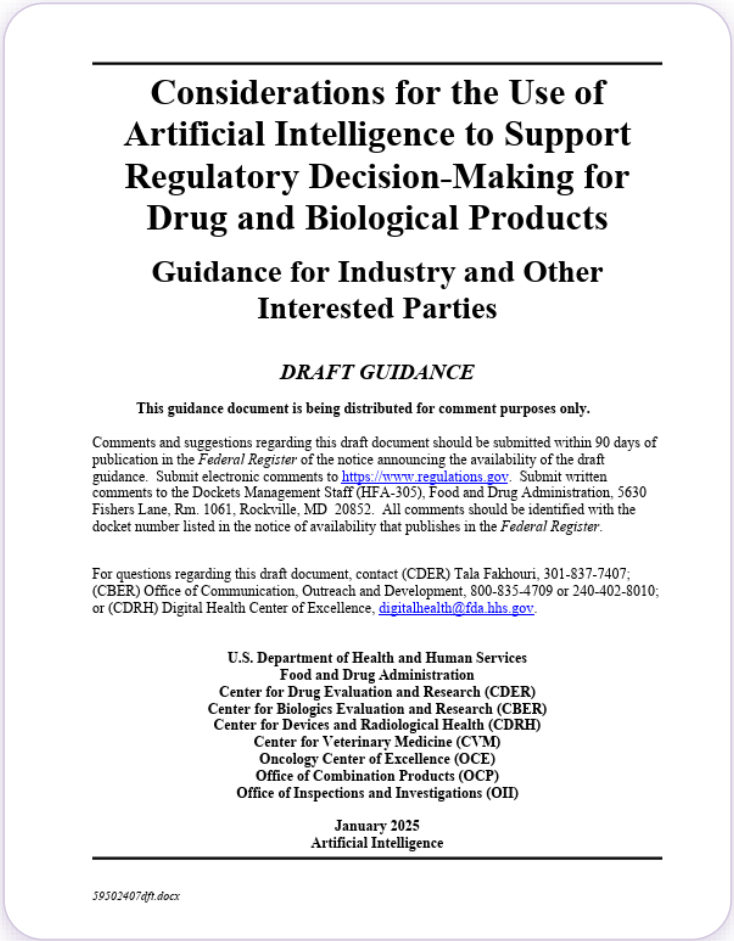
## EU AI Act

Establishes harmonized rules for AI development and deployment within the EU, categorizing AI systems based on risk levels to ensure safety and fundamental rights protection.


## ISO/IEC 42001

Provides a global standard for AI management systems, guiding organizations in implementing responsible AI practices and addressing ethical considerations.

# New FDA Guidelines



## Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

### Guidance for Industry and Other Interested Parties

***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tala Fakhouri, 301-837-7407; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Digital Health Center of Excellence, digitalhealth@fda.hhs.gov.

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**Artificial Intelligence**

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# How to build an Adoption Strategy

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# Thank you!