



REDICA
Systems

Beyond ChatGPT

RX360 CONFERENCE

My dream - Investigation of an issue



Here is an issue of interest ...

1) How widespread is this? 2) Do we have this problem?"

Click ->

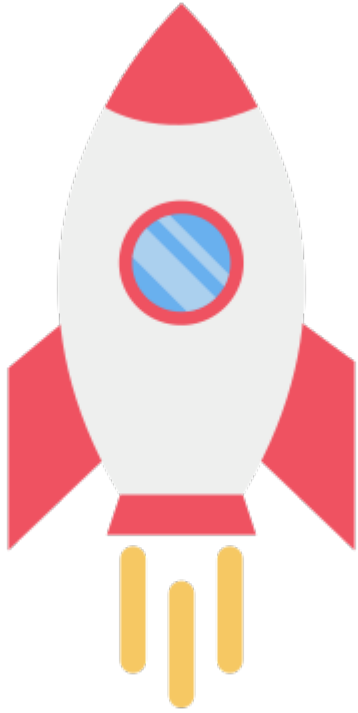
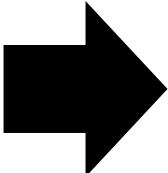
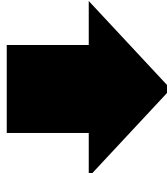
1) "Looking at enforcement documents, recalls, adverse events – the issue first appeared 2 years ago and multiple companies have been affected, including 2 of your CMOs and 1 of your competitors"

2) "Looking at batch records, deviations and investigations, complaints, and audit records – there is a high likelihood that you have this issue. Here is the highlighted evidence and my confidence intervals for each item..."

"Would you like alerts on this topic as it evolves? check all that apply a) Guidance b) proposed regulations c) enforcement d) recalls e) AE's f) deviations ...

Click ->

How do we get there?



Hint: the answer is
beyond ChatGPT...

But, isn't ChatGPT is “scary good”?

ChatGPT Prompt

“Write me a 10 line sonnet in iambic pentameter about auditing a drug facility in China, using issues found like - sterility issues, lack of a quality unit, and other items found in FDAs 21 CFR 211”



ChatGPT Output

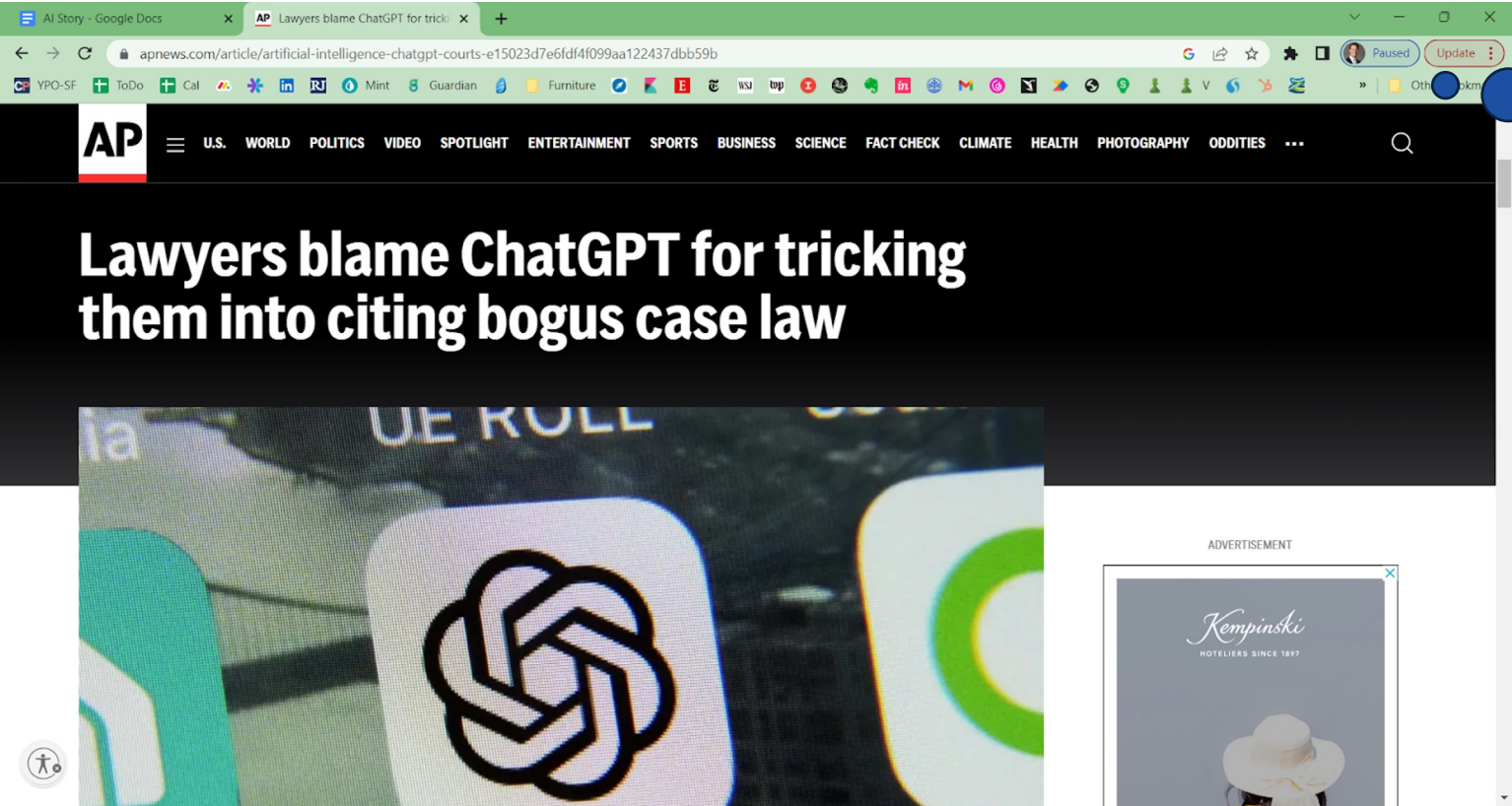
In sterile chambers, flaws of cleanliness,
Revealed, where sterility's reign was weak.
A quality unit's absence, stark distress,
A void that hindered standards they should seek.

Within those walls, FDAs keenly roved,
Unveiling faults in 21 CFR 211.
Missteps, discrepancies, so much unproved,
In regulations, compliance far undone.

Expired compounds, their potency decayed,
Improper labeling, a chaotic scene.
With findings stacked, concerns were not allayed,
A drug facility's flaws were unforeseen.

Yet audits shed light on shadows concealed,
To rectify, ensure the best revealed.

Or is it?



“I did not comprehend that ChatGPT could fabricate cases,”

Chat GPT “hallucinated” precedent cases that “looked real”

Fact: Chat GPT loves to “hallucinate”

ChatGPT Prompt

Using the FDAs 21 CFR 211, what is being cited in this Observation

"OBSERVATION 3

Floors in the ~~~~~(b)(4)~~~~~ room, #(b)(4) in Building (b)(4) are not level. This was observed on Wednesday, April 30, 2014 during a walk-through of the facility ~~~~~(b)(4)~~~~~ was not ~~~(b)(4)~~~



ChatGPT Output

The primary issue being cited in this observation is **21 CFR 211.58(c)**, which requires that the "buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations." The secondary issue being cited is **21 CFR 211.56(b)**, which requires that "buildings shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in process materials, or drug products, and to prevent contamination." The uneven floors in the room could hinder proper cleaning and maintenance and may pose a contamination risk, which is a violation of these regulations.

"It is from 211.42, not 211.58. §58 doesn't even have lettered subsections."

"The correct citation should be 21 CFR 211.42(b)"

"The content is great, seriously. It's just really weird that ChatGPT would just make up the citation"

Is it good or not? ... it depends

This list pretty much describes the job of a regulatory and quality professional

What it is great at

1. **Knowledge and Information:** access to a vast amount of information and can provide accurate facts, explanations, and summaries on diverse subjects.
2. **Language Fluency:** It can generate coherent and grammatically correct sentences, making it proficient in constructing detailed responses.
3. **Creativity:** can assist with creative writing, offer suggestions, and help develop ideas by generating imaginative and engaging content.
4. **Conversation Handling:** It can understand context, maintain context across multiple turns, and respond appropriately, creating a conversational flow.

What it is not great at

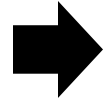
1. **Factual Accuracy:** can occasionally generate incorrect or incomplete responses- aka **Hallucination**
2. **Explainability:** responses are generated based on complex patterns learned from extensive training data, making it difficult to trace the exact reasoning or decision-making process behind each response.
3. **Repeatability:** due to the inherent randomness in the model's architecture and the generation process, there might be variation in the responses.
4. **Understanding Nuance and Context:** it may still occasionally misinterpret or fail to grasp the subtleties, sarcasm, or context-dependent meanings in a conversation.
5. **Real-Time Information:** ChatGPT's knowledge cutoff is in September 2021

The more specific, obscure, or recent the data needs to be, the more LLMs like ChatGPT struggle

How is Enterprise AI different from ChatGPT?

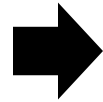
Types of AI

Supervised learning



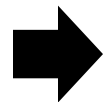
“Labeling things” – text extraction, information extraction, translation, scoring

Unsupervised learning



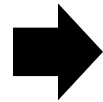
“Clustering things” – trend and anomaly detection (e.g. GE airplane turbines)

Reinforcement learning



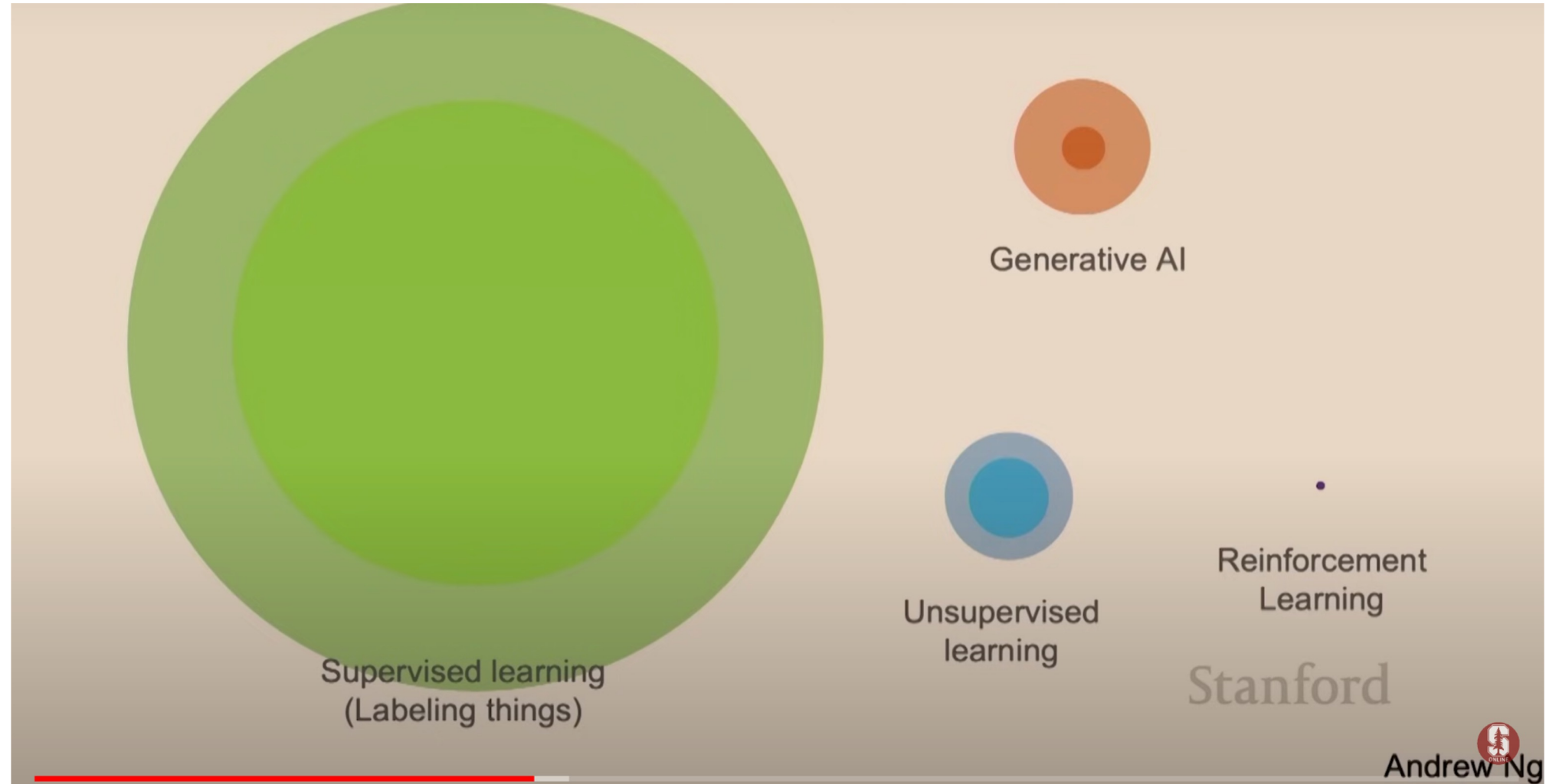
Optimization through rewards

Generative AI



Text / image / song creation

Value to the Enterprise -> 3 year view





Most of the value comes from “Labeling things?”

A music example

Analog / Expert Driven



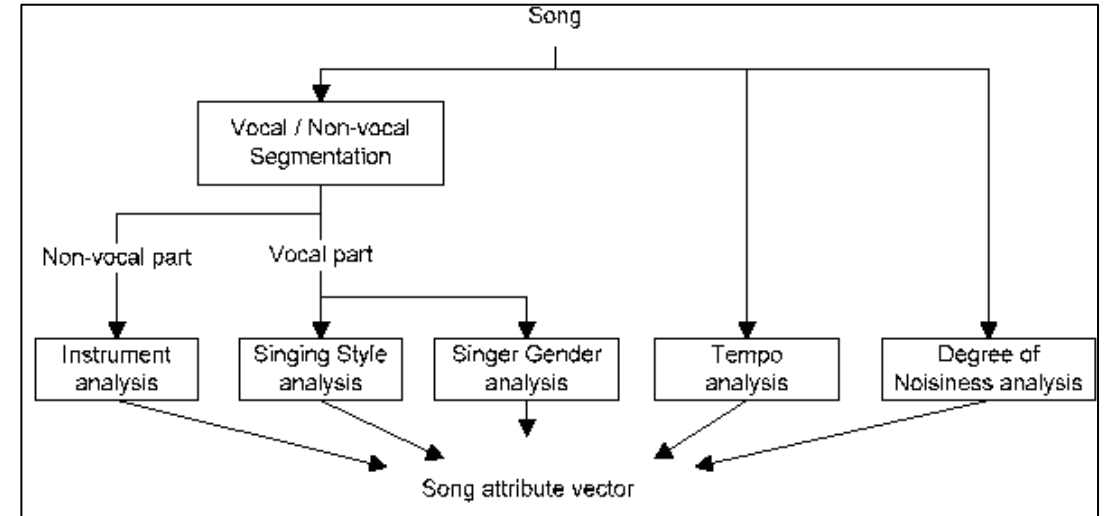
Digital / AI driven



Pandora – the “Music genome project”

<i>attribute</i>	<i>description</i>	<i>type</i>	<i>example</i>
song ID	a unique identifier	nominal	101
title	the title of the song	nominal	Dancing Queen
artist	the name of the performing artist	nominal	ABBA
album	the name of the album of the song	nominal	Greatest Hits
track	the track number of the song on the album	numerical	1
duration	the duration of the song (in seconds)	numerical	232
file size	the size of the file of the song (in MB)	numerical	3.63
genre	the genre to which the song belongs	categorical	popular
year	the year the song was released	numerical	1975
tempo	the tempo of the song (in beats per minute)	numerical	100
tempo marking	the description of the tempo of the song	ordinal	medium
mood	the overall mood of the song	categorical	happy
key	the tonality of the song	categorical	G major

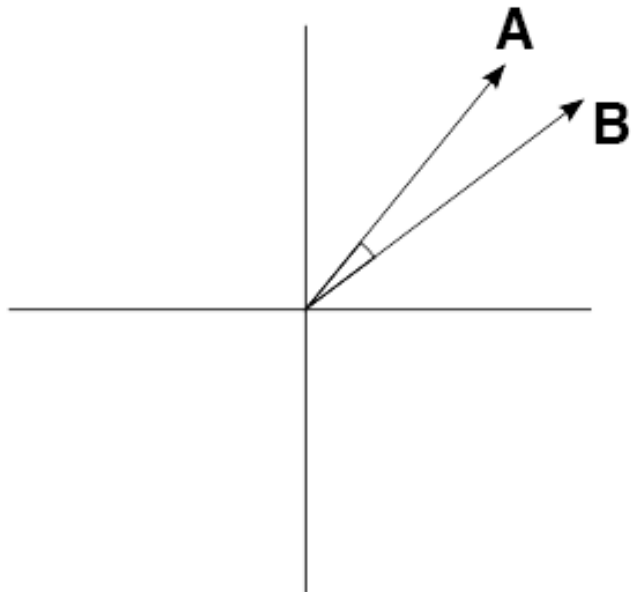
Attribute	Appearances
Minor Key tonality	11
Hard rock roots	9
A subtle use of vocal harmony	9
Mild rhythmic syncopation	8
Extensive vamping	6
A vocal-centric aesthetic	5
Repetitive melodic phrasing	4
Electric rock instrumentation	4



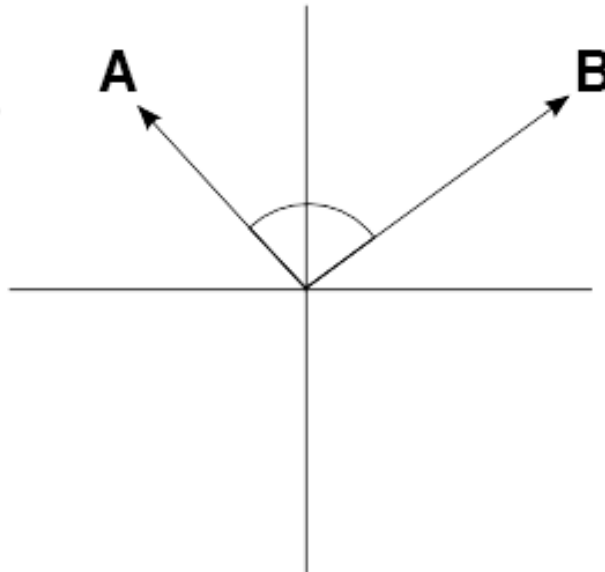
Started with dozens of humans categorizing and labeling tens of thousands of songs ...

Turning features into statistics (aka **vectors**)

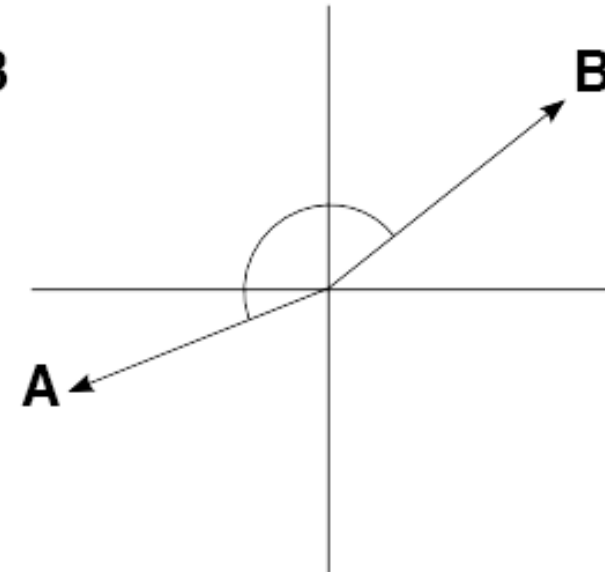
Similar



Unrelated

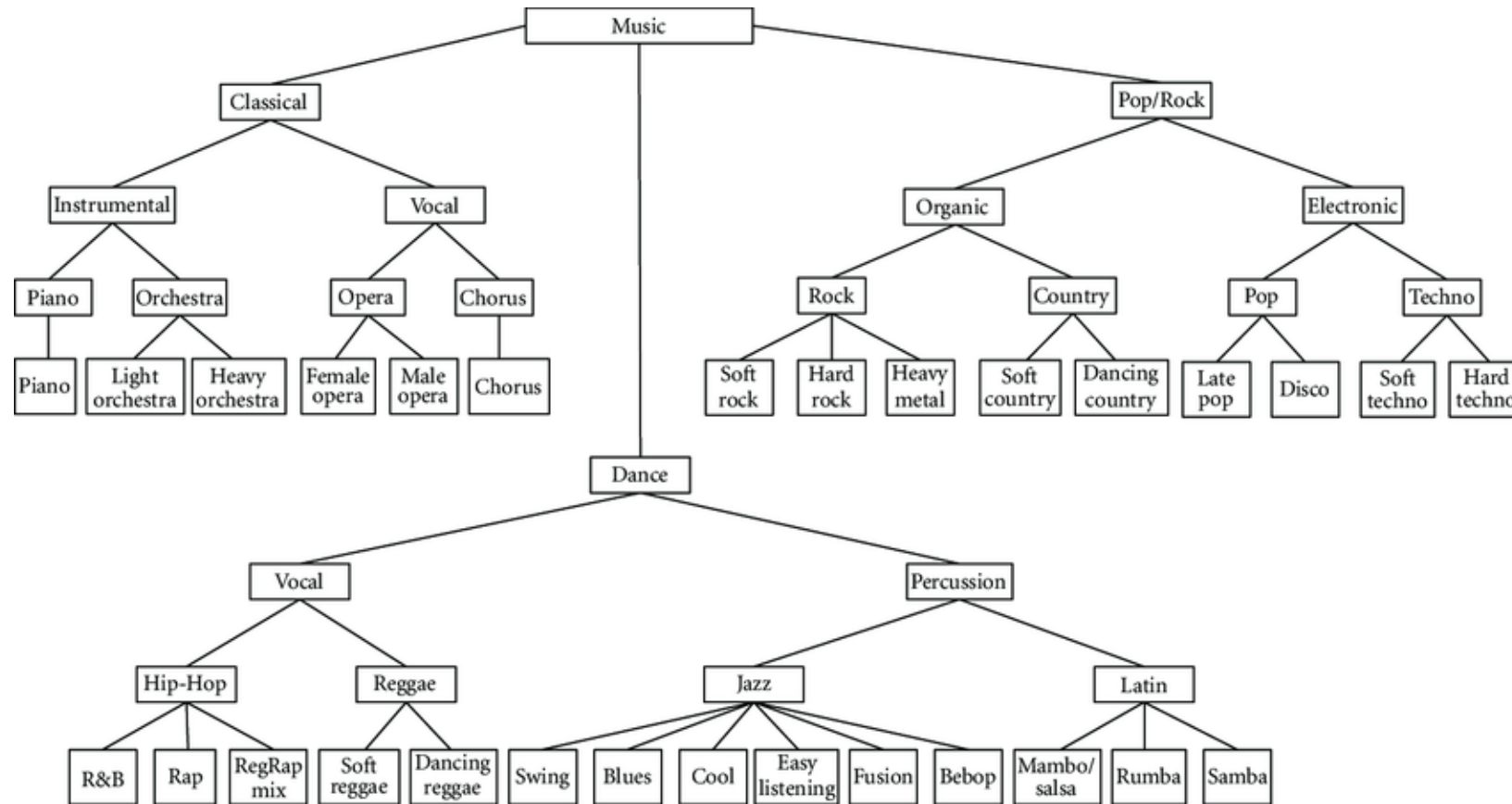


Opposite



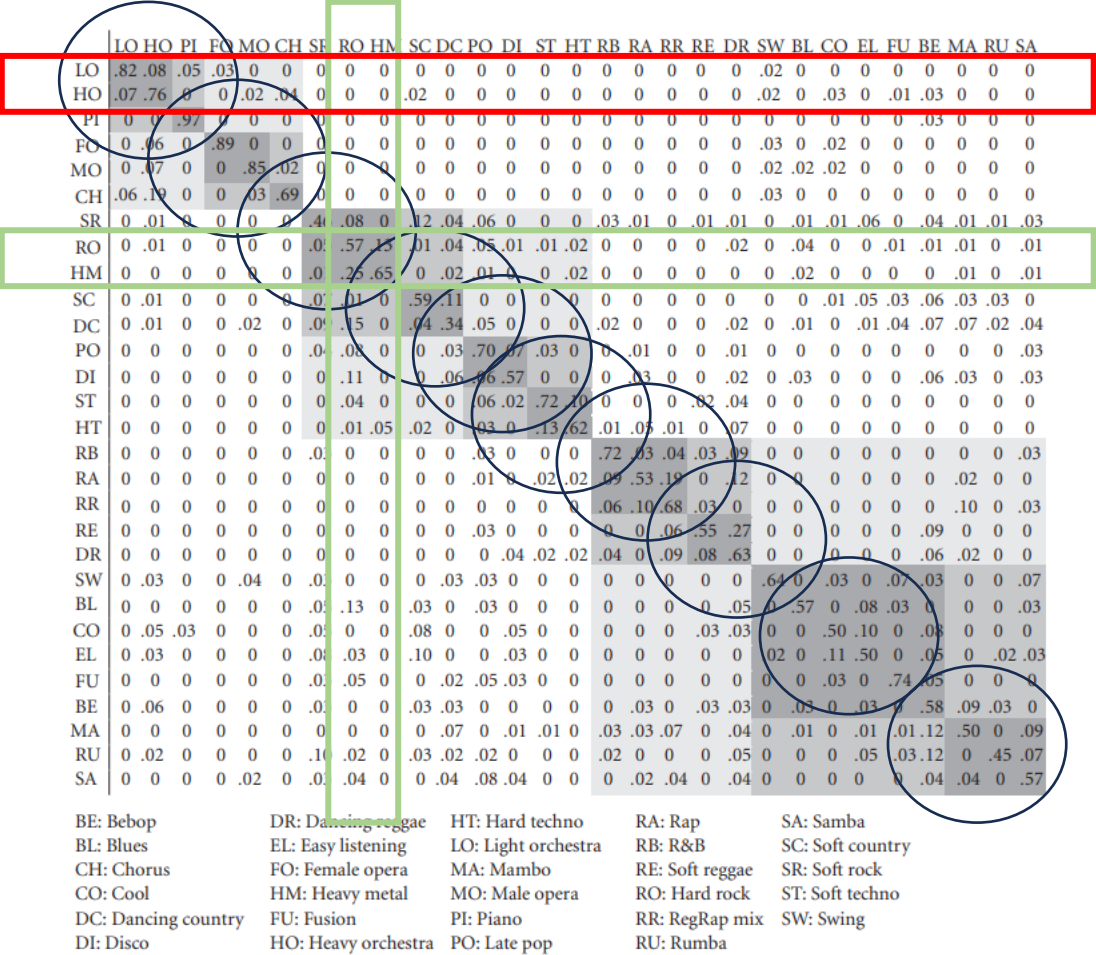
Then the statisticians and engineers created mathematical representations of each label (Machine Learning)

Genre categorization (clusters)



Mathematical categorization of “clusters” of music

The math behind the clusters (similarity)

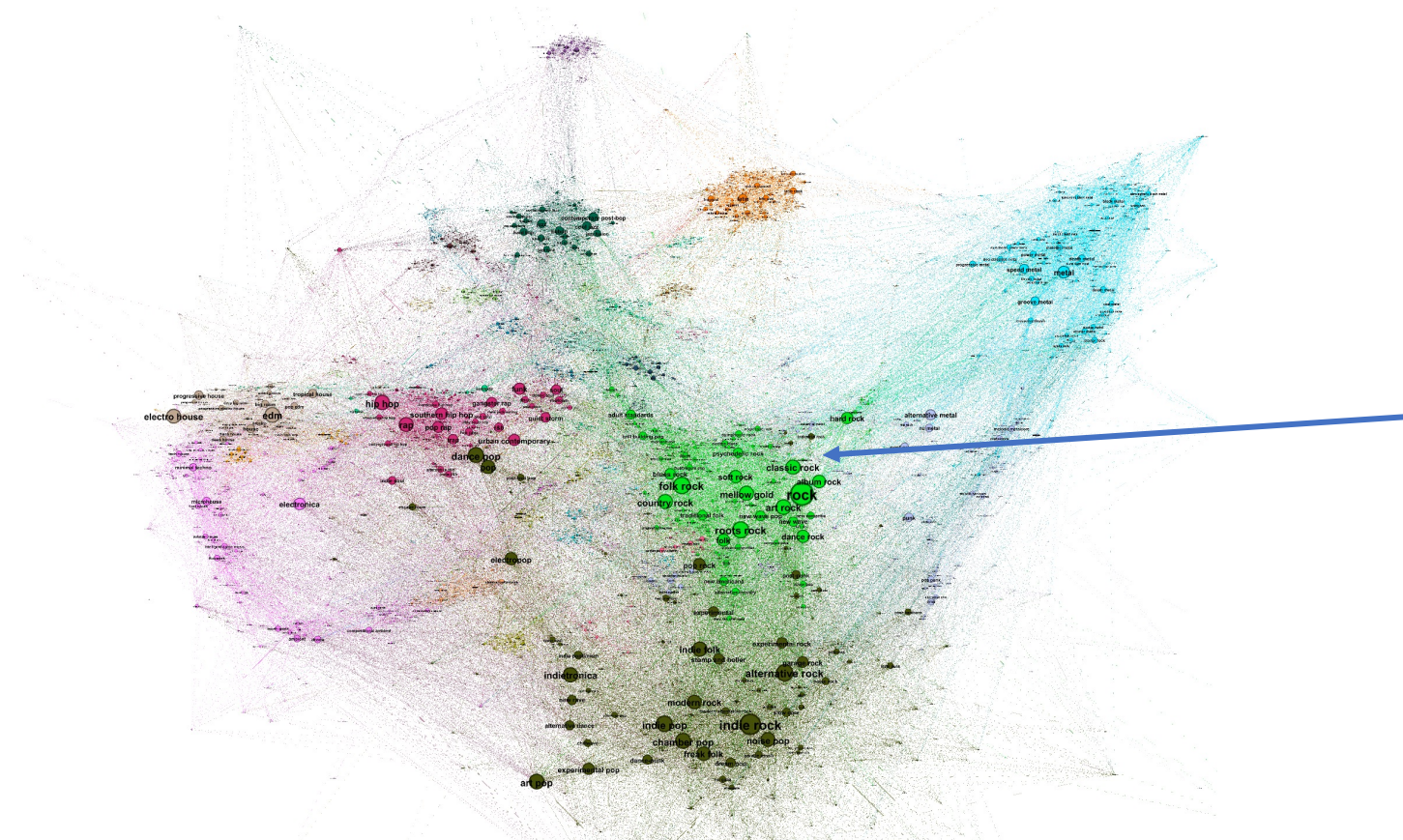


Heavy metal has no similarity to “heavy orchestra”

Hard rock and Heavy metal are quite similar

FIGURE 3: Confusion matrix.

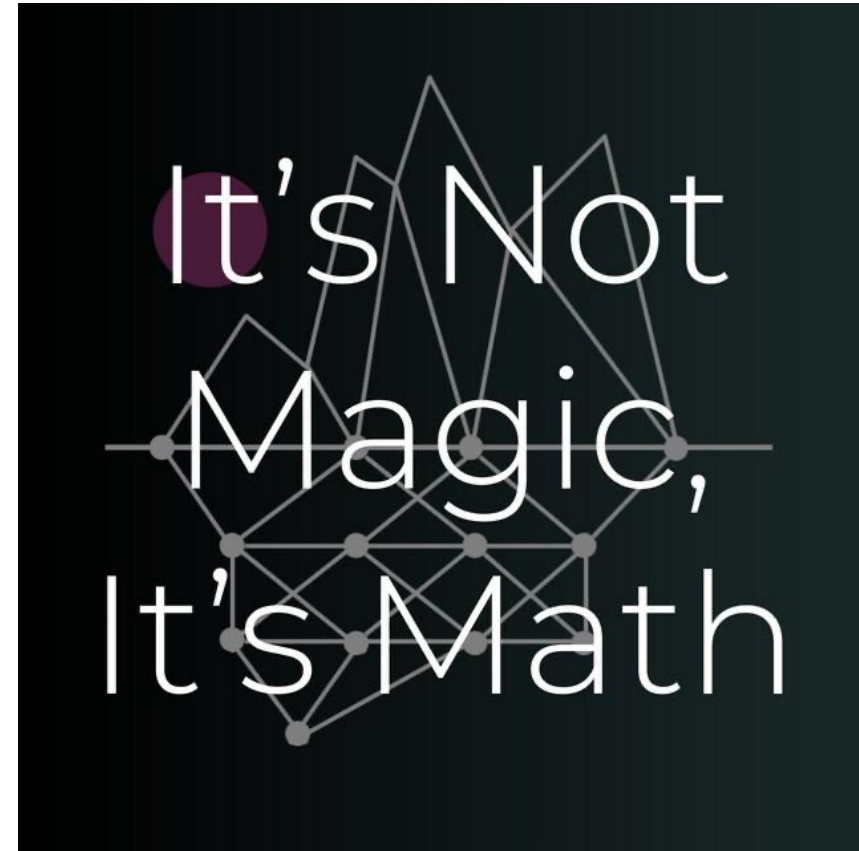
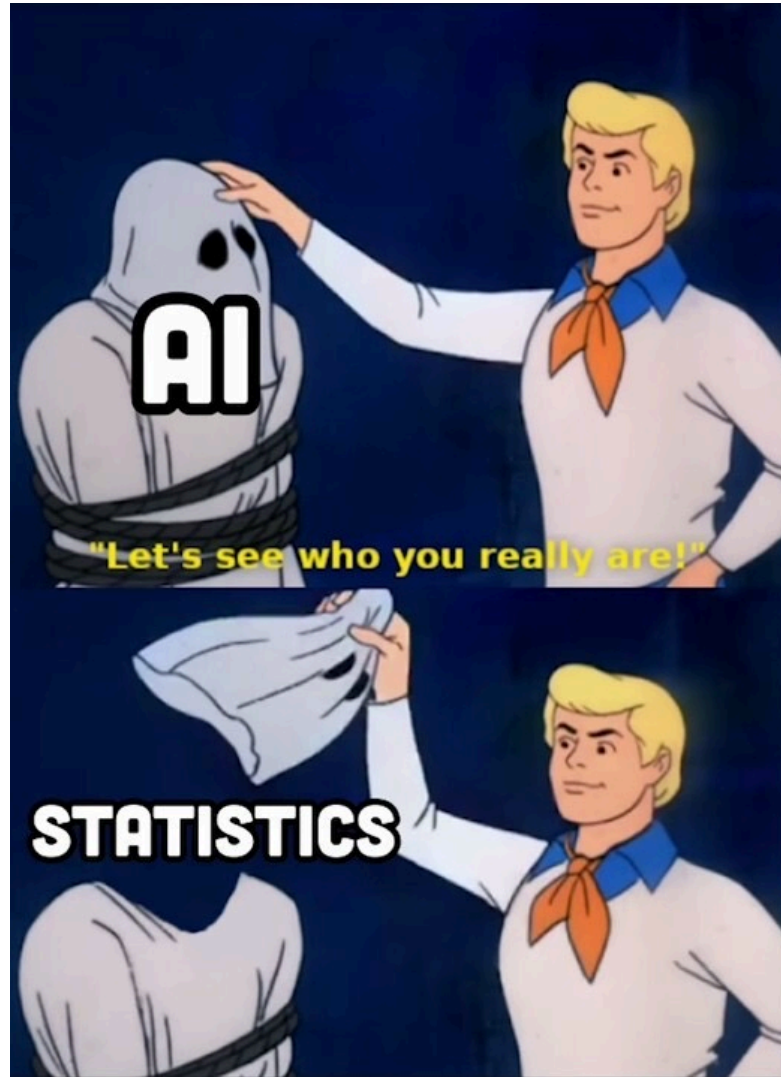
Recommendation engines – ML Labeling -> ML Clustering -> Software



David Bowie
and Queen are
~here

The recommendation engine is software that picks from the local cluster and adjusts to preferences based on thumbs up/down

In other words...



A.I. in music – it all starts with data and labeling

Step 1- Process, label, and link data

Supervised Learning

- Auto label and cluster for the “music genome”
- Generate “stems” – pulling out pieces of songs

Step 2- Assist the human in making decisions

Automation (and a little Unsupervised Learning)

- Pandora-style playlists
- Personalized music - alerts and AI generated playlists
- Spot new trends
- Predict the next hit

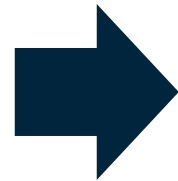
Step 3- Create for the human

Generative AI

- Create original lyrics
- Create original compositions and melodies
- Mimic artists - “Fake Drake”

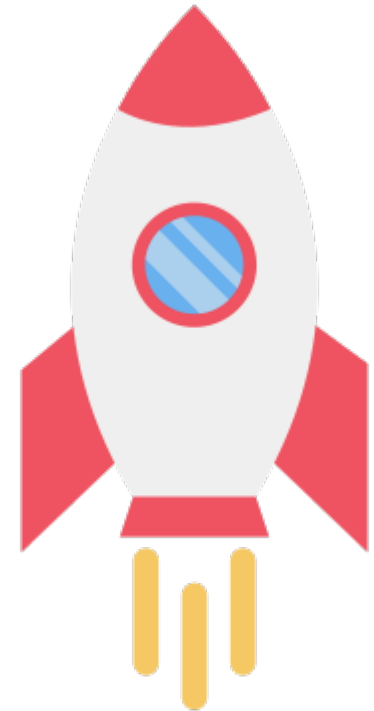
How does Enterprise AI apply to Quality?

Processing, labeling, and linking leads to rocket ships



Use A.I.* to
gather, process,
label, and link
data

*(and good old
fashioned data
engineering, ML,
and automation)



A.I. in quality – it all starts with data and labeling

Wave 1- AI based data processing – extract, label, and link data

Supervised Learning (and good data engineering)

- a. Text extraction
- b. Entity and info extraction
- c. Text translation
- d. Text vectorization
- e. Text labeling
- f. Entity resolution
- g. ...

Wave 2- Assist the human in making decisions

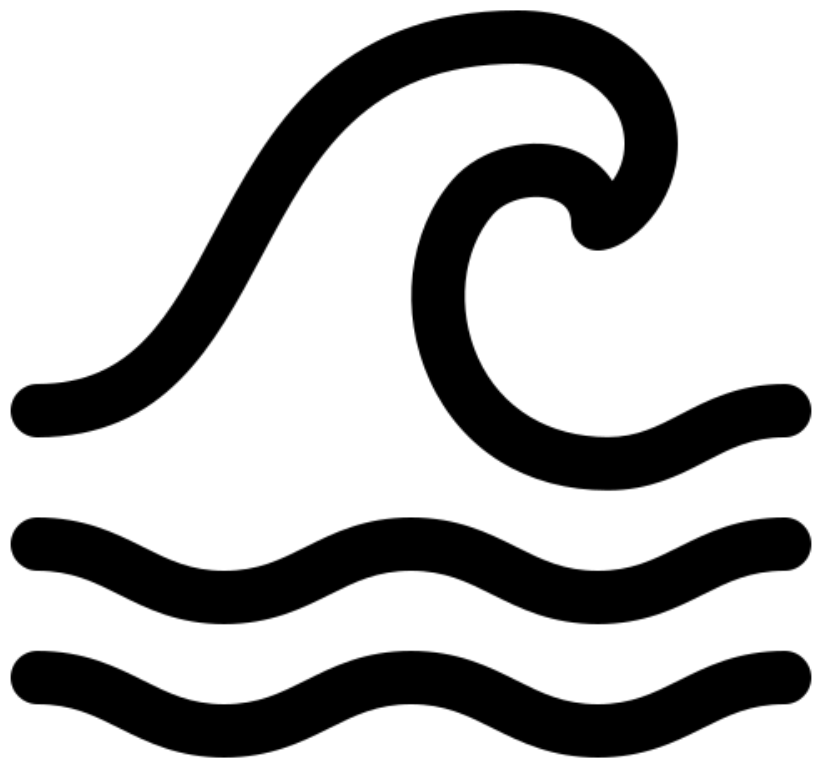
Automation (and a little Unsupervised Learning)

- a. Auto-notifications
- b. Auto-routing
- c. Auto-impact assessments
- d. Auto-diagnostics
- e. Trend detection
- f. Predictive alerts
- g. Natural language search
- h.

Wave 3- Create for the human

Generative AI

- a. Suggest edits to SOPs
- b. Suggest agency response
- c. ...

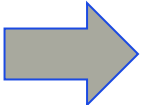
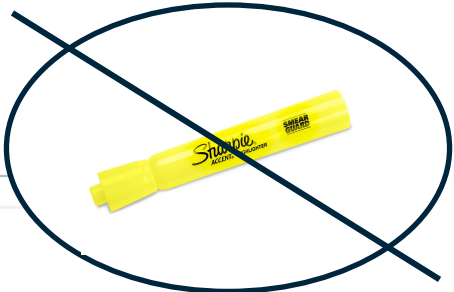


Wave 1

**Structuring the
unstructured:**

**AI based text extraction
(aka IDP)**

Wave 1: AI based data processing



**Word-level
segmentation
and OCR**

WARNING LETTER
Episciences Inc.
MARCS-CMS 631902 – AUGUST 25, 2022

Delivery Method:
VIA EMAIL CONFIRMED DELIVERY

Product:
Drugs

Recipient:
Mr. Chad M. Thayer
Chief Operating Officer
Episciences Inc.
10211 West Emerald Street
Boise, ID 83704-8987
United States
✉ (b)(4) (mailto:(b)(4))

Issuing Office:
Division of Pharmaceutical Quality Operations IV
United States

WARNING LETTER

August 25, 2022

Dear Mr. Thayer:

The U.S. Food and Drug Administration inspected your drug manufacturing facility, Episciences Inc., FEI 3006435842, at 10211 West Emerald Street, Boise, from March 7 to 11, 2022.

This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

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Wave 1: AI based data processing



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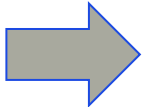
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August 25, 2022

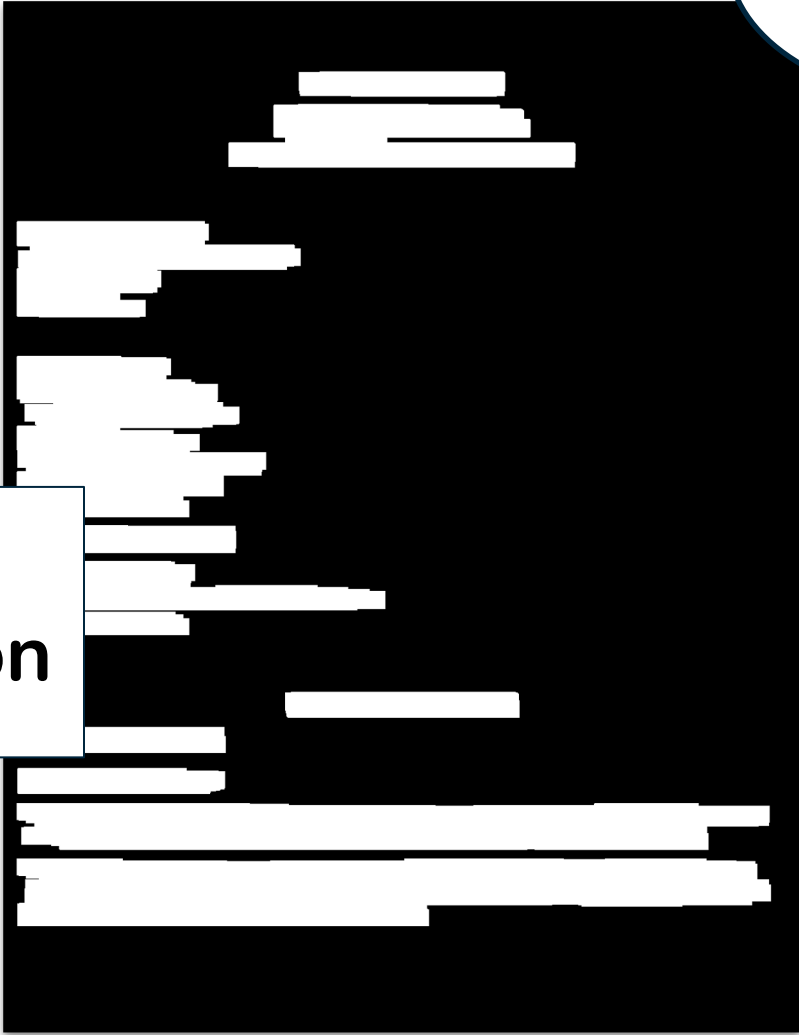
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**Layout
segmentation**



Wave 1: AI based data processing



Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your March 17, 2022, response to our Form FDA 483 in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether the batch has already been distributed (21 CFR 211.192).

Your investigations into out-of-specification (OOS) laboratory results are inadequate because they do not include scientifically supported conclusions and lack corrective actions and preventive actions (CAPA). For example:

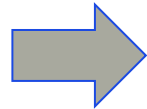
A. Your investigation into bulk drug product assay OOS result of active ingredient zinc oxide reported by your contract testing laboratory for "(b)(4)" Sunscreen, Lot # (b)(4), was inadequate. You determined the root cause to be sampling error and attributed it to a non-homogenous blending sample collected from the "top of the mixer scrapings." The bulk batch was subsequently resampled, retested for assay, and released after obtaining passing results. Your investigation lacked hypothesis testing and adequate evidence to identify the root cause and you did not document whether other batches and drug products manufactured in your facility were affected. In addition, your investigation failed to address the non-homogeneity of your products based on where test samples are collected.

B. Your investigation into OOS bulk test results for appearance and viscosity for "Purifying Wash, Lot #s 21A044, 21A045, 21A046, and 21A085, reported by your contract testing laboratory was inadequate. You failed to adequately determine the root cause for these failures. Instead, you inspected sample tubes from each lot for appearance, retested only one of the four lots for assay and subsequently released all four lots on the basis of this limited testing.

You failed to identify appropriate CAPA for these investigations to prevent recurrence of such events. There is no assurance that all batches produced under inadequate conditions have been thoroughly evaluated, and that your firm has identified all significant variables associated with your manufacturing process.

Moreover, your standard operating procedure (SOP) titled "Out of Specification Investigations," states that batches may be released with OOS results at the discretion of the Quality Assurance (QA) manager.

For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document, *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production* at: <https://www.fda.gov/media/158416/download>. (<https://www.fda.gov/media/158416/download>)



Segment Extraction

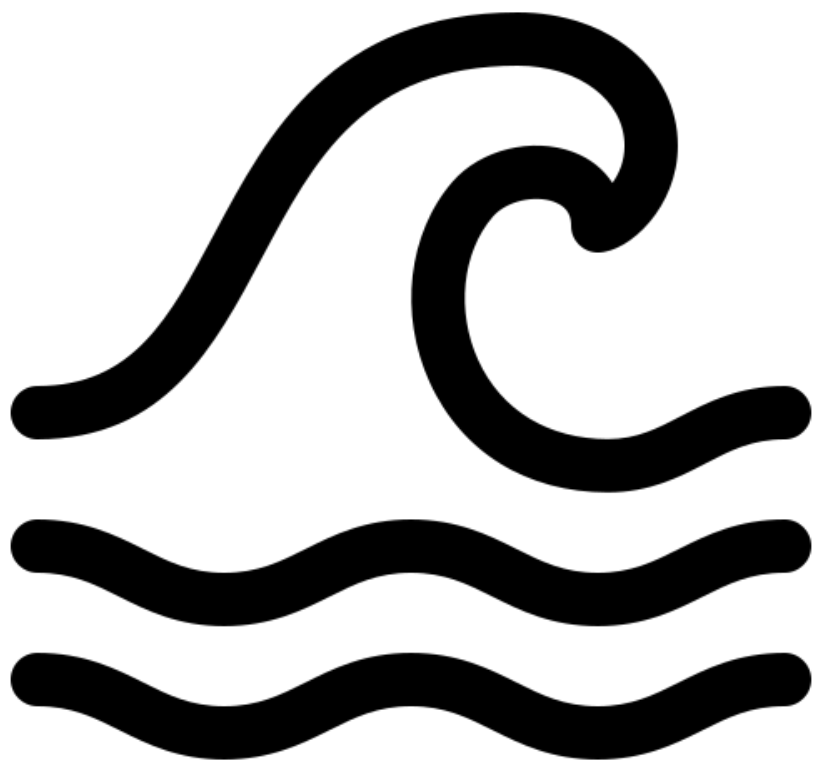
page_num	segNum	LineText
2	10	Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).
2	9	We reviewed your March 17, 2022, response to our Form FDA 483 in detail.
2	8	During our inspection, our investigator observed specific violations including, but not limited to, the following.
2	7	1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether the batch has already been distributed (21 CFR 211.192).
2	6	Your investigations into out-of-specification (OOS) laboratory results are inadequate because they do not include scientifically supported conclusions and lack corrective actions and preventive actions (CAPA). For example:
	5	A. Your investigation into bulk drug product assay OOS result of active ingredient zinc oxide reported by your contract testing laboratory for "(b)(4)" Sunscreen, Lot # (b)(4), was inadequate. You determined the root cause to be sampling error and attributed it to a non-homogenous blending sample collected from the "top of the mixer scrapings." The bulk batch was subsequently resampled, retested for assay, and released after obtaining passing results. Your investigation lacked hypothesis testing and adequate evidence to identify the root cause and you did not document whether other batches and drug products manufactured in your facility were affected. In addition, your investigation failed to address the non-homogeneity of your products based on where test samples are collected.
	4	B. Your investigation into OOS bulk test results for appearance and viscosity for "Purifying Wash, Lot #s 21A044, 21A045, 21A046, and 21A085, reported by your contract testing laboratory was inadequate. You failed to adequately determine the root cause for these failures. Instead, you inspected sample tubes from each lot for appearance, retested only one of the four lots for assay and subsequently released all four lots on the basis of this limited testing.
	3	You failed to identify appropriate CAPA for these investigations to prevent recurrence of such events. There is no assurance that all batches produced under inadequate conditions have been thoroughly evaluated, and that your firm has identified all significant variables associated with your manufacturing process.
2	2	Moreover, your standard operating procedure (SOP) titled "Out of Specification Investigations," states that batches may be released with OOS results at the discretion of the Quality Assurance (QA) manager.
2	1	For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document, <i>Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production</i> at: https://www.fda.gov/media/158416/download . (https://www.fda.gov/media/158416/download)

Wave 1: AI based data processing



segNum	relavenceTag	relavenceTag_prob	Line Text	page_num
10	introduction	0.98	Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).	2
9	introduction	0.98	We reviewed your March 17, 2022, response to our Form FDA 483 in detail.	2
8	introduction	0.98	During our inspection, our investigator observed specific violations including, but not limited to, the following.	2
7	deficiencytitle	0.99	1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether the batch has already been distributed (21 CFR 211.192).	2
6	deficiency	0.98	Your invest... they do not include scientifically supported conclusions and lack	2
5	deficiency	0.98	A. Your inv... reported by your contract testing laboratory for "(b)(4)" Sunscreen, ed it to a non- homogenous blending sample collected from the ; and released after obtaining passing results. Your investigation oment whether other batches and drug products manufactured neity of your products based on where test samples are collected.	2
4	deficiency	0.99	B. Your investigation into OOS bulk test results for appearance and viscosity for "Purifying Wash, Lot #s 21A044, 21A045, 21A046, and 21A085, reported by your contract testing laboratory was inadequate. You failed to adequately determine the root cause for these failures. Instead, you inspected sample tubes from each lot for appearance, retested only one of the four lots for assay and subsequently released all four lots on the basis of this limited testing.	2
3	deficiency	0.96	You failed to identify appropriate CAPA for these investigations to prevent recurrence of such events. There is no assurance that all batches produced under inadequate conditions have been thoroughly evaluated, and that your firm has identified all significant variables associated with your manufacturing process.	2
2	deficiency	0.98	Moreover, your standard operating procedure (SOP) titled "Out of Specification Investigations, states that batches may be released with OOS results at the discretion of the Quality Assurance (QA) manager.	2
1	feedback,fdarequestforinformation	0.44,0.32	For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document, Investigating Out-of- Specification (OOS) Test Results for Pharmaceutical Production at: https://www.fda.gov/media/158416/download	2

Segment Categorization



Wave 1

**Structuring the
unstructured:**

**Understanding meaning
(NLP)**

Understanding meaning – how do we do it?

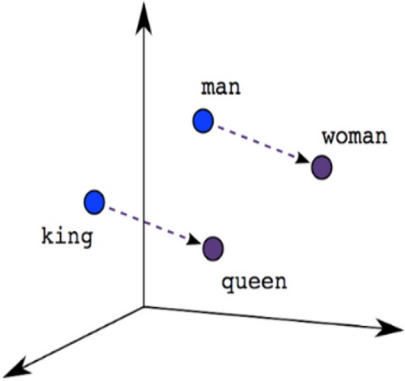
segNum	relavenceTag	relavenceTag_prob	LineText	page_num
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6	deficiency	0.98	Your investigations into out-of-specification (OOS) laboratory results are inadequate because they do not include scientifically supported conclusions and lack corrective actions and preventive actions (CAPA). For example:	2
5	deficiency		Text:1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether the batch has already been distributed (21 CFR 211.192).	2
4	deficiency		Area: Quality Unit; 1.0 L1/L2: Reviews and Approvals->Batch Release, 0.74	2
3	deficiency		Common Object: Specifications; 0.89	2
2	deficiency		Deficiency Reason : Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications	2
1	feedback,fd		Summary: The CFR Title, Part, and Section that corresponds to the violation mentioned in the text snippet is 21 CFR 211.192.	2

Understanding meaning: vectors

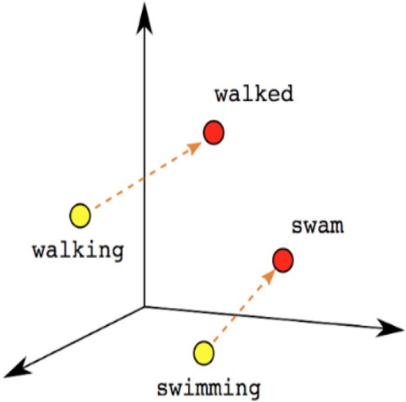
Quiz:
What is the **Berlin**
of **France**? (fill in
the blank)



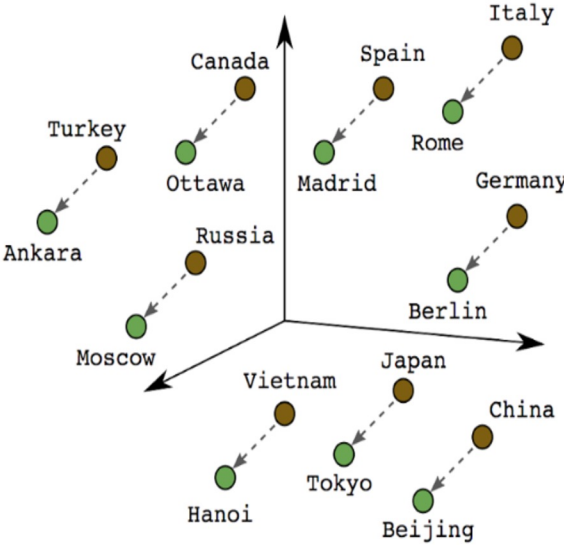
Understanding meaning: many types of vectors



Male-Female

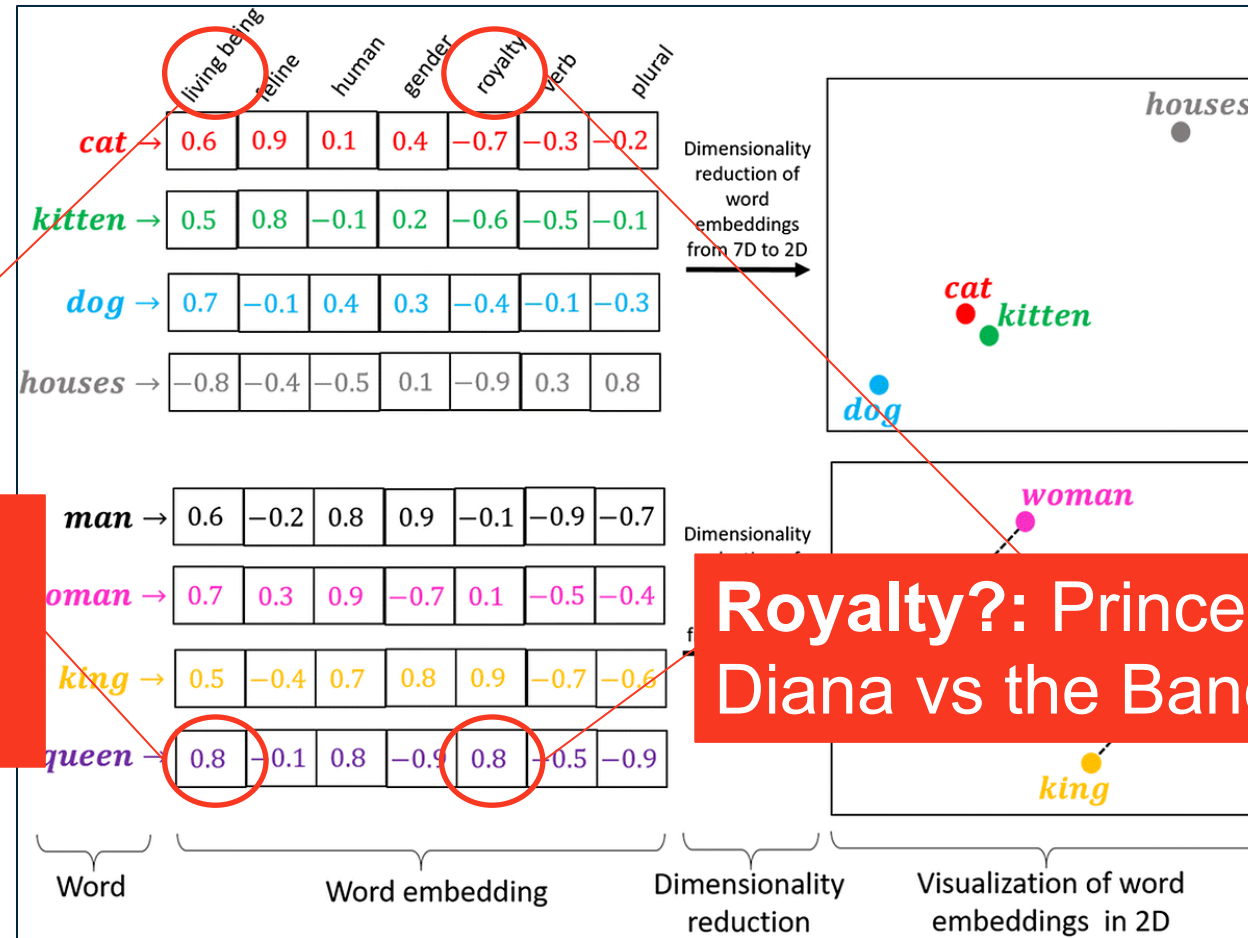


Verb Tense



Country-Capital

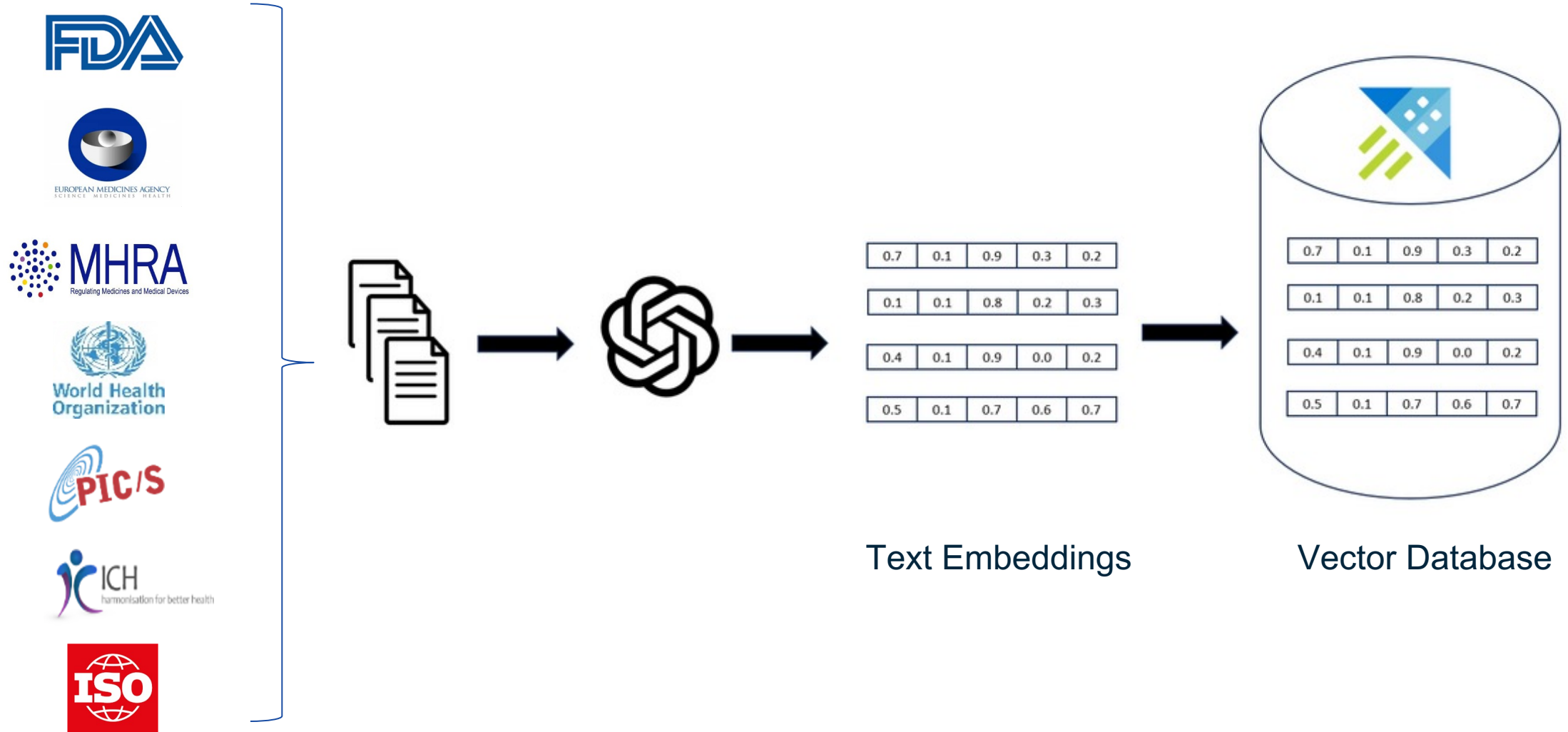
Understanding meaning: embeddings



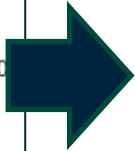
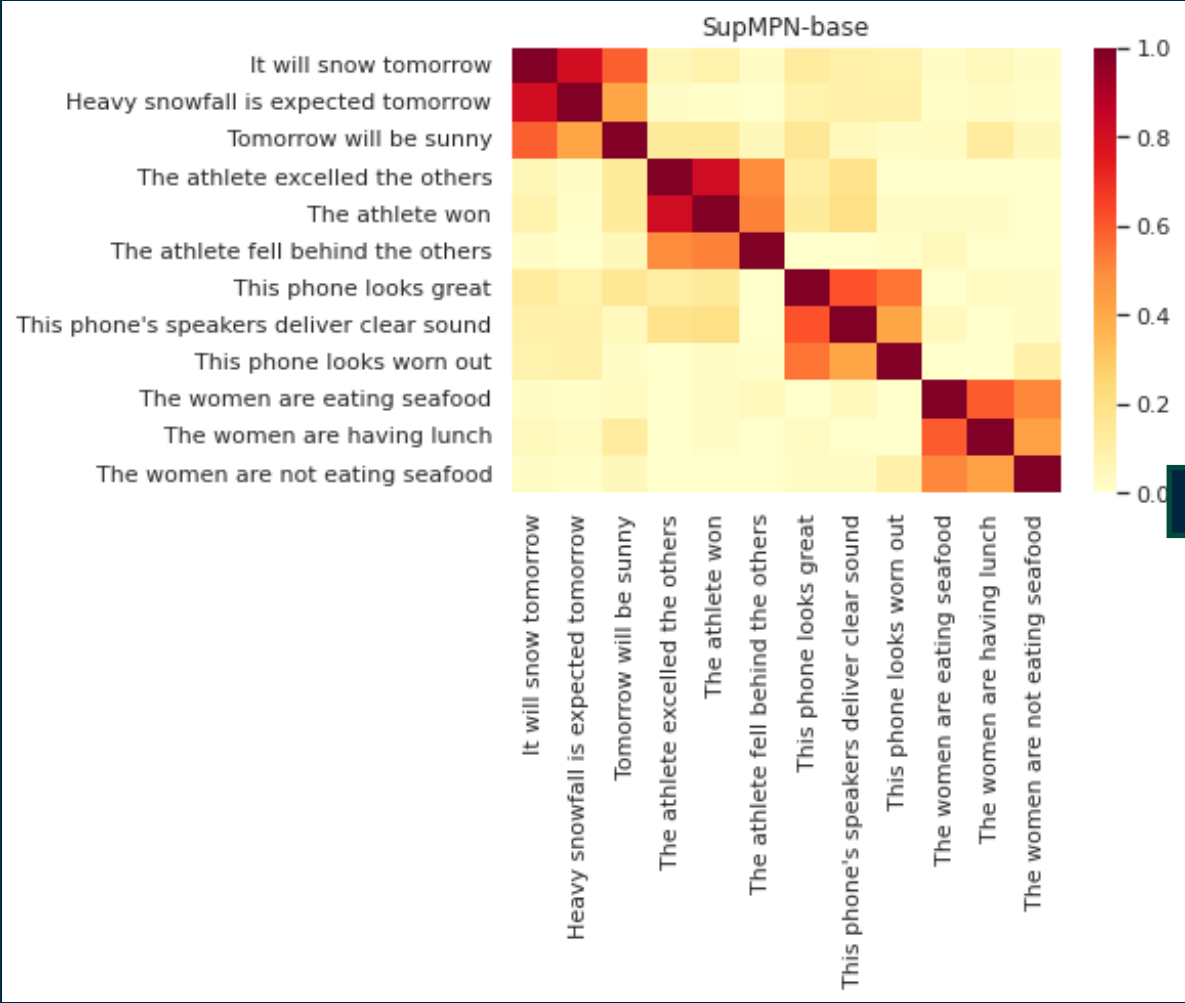
**Living being?:
chess vs
monarchy**

**Royalty?: Princess
Diana vs the Band**

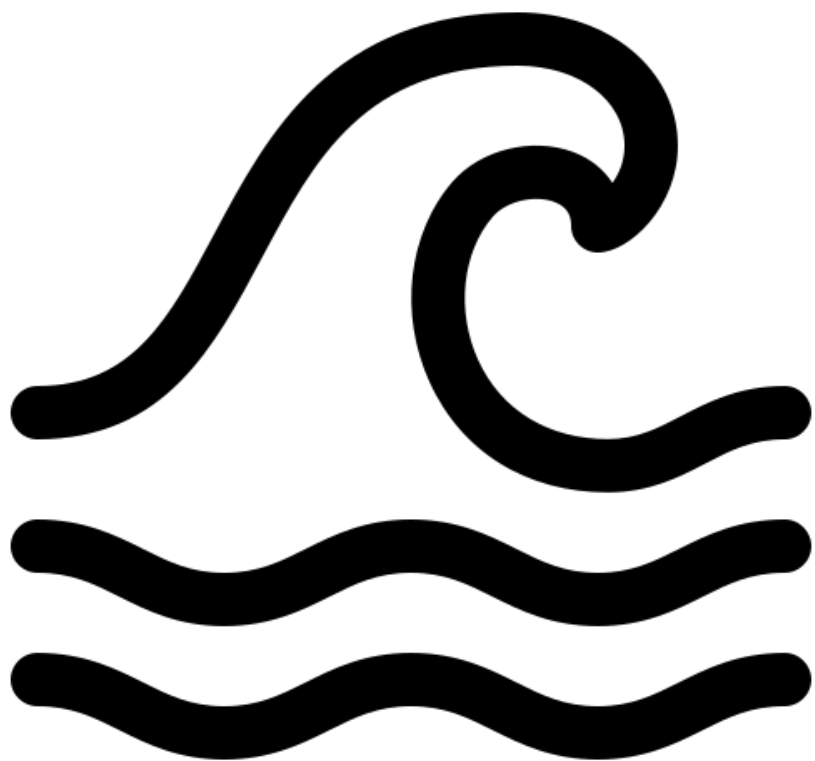
1000's of examples to "teach" the model



Sentence similarity – Just like music!



Hint: this is the underlying technology that powers natural language search

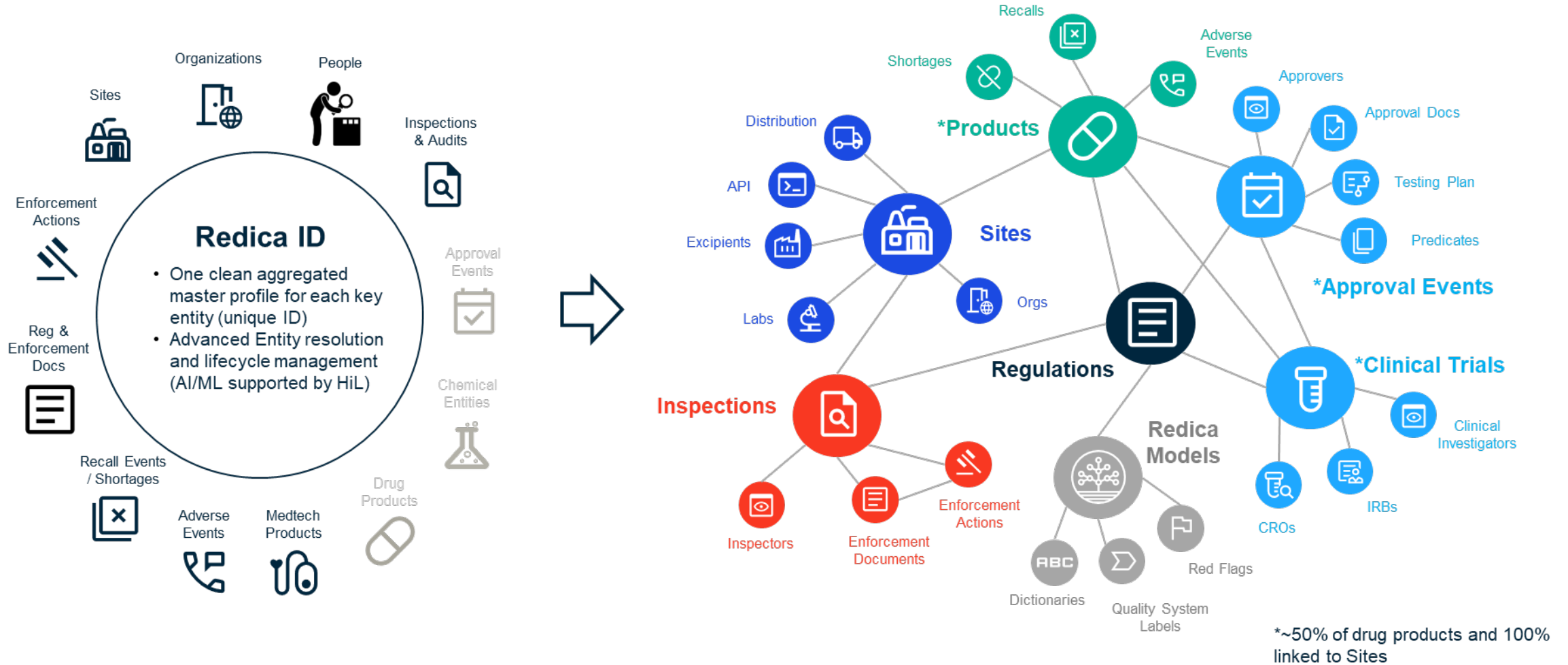


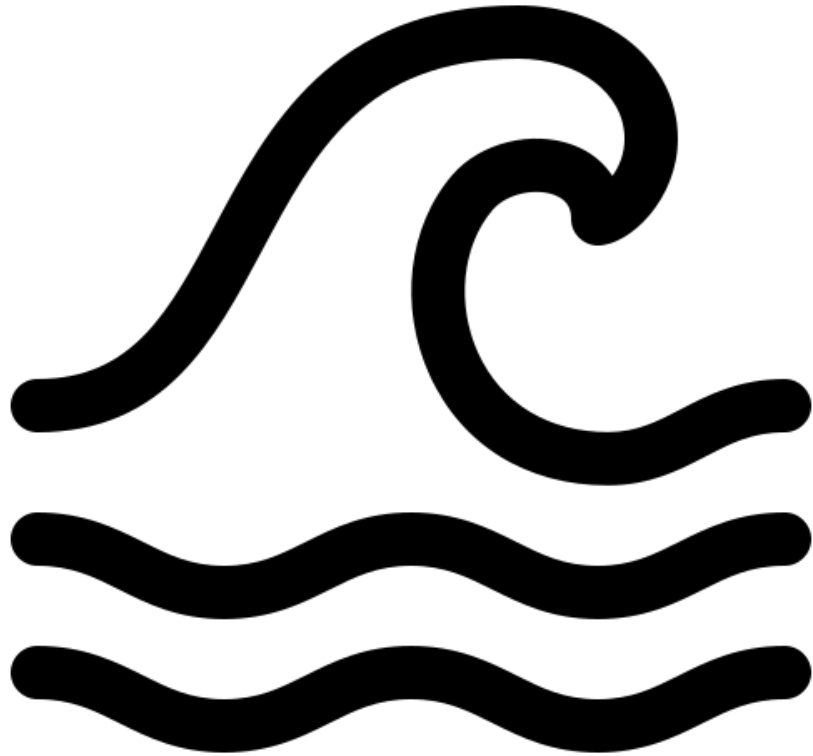
Wave 1

**Structuring the
unstructured:**

**Entity extraction and
linking**

Entity creation and linking





Wave 2

Amplify the intelligence of humans:

AI powered processing - simple visualizations

Date range: All time | Site Group Name: all cmo, All CMOs, ... (7) | Site Country: All

Site App Url	Site Display Name	Site Country	Cum. Site Score	Last 20 Year Score	Last 10 Year Score	Last 5 Year Score
sites/100007787	Jubilant HollisterStier LLC [Spokane / United States of America]	United States of America	424	417 - Very Poor	259 - Very Poor	69 - Very Poor
		United States of America	289	281 - Very Poor	233 - Very Poor	76 - Very Poor
		United States of America	258	244 - Very Poor	135 - Very Poor	61 - Very Poor
		United States of America	212	154 - Very Poor	133 - Very Poor	41 - Poor
		United States of America	200	186 - Very Poor	129 - Very Poor	80 - Very Poor
		United States of America	184	146 - Very Poor	70 - Poor	40 - Poor
		Australia	134	124 - Very Poor	37 - Poor	14 - Okay
		India	126	126 - Very Poor	133 - Very Poor	71 - Very Poor
		Canada	106	101 - Poor	80 - Poor	14 - Okay
		United States of America	94	69 - Poor	30 - Okay	13 - Okay
		United States of America	92	79 - Poor	13 - Okay	0 - Okay
		Germany	89	83 - Poor	32 - Okay	18 - Okay
		United States of America	85	85 - Poor	28 - Okay	3 - Okay
		United States of America	82	86 - Poor	48 - Poor	15 - Okay
		United Kingdom of Great Britain and Northern Ireland	75	75 - Poor	54 - Poor	20 - Okay
		United States of America	73	73 - Poor	2 - Okay	-23 - Very Good
		India	70	80 - Poor	75 - Poor	12 - Okay
		United States of America	70	17 - Okay	26 - Okay	13 - Okay
		United States of America	61	61 - Poor	39 - Poor	31 - Poor
		United States of America	60	52 - Poor	21 - Okay	10 - Okay
Germany	58	58 - Poor	44 - Poor	4 - Okay		
United States of America	57	35 - Okay	2 - Okay	-11 - Good		
Italy	55	50 - Poor	38 - Poor	12 - Okay		
United States of America	53	45 - Poor	-11 - Good	-12 - Good		

AI powered processing - simple visualizations



AI powered processing - simple visualizations



My dream - Investigation of an issue



Here is an issue of interest ...

1) How widespread is this? 2) Do we have this problem?"

Click ->

1) "Looking at enforcement records, recalls, adverse events – the issue first identified in 2015. Multiple companies have been identified. 2) "We have identified 3 of our CMOs and 1 of your competitors"

3) "Review of batch records, deviations and investigations, complaints, and audit records – there is a high likelihood that you have this issue. Here is the highlighted evidence and my confidence intervals for each item..."

"Would you like alerts on this topic as it evolves? check all that apply a) Guidance b) proposed regulations c) enforcement d) recalls e) AE's f) deviations ...

Click ->

Achievable!

~~Artificial~~ Intelligence Augmented

Special thanks to Syama Adhibhatta from Vertex