

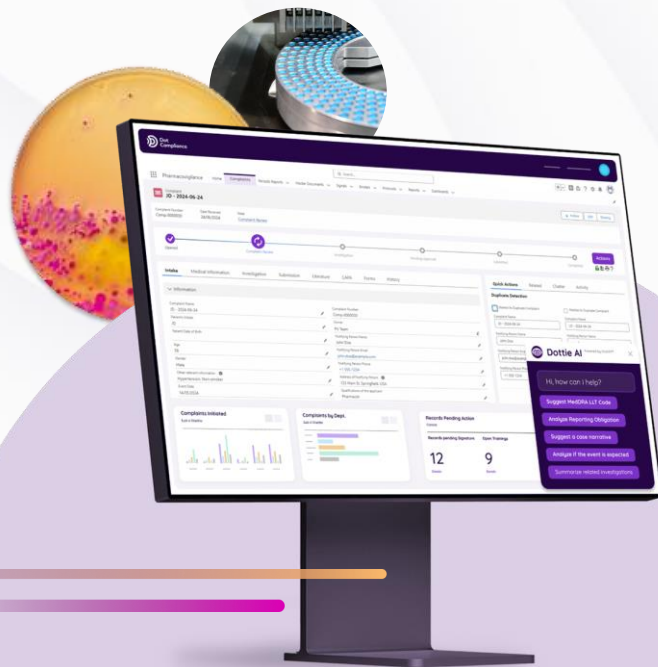


How AI will shape the future of Quality & Compliance

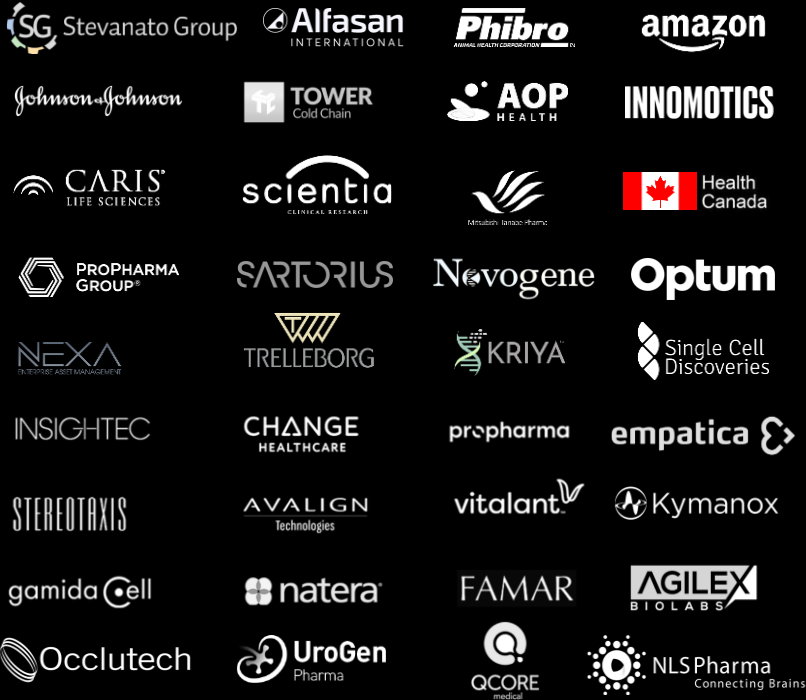
Dr. Yuval Nardi Chief Data Scientist
Doron Sitbon, CEO

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



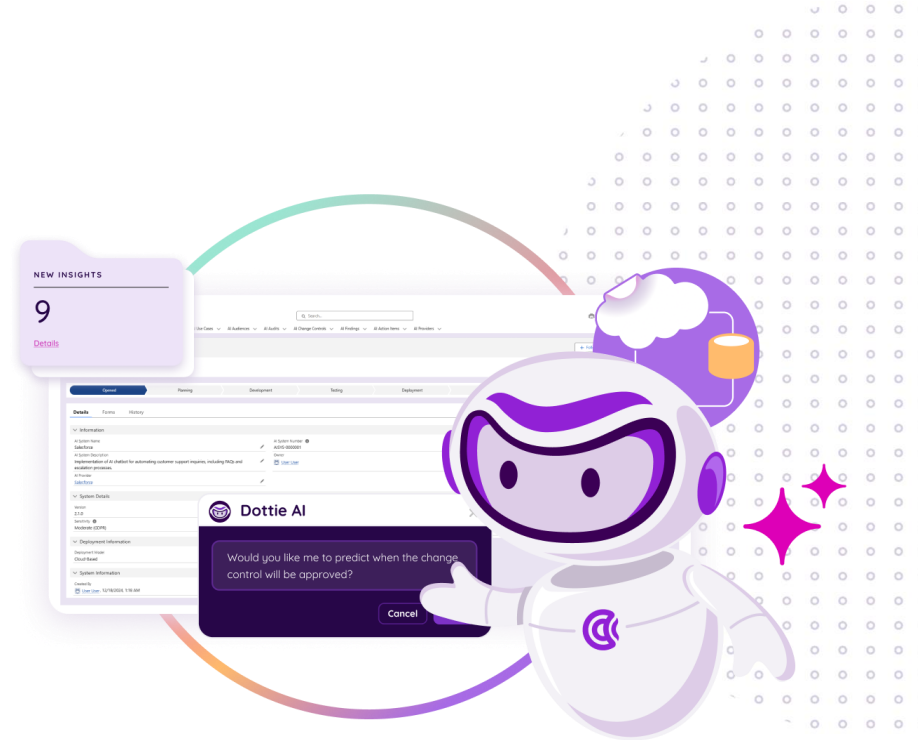
Meet Dottie: Vertical AI for Life Sciences

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



How is AI evolving ?

- What is the expected technological capabilities?
- Can it replace Knowledge workers?
- Can it replace physical 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

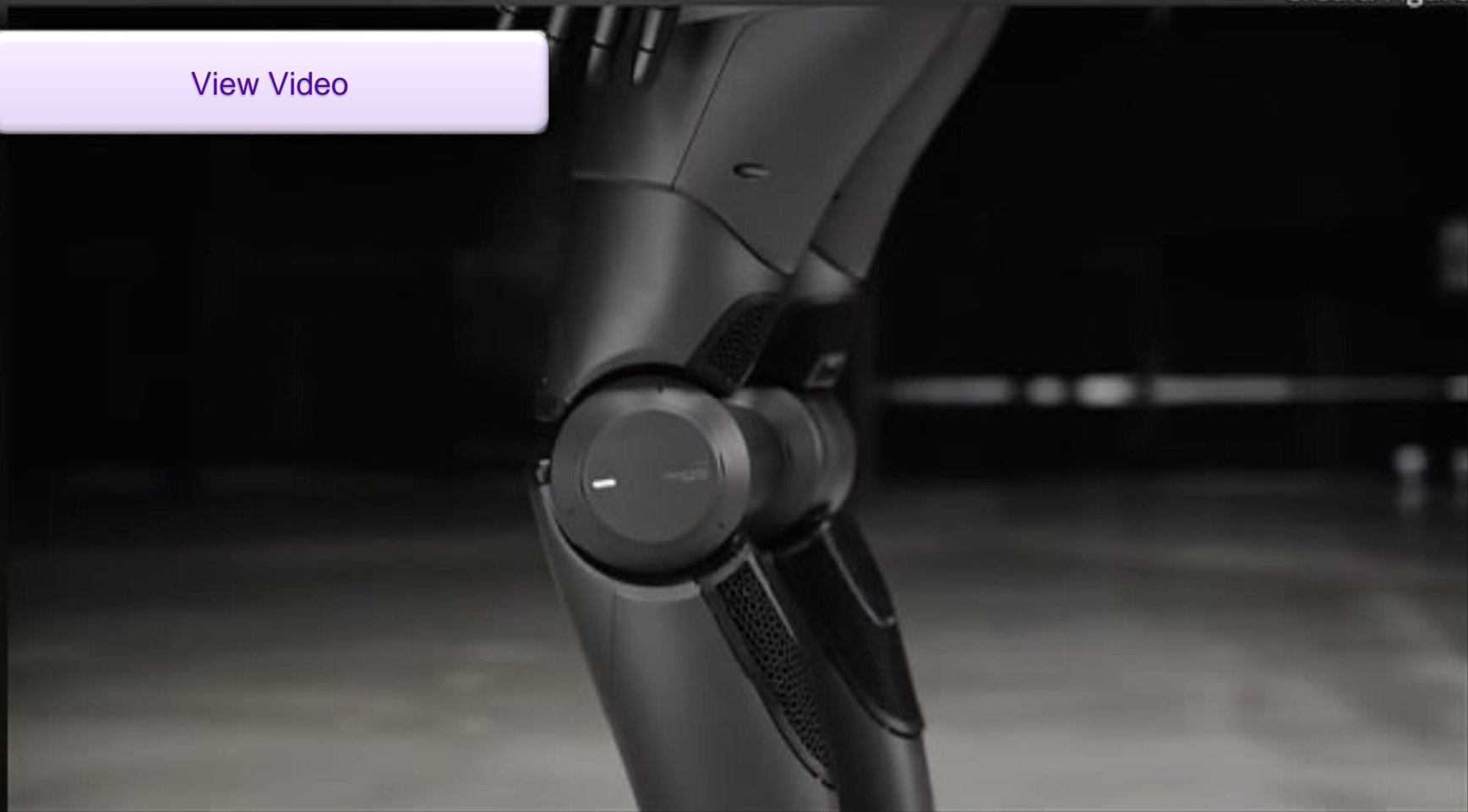
03 בפברואר 2025

תקציר הכתבה ב-71 מילים

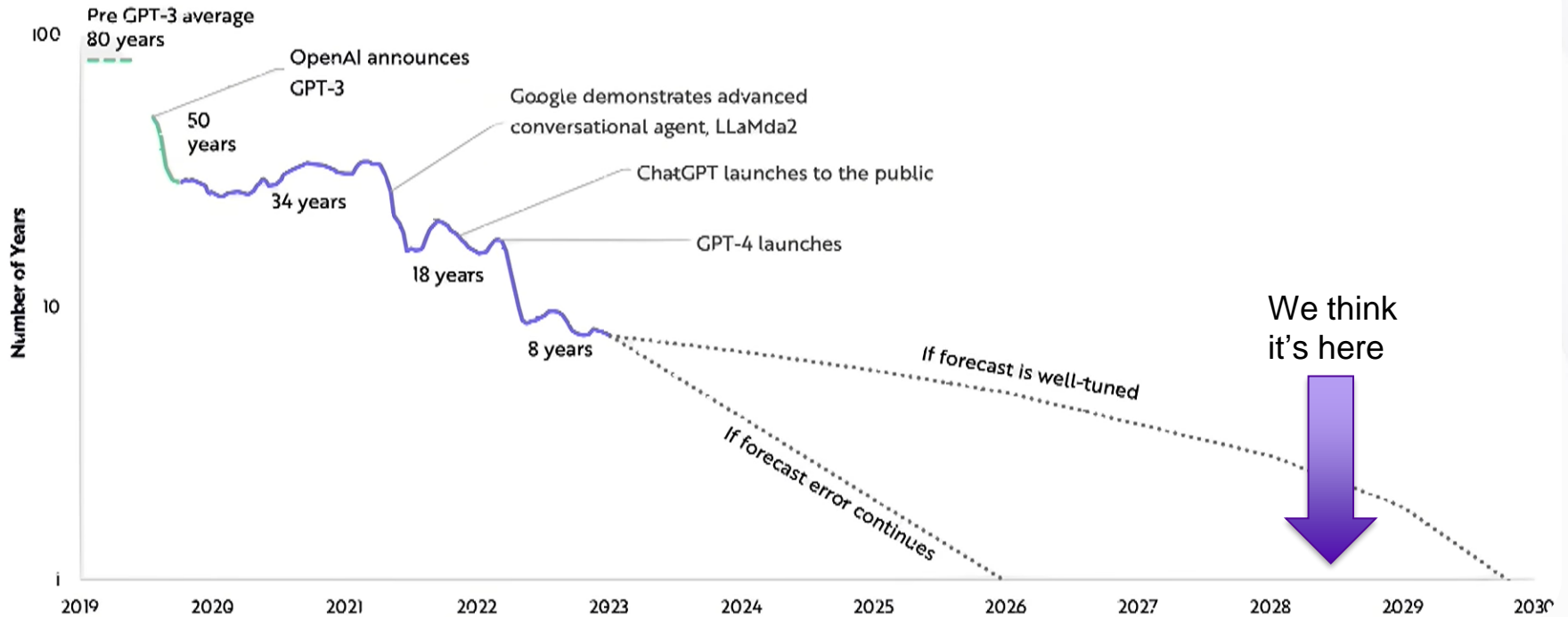
האם מערכות בינה מלאכותית הופכות לחכמות מכדי שנמדוד אותן? חוקרים הציגו מבחן חדש שנקרא "המבחן האחרון של האנושות", שהם טוענים כי הוא המבחן הקשה ביותר שניתן לבינה מלאכותית. המבחן כולל כ-3,000 שאלות ברמת קושי גבוהה במיוחד. התוצאות הראשונות מפתיעות: אפילו המודלים המתקדמים ביותר נכשלו. ואולם המומחים צופים שעד 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](#)

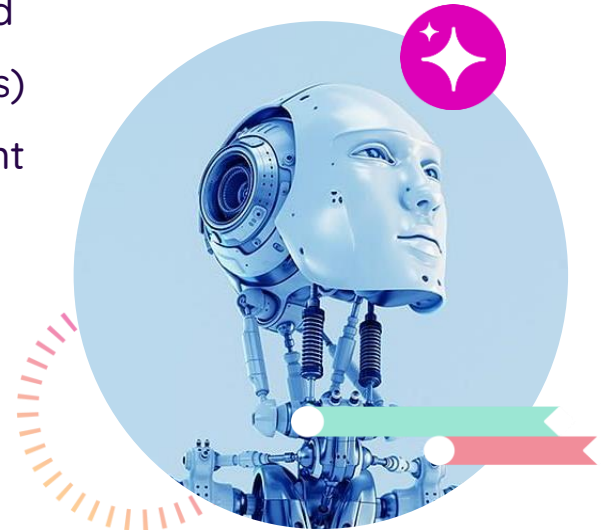


Timeline predictions for Artificial General Intelligence



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.**

Where to start?

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

[View Video](#)



Introducing Dottie AI 3.0



Similarity and Explainability Agent

The screenshot shows a software interface with a deviation report on the left and a chat window on the right. The chat window, titled "Dottie powered by ChatGPT", displays a table of similar deviations and a detailed explanation for one of them.

Deviation Report:

- Deviation Name: Foreign Material in API Lot No. X-12U12
- Main Deviation Type: Material
- Planned Deviation?: No
- Event Date: 02/01/2022
- Reporting Date: 02/01/2022
- Criticality: Major
- Location: Production
- Department: Production
- Deviation Description: On January 4th 2021, during the weighing of API X lot No. X-12U12 for Batch BA-78Y123, it was identified that there a piece of rubber in the API

Chat Window - Similar Deviations:

Record Number	Record Name	State
Dev-00000007	High temp. in SI-98 refrigerator	CAPA Plan
Dev-00000001	Microchip not functional in BP...	Completed
Dev-00000035	Low temp. in XX-123 refrigerator...	Completed
Dev-00000002	Broken window in production ro...	Investigation

Chat Window - Similar Complaints:

- (1) Similar Complaints
- (3) Similar Quality Event
- (4) Similar Malfunction

Chat Window - Similar Deviations (Detailed):

Record Number	Record Name	State
Dev-00000007	The current Deviation and the found Deviation both describe an ...	
Dev-00000001	Both Deviations mention that the ... with an acceptance criteria of ...	
Dev-00000035	Low temp. in XX-123 refrigerator...	Completed
Dev-00000002	Broken window in production ro...	Investigation

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

The screenshot displays the 'Dot Compliance' software interface. At the top, a navigation bar includes 'Home', 'Master Documents', 'Change Controls', 'Deviations', 'Complaints', 'Quality Events', 'Assessments', 'Employees', 'Training Assignments', 'Classrooms', and 'More'. The main header shows the complaint title 'Confusing infusion rate entry' with '+ Follow', 'Edit', and 'Sharing' buttons. Below this, a summary row lists: Complaint Number (Comp-0000122), Date Received (18.05.2024), Owner (Admin DottieDemo), State (Opened), and Record Type (Medical Device). A progress bar below the summary shows stages: Opened, Complaint Review, Investigation, CAPA Plan, Pending Final Approval, Pending CAPA Approval, Pending CAPA Completion, Pending Approval, and Completed. The 'Details' tab is active, showing a table with fields like Complaint Name, Date Received, Event Date, Due Date, and Department. A 'Complaint Description' at the bottom reads: 'The step where I enter the infusion rate is confusing. As a result, I mistakenly entered an incorrect infusion rate during the setup process. This error led to the...'. On the right side, there are sections for '20 Available Questions' and '6 Available AI Insights', along with 'Related Chatter Activity' and 'Related Documents'.

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

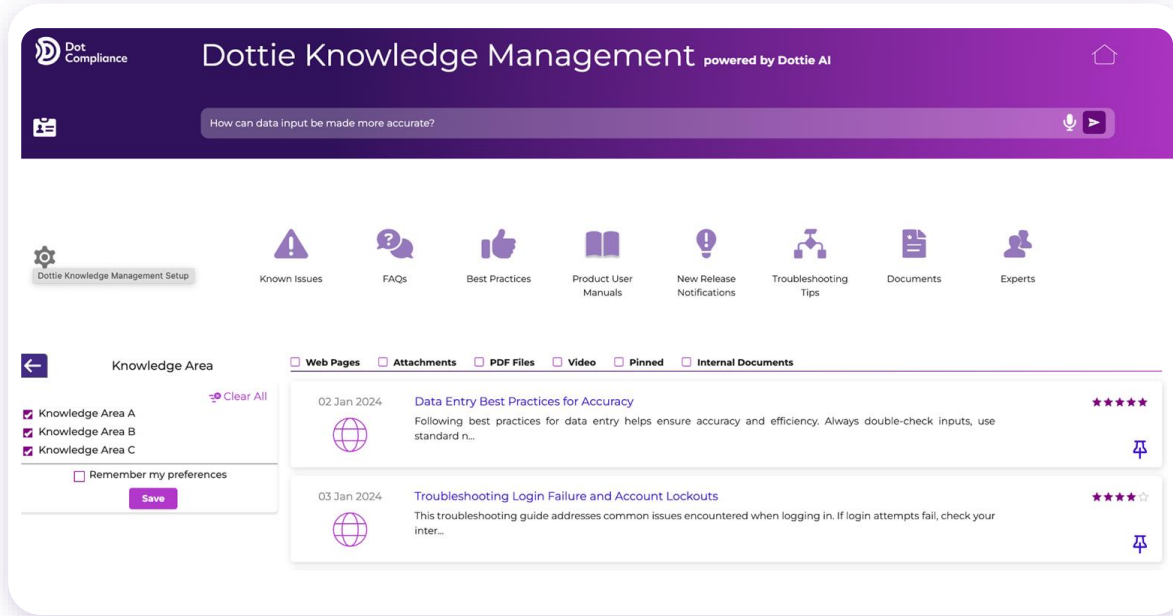
2. Pain Alleviated

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 (**internal, 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.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Veterinary Medicine (CVM)
Oncology Center of Excellence (OCE)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

January 2025
Artificial Intelligence

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How to build an Adoption Strategy



Define Clear Business Objectives

Build a Strong Data Foundation

Ensure Regulatory Compliance and Ethical AI

Start Small, Scale Fast (Pilot & Iterate)

Foster Cross-Functional Collaboration

Partner with AI and Tech Leaders

Focus on Change Management & AI Adoption

Continuously Monitor, Evaluate & Improve

Thank you!

