Redica Systems

DATA DRIVEN INSPECTION INTELLIGENCE AND CMO SELECTION

Is this presentation for me?

Innovator / Sponsor

Generics/ Biosimilars

CMO

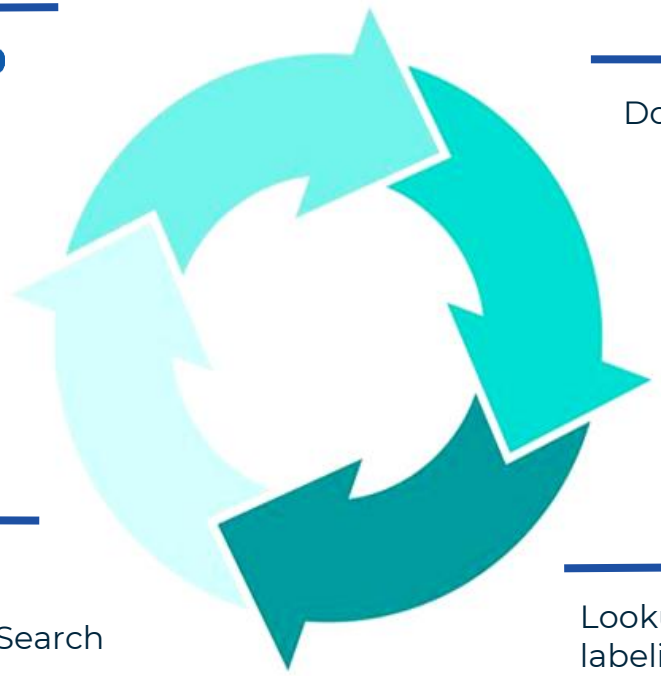
Contents

Decoding regulatory data

Structuring the unstructured

1. Data Acquisition

...100s of agencies



2. Data Normalization & Enrichment

- Doc Versioning
- **Entity Extraction**
- **Entity Linking**
- Term Standardization
- **Text Extraction**
- **Text Parsing**
- Text Translation

3. Embed Intelligence

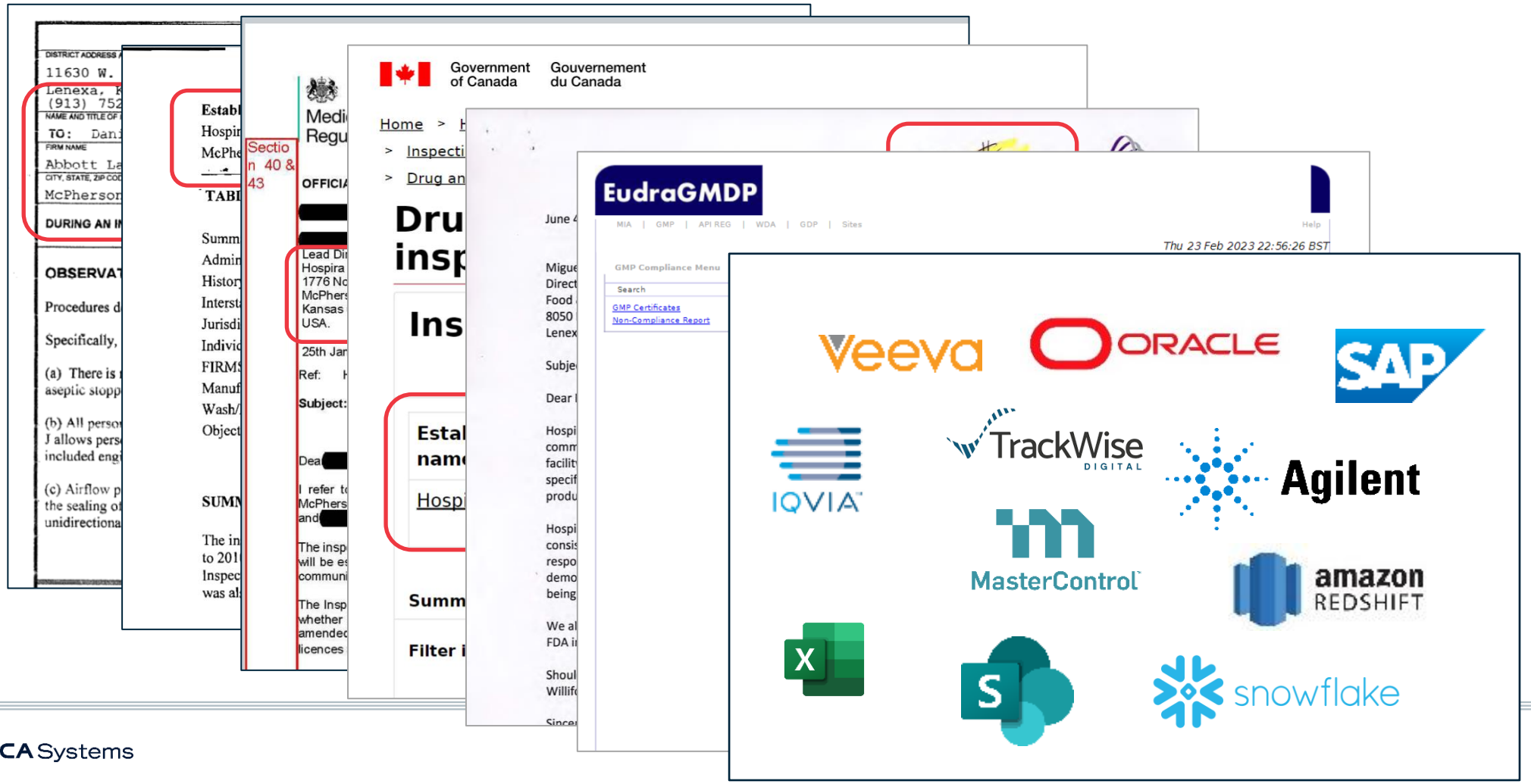
- Lookup-based labeling
- **AL/ML -based labeling**
- Relevance scoring
- **Risk scoring (red flags)**
- Flexible schema development

4. Data Driven Workflows

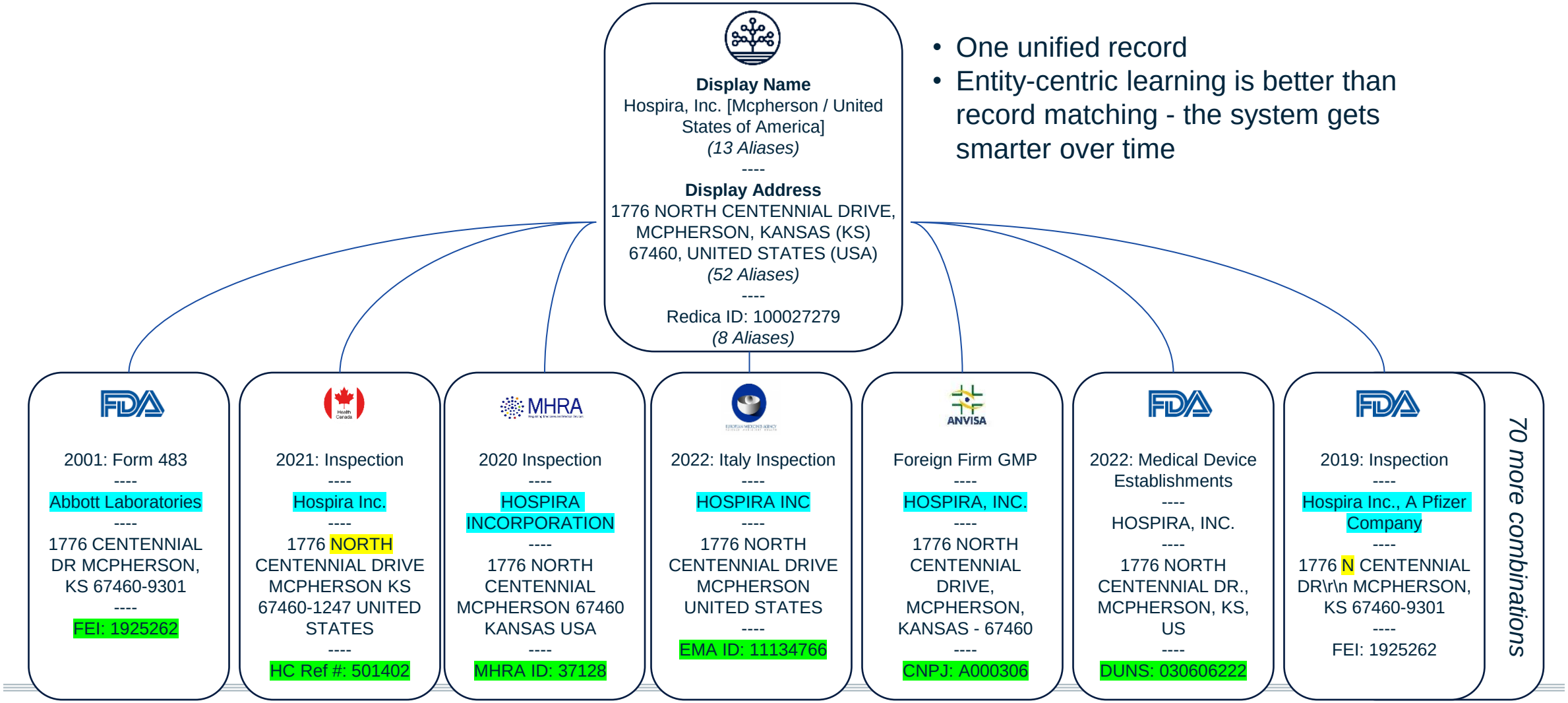
- Reports
- Benchmarking
- Interactive Dashboards
- Faceted Search
- APIs / Data Contracts
- Semantic Search

The key problem

The same entity being described (very) differently

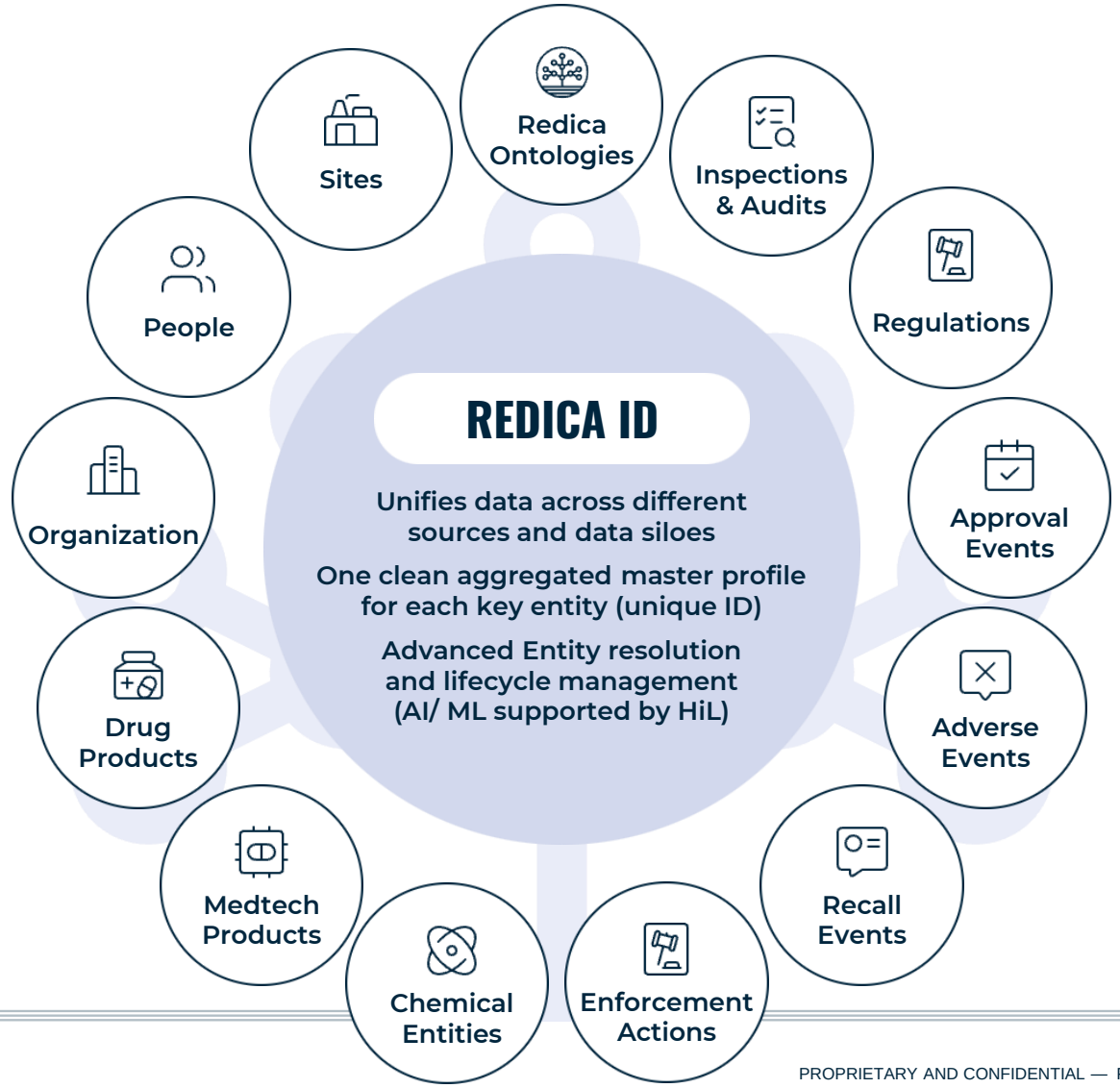


Solution = Redica ID



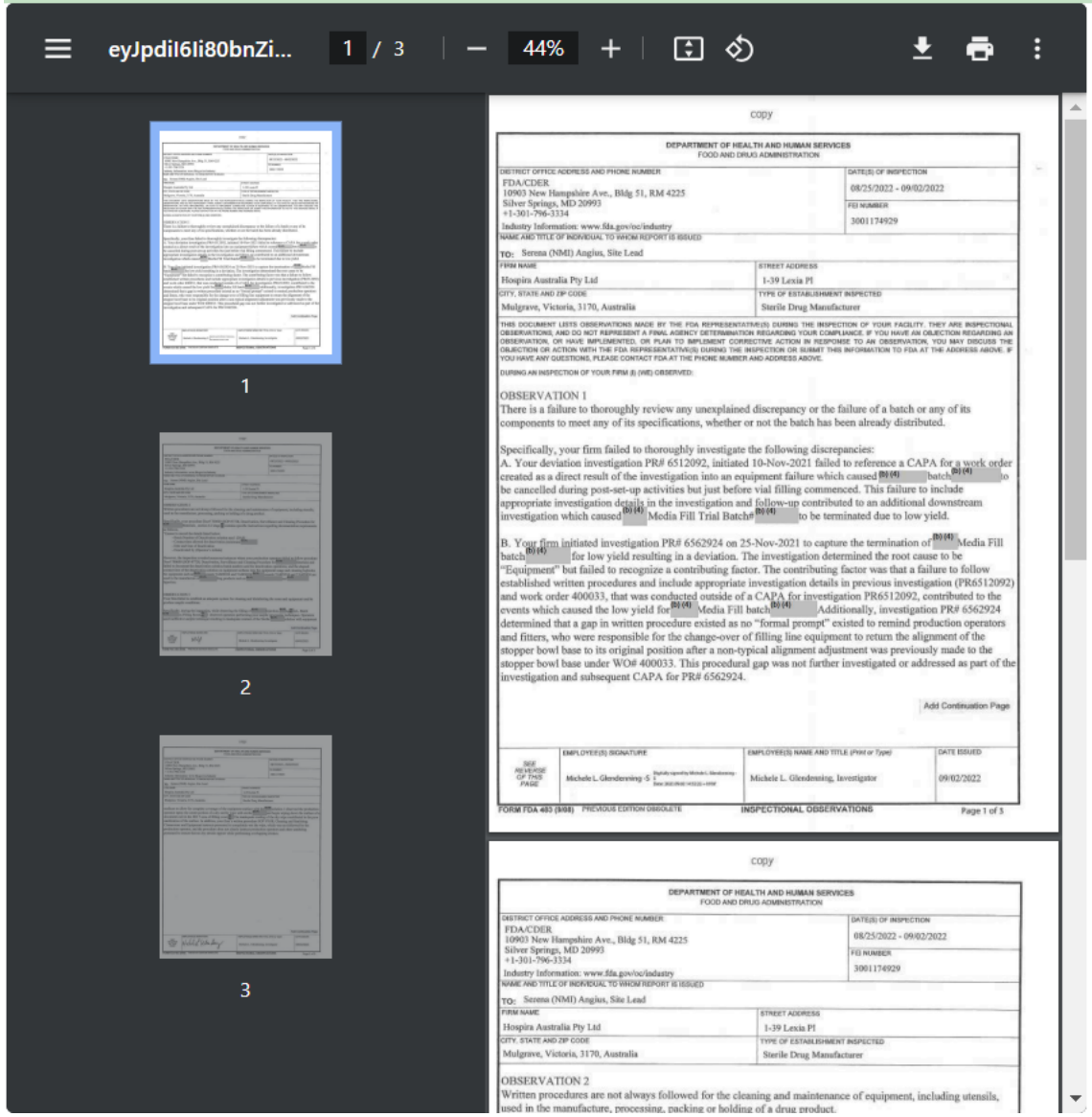
- One unified record
- Entity-centric learning is better than record matching - the system gets smarter over time

Same problem exists for many entities



Knowledge Graph – connect events and entities

Document processing - Behind the scenes



Inspections

09/01/2022 (Thu)

09/02/2022 (Fri)

Site References

FEI | us_fda | 3001174929

Add Site Reference

Firm Name (Site Name)

Hospira Australia Pty Ltd.

Inspected Site Address (Raw)

1-39 Lexia Pl
Mulgrave, Victoria 3170, Australia

Type of Establishment Inspected

Sterile Drug Manufacturer

Add Inspection

Investigators

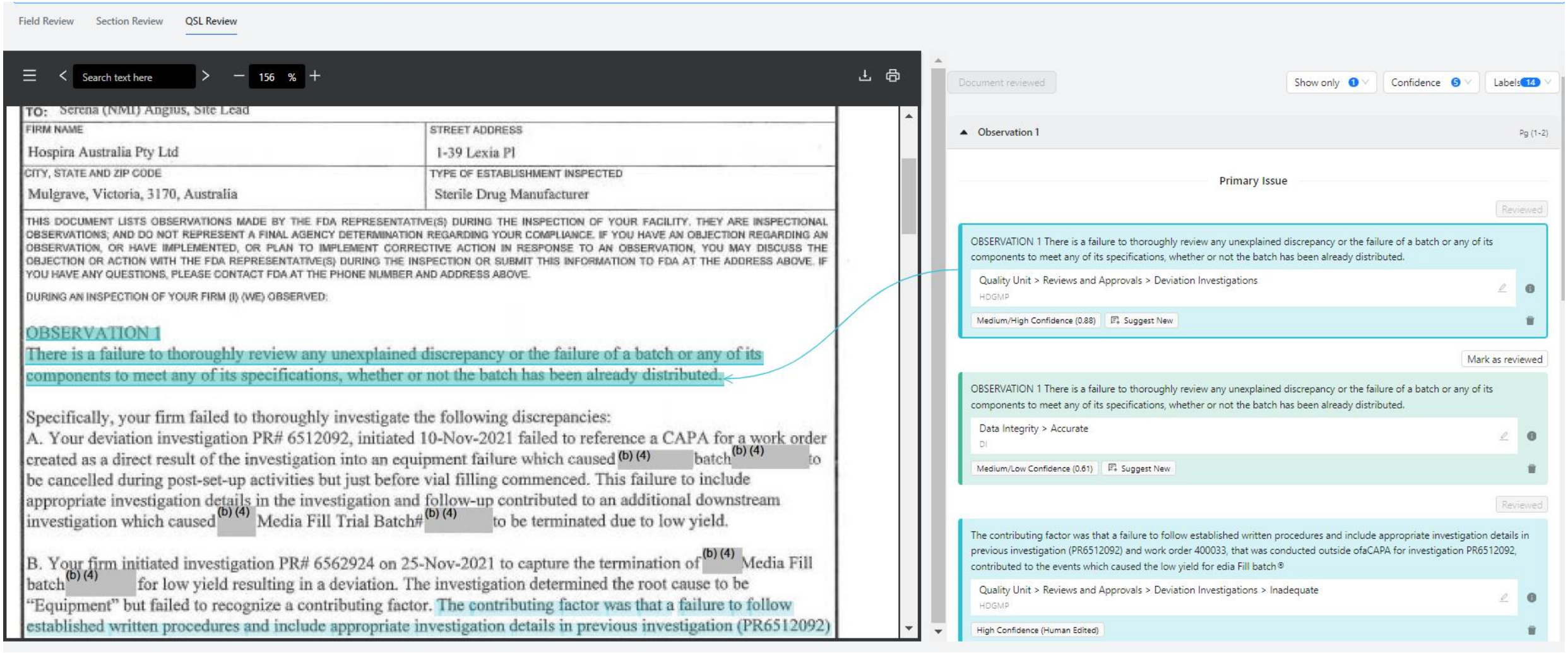
Name	Title
Michele L. Glendenning	Investigator

Add Investigator

Issued Date

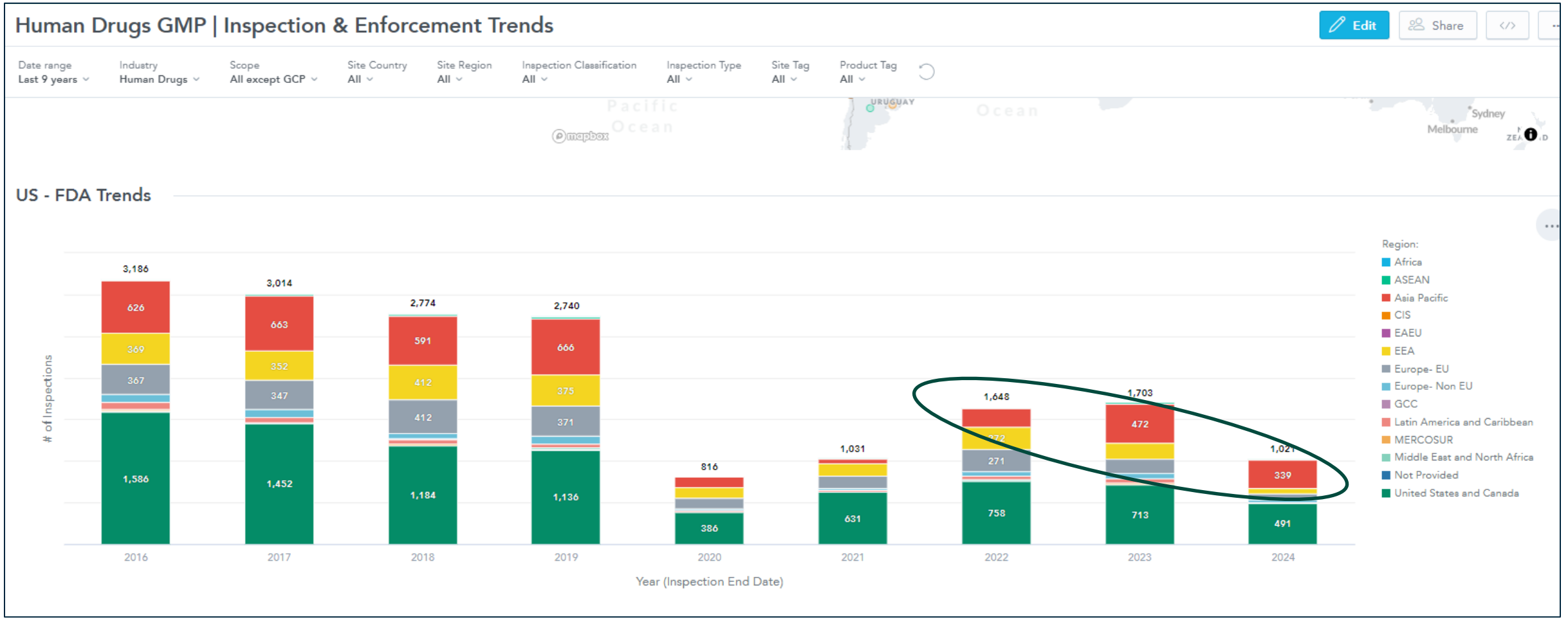
09/02/2022

Document processing - Behind the scenes



Inspections and Enforcment

FDA Inspections have NOT bounced back since COVID

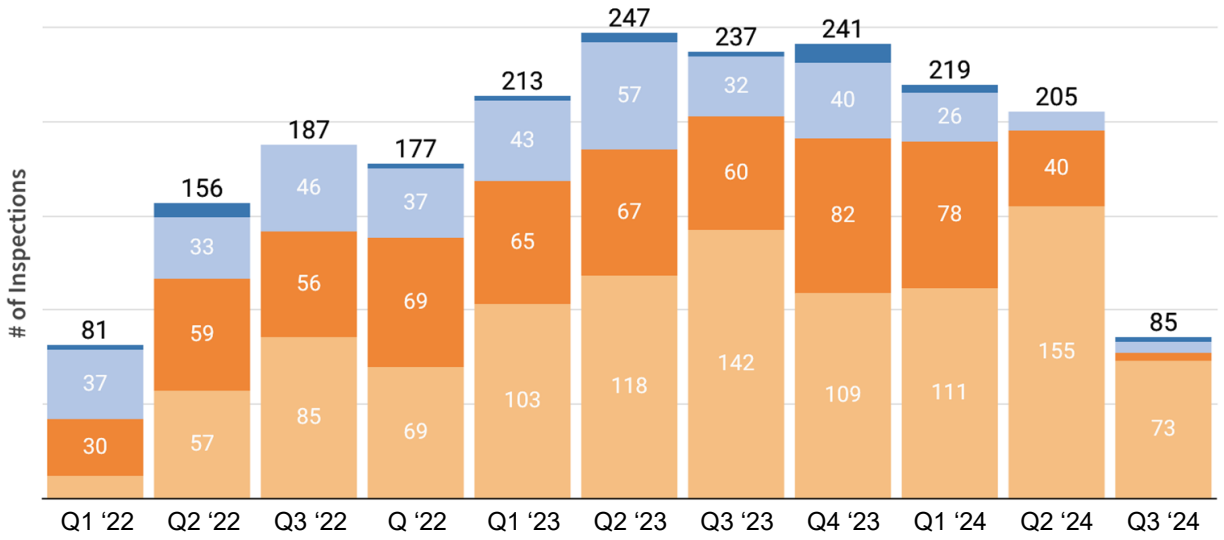


Human Drugs GMP Inspections – mostly India and China

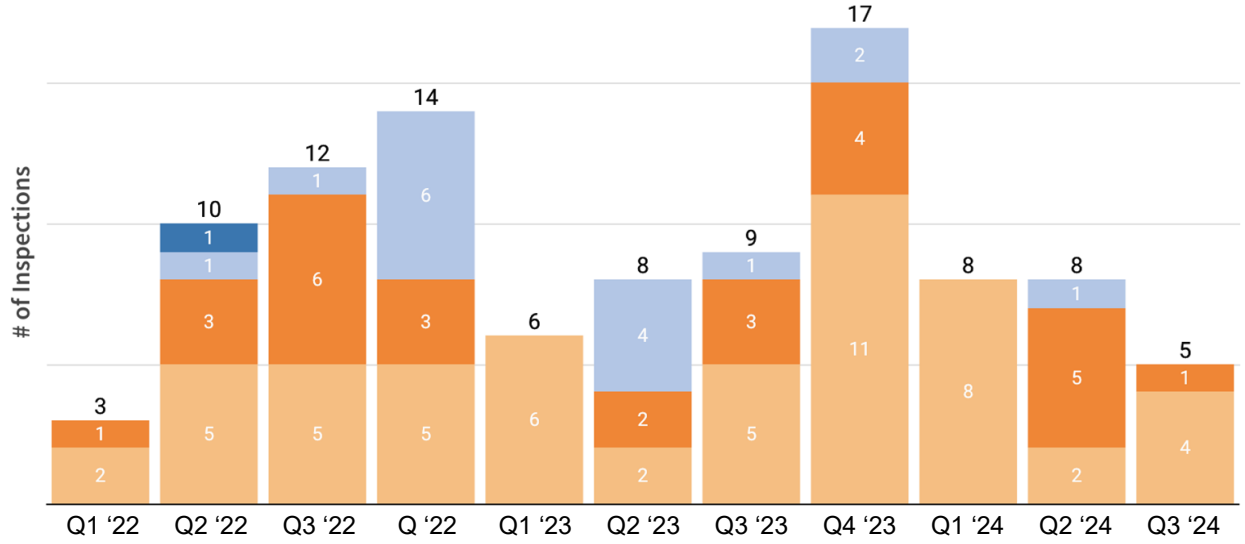
# of Inspections	# of Sites
2,048	1,511

Primarily driven by FDA and EMA

Asia Pacific



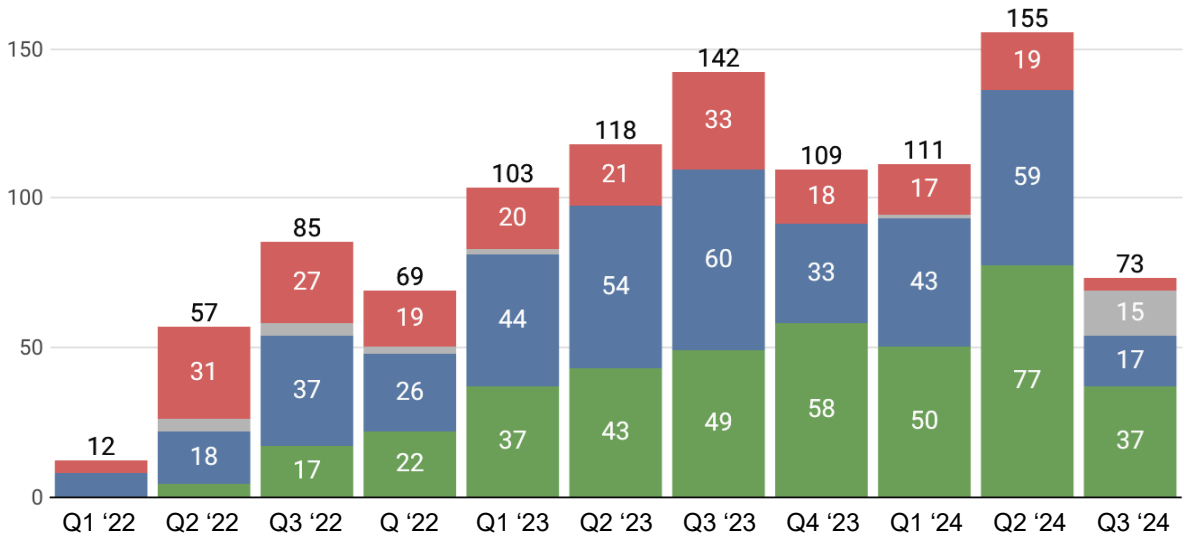
South Korea

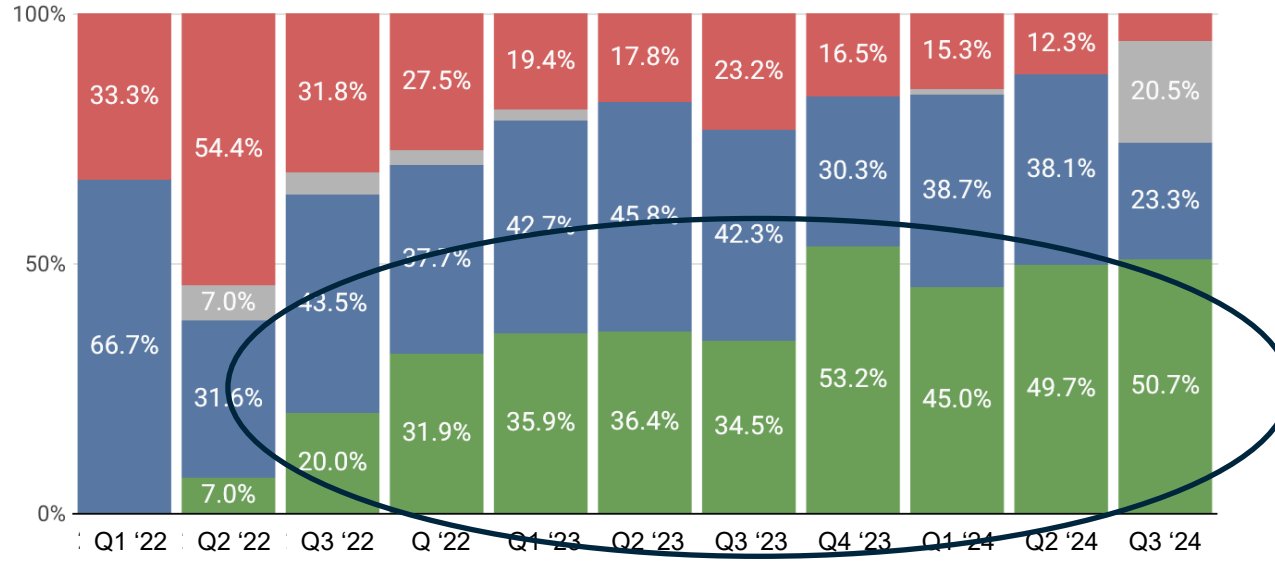


MHRA HC EMA FDA

Routine Inspections on the Rise by the FDA since COVID

Asia Pacific

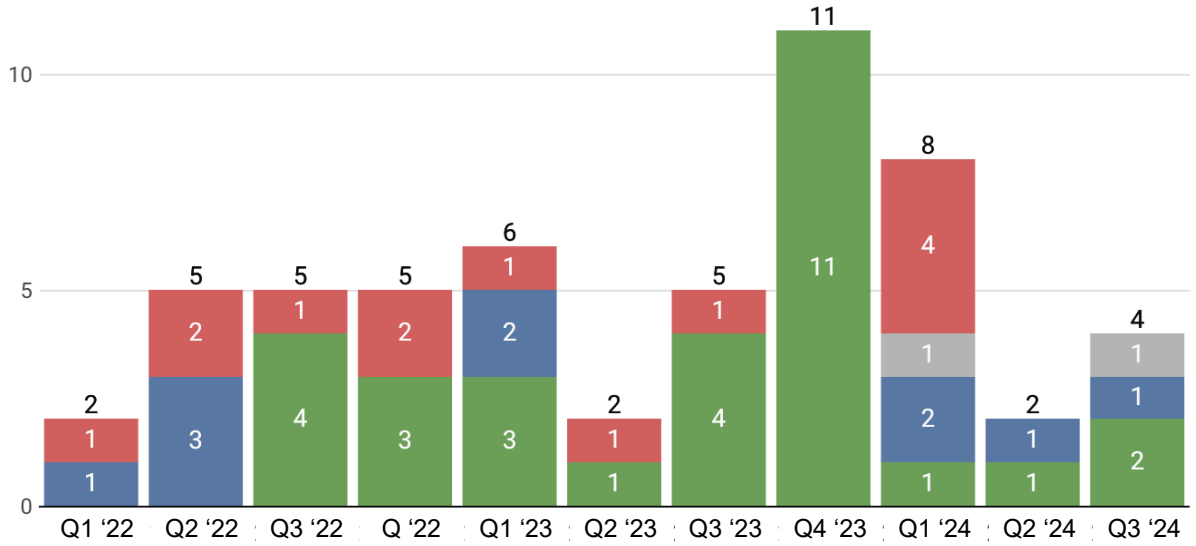


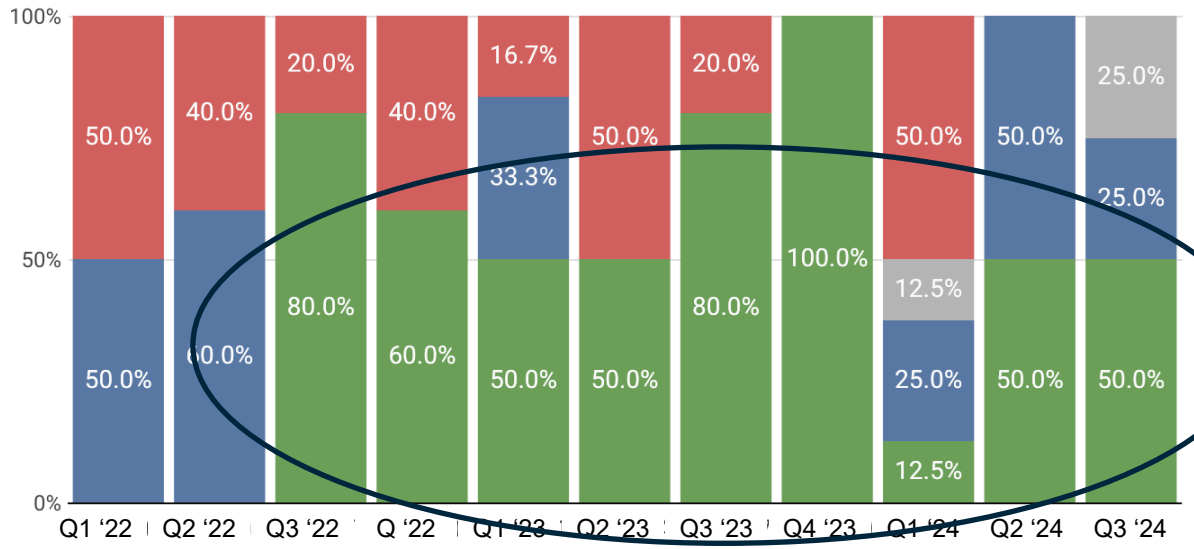


For-Cause Not Provided Pre-Approval Routine

…Even more so in Korea

South Korea

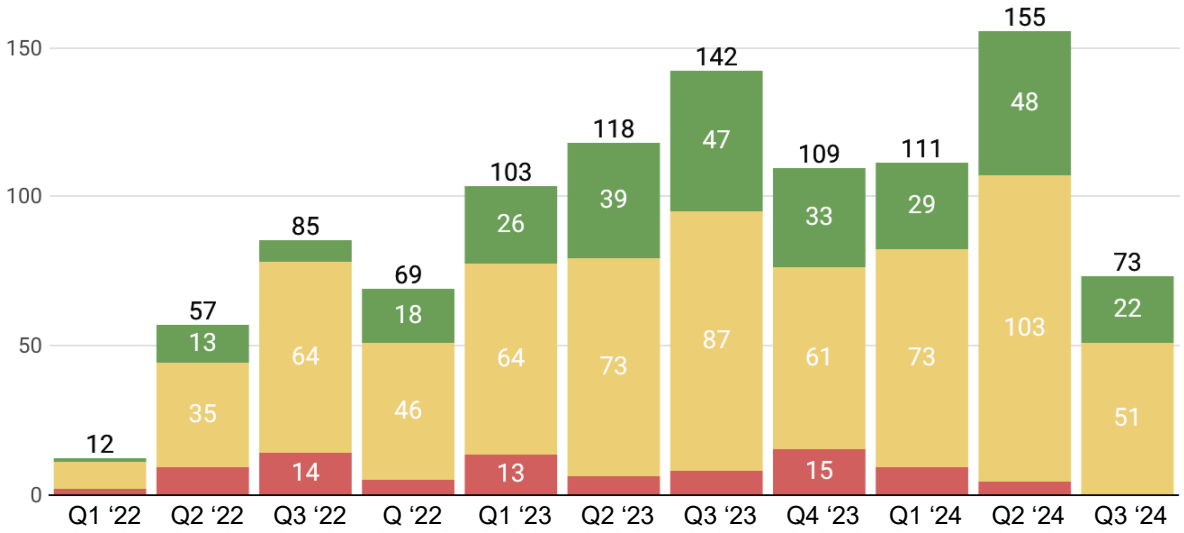


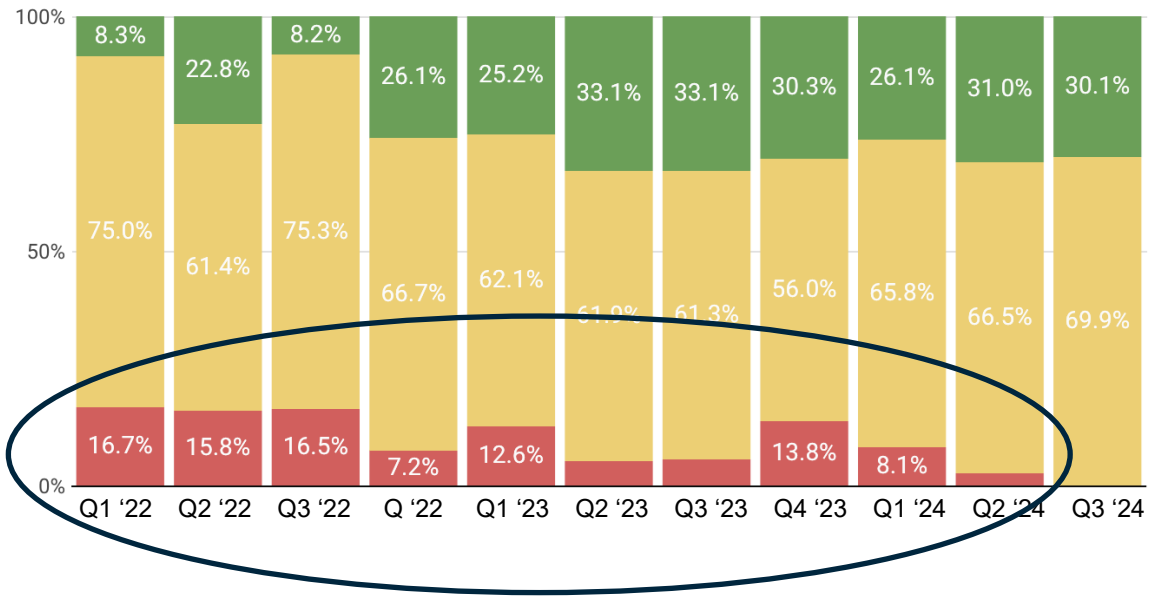


For-Cause Not Provided Pre-Approval Routine

“Red” inspections dropping a little

Asia Pacific

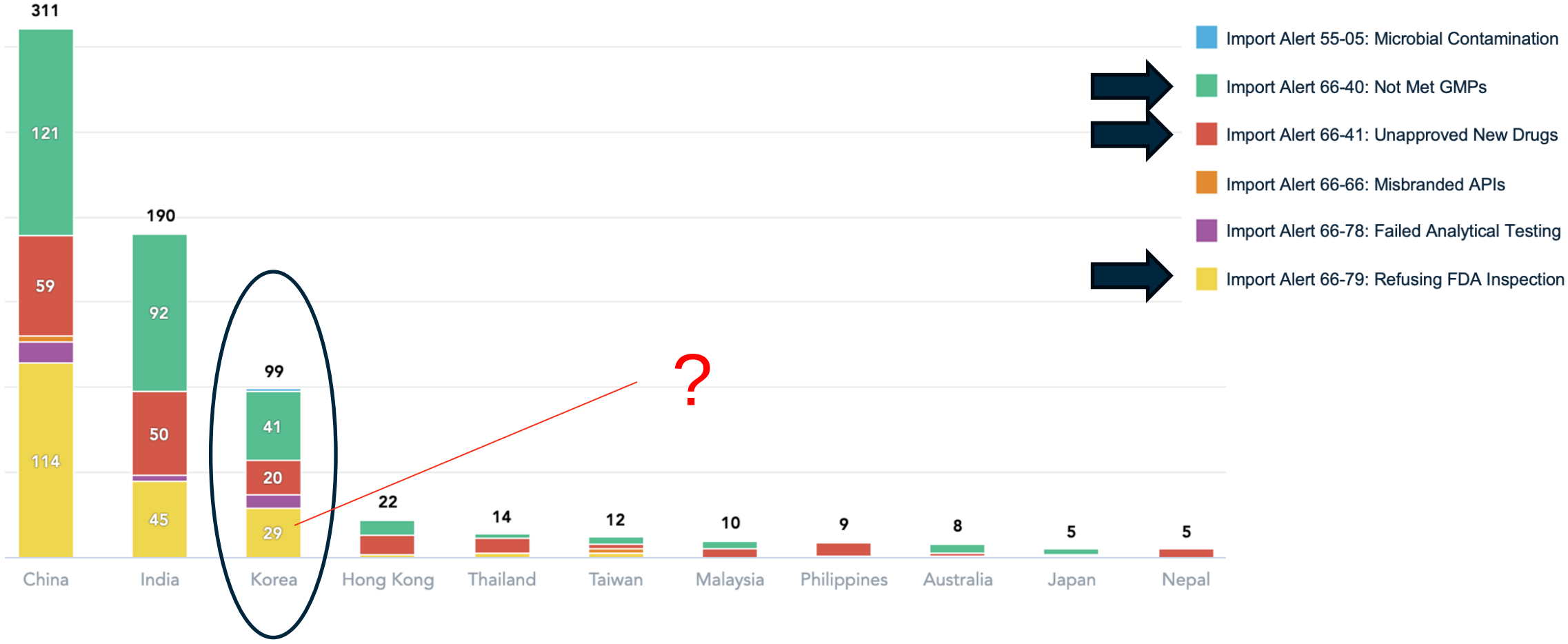




1.Green: No 483/NAI 2.Yellow: 483/VAI/Citation 3.Red: OAI/WL/Import Alert

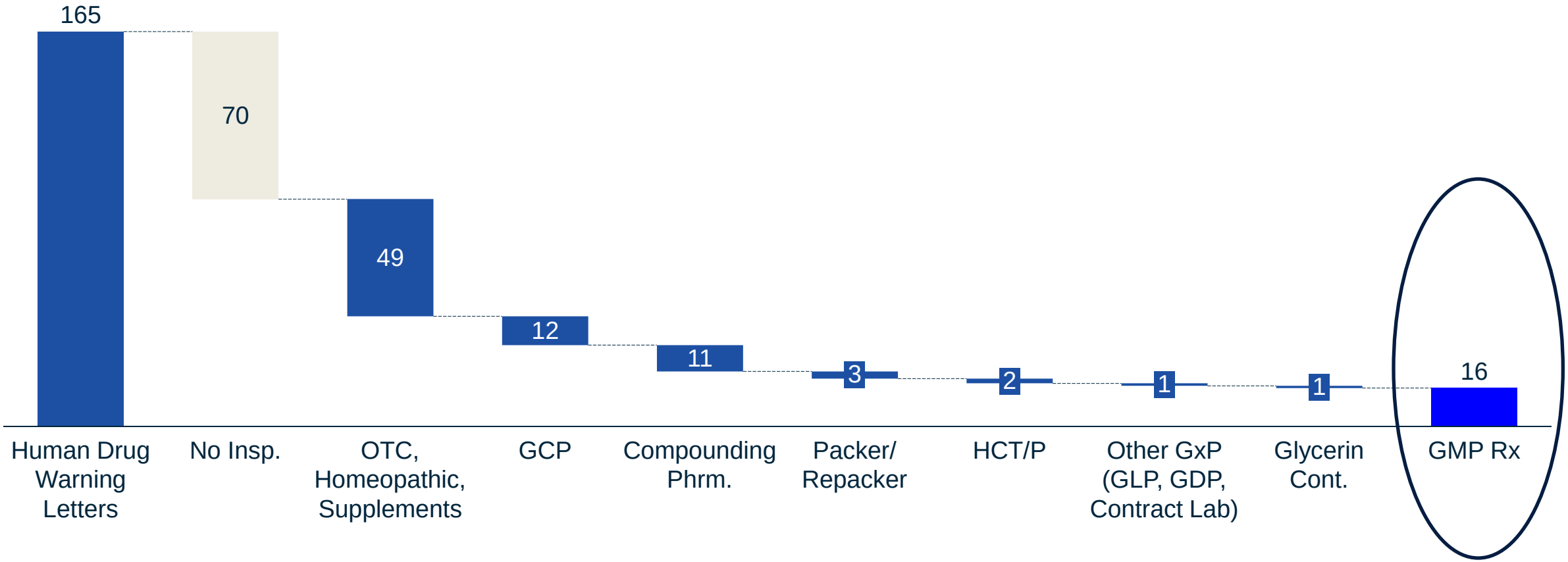
Korea: Suprisingly high number of Import Alerts

Human Drug Import Alerts, 2022-Present, Asia Pacific

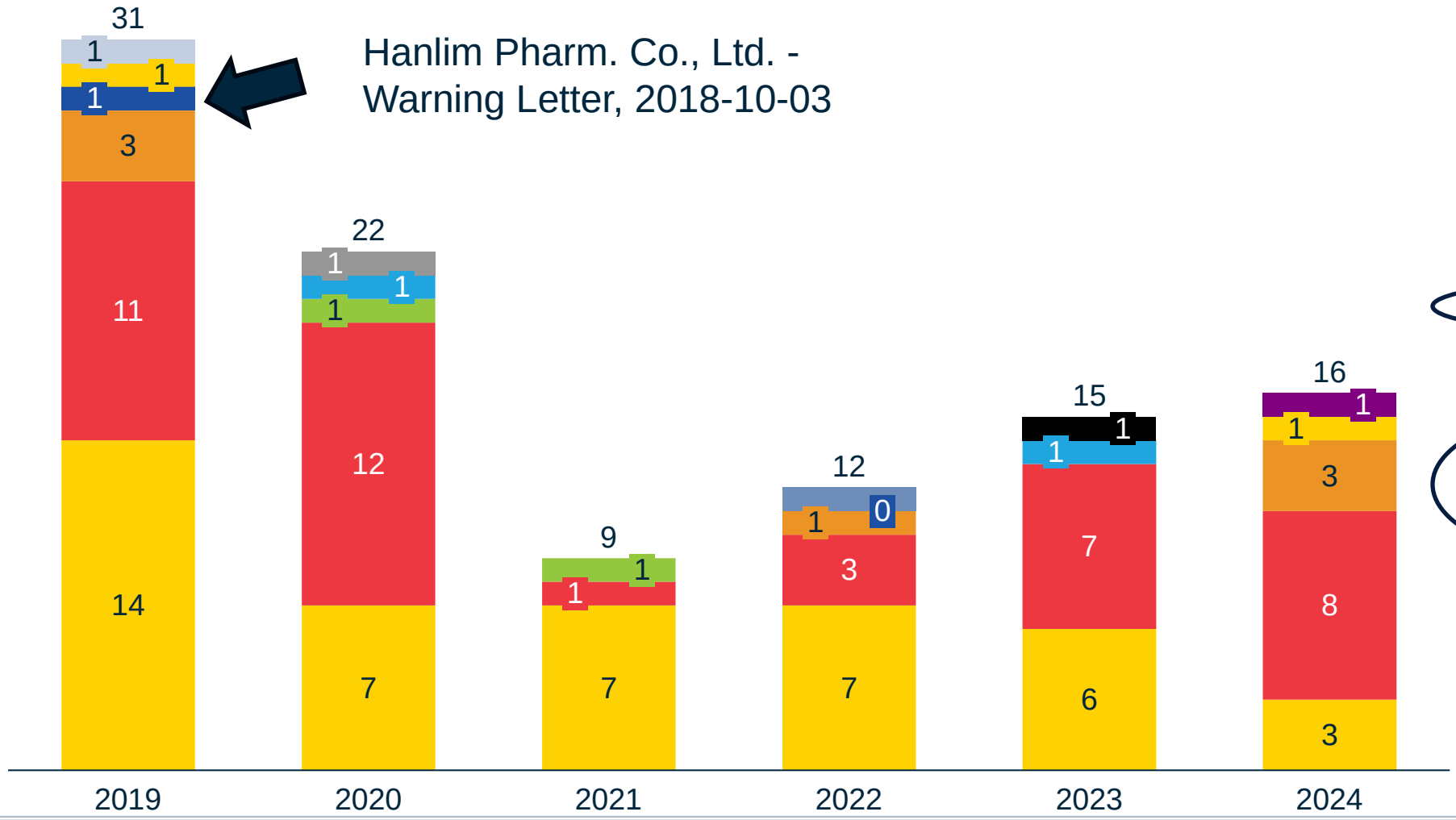


Warning Letters

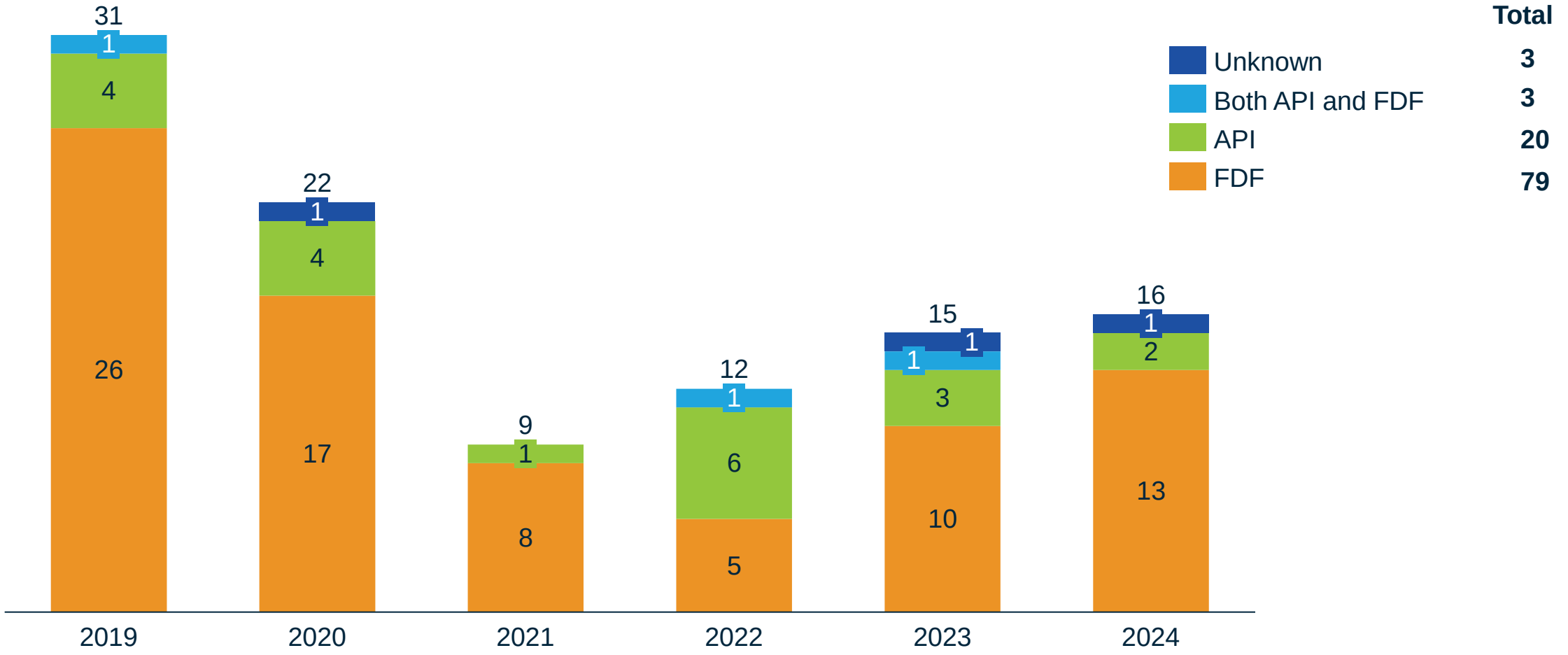
Warning letter waterfall 2024



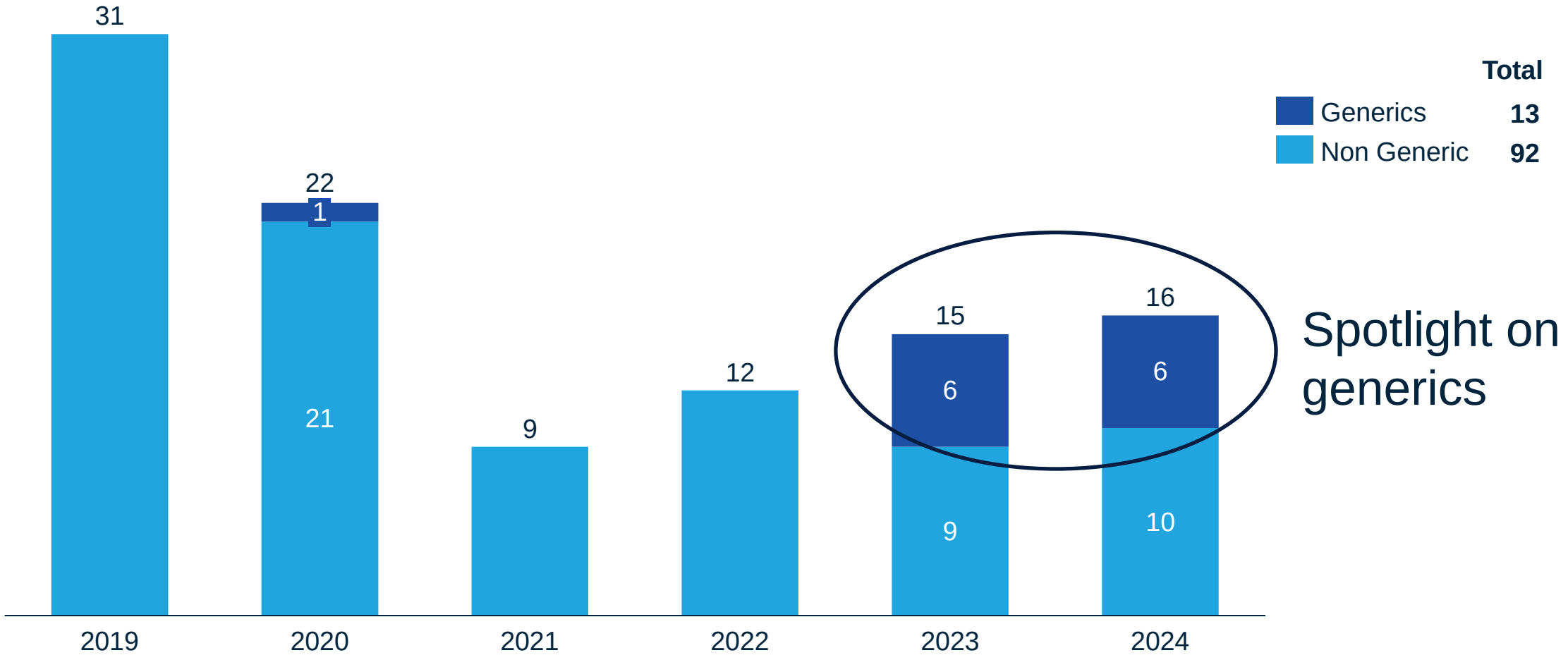
GMP Rx Warning Letters by Country



GMP Rx Warning Letters by Facility Type

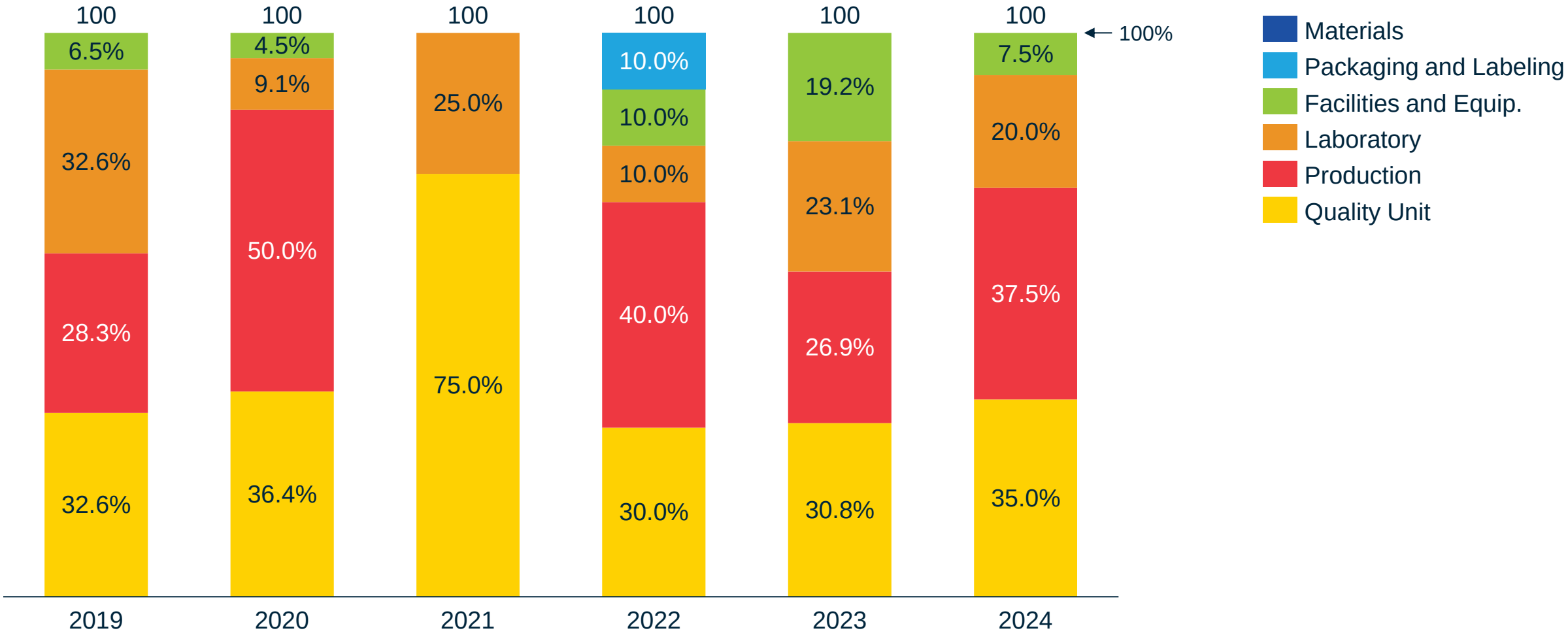


GMP Rx Warning Letters by License Type

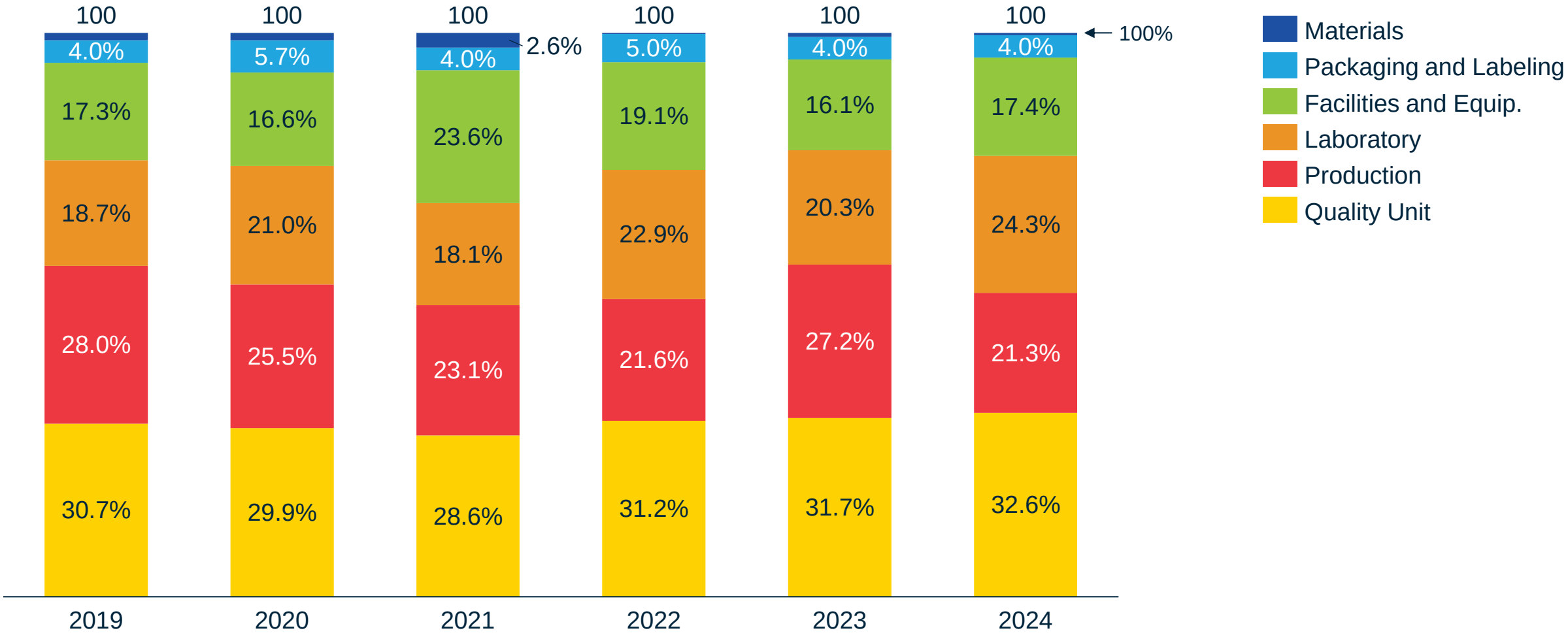


GMP Items Cited

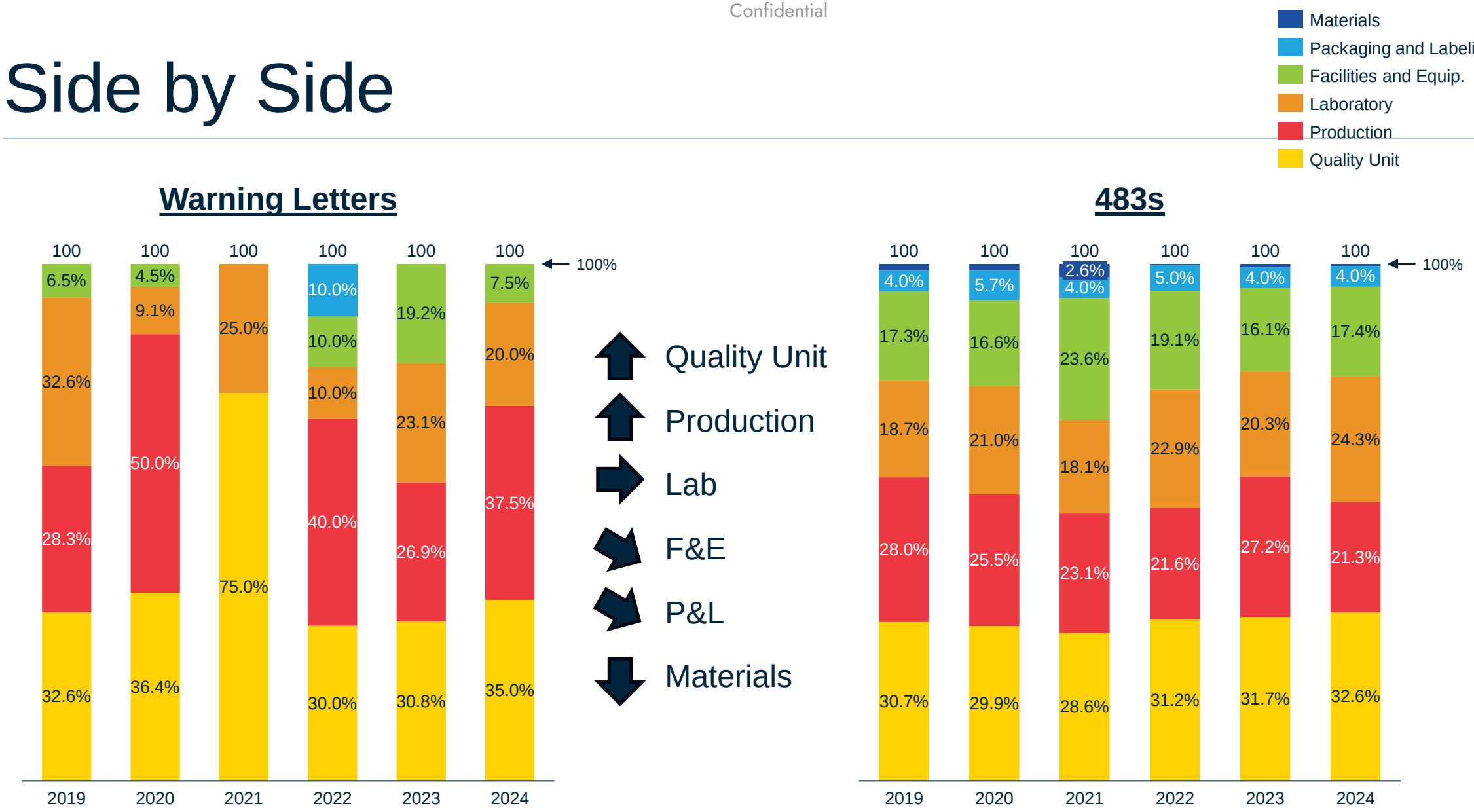
Asia GMP Citation Trends: Warning Letters



Asia GMP Citation Trends: 483s



Side by Side


Materials
Packaging and Labeling
Facilities and Equip.
Laboratory
Production
Quality Unit
Warning Letters
100 100 100 100 100 100 100%
6.5% 32.6% 28.3% 32.6%
4.5% 9.1% 50.0% 36.4%
25.0% 75.0%
10.0% 10.0% 10.0% 40.0% 30.0%
19.2% 23.1% 26.9% 30.8%
7.5% 20.0% 37.5% 35.0%
2019 2020 2021 2022 2023 2024
Quality Unit
Production
Lab
F&E
P&L
Materials
483s
100 100 100 100 100 100 100%
4.0% 17.3% 18.7% 28.0% 30.7%
5.7% 16.6% 21.0% 25.5% 29.9%
2.6% 4.0% 23.6% 18.1% 23.1% 28.6%
5.0% 19.1% 22.9% 21.6% 31.2%
4.0% 16.1% 20.3% 27.2% 31.7%
4.0% 17.4% 24.3% 21.3% 32.6%
2019 2020 2021 2022 2023 2024

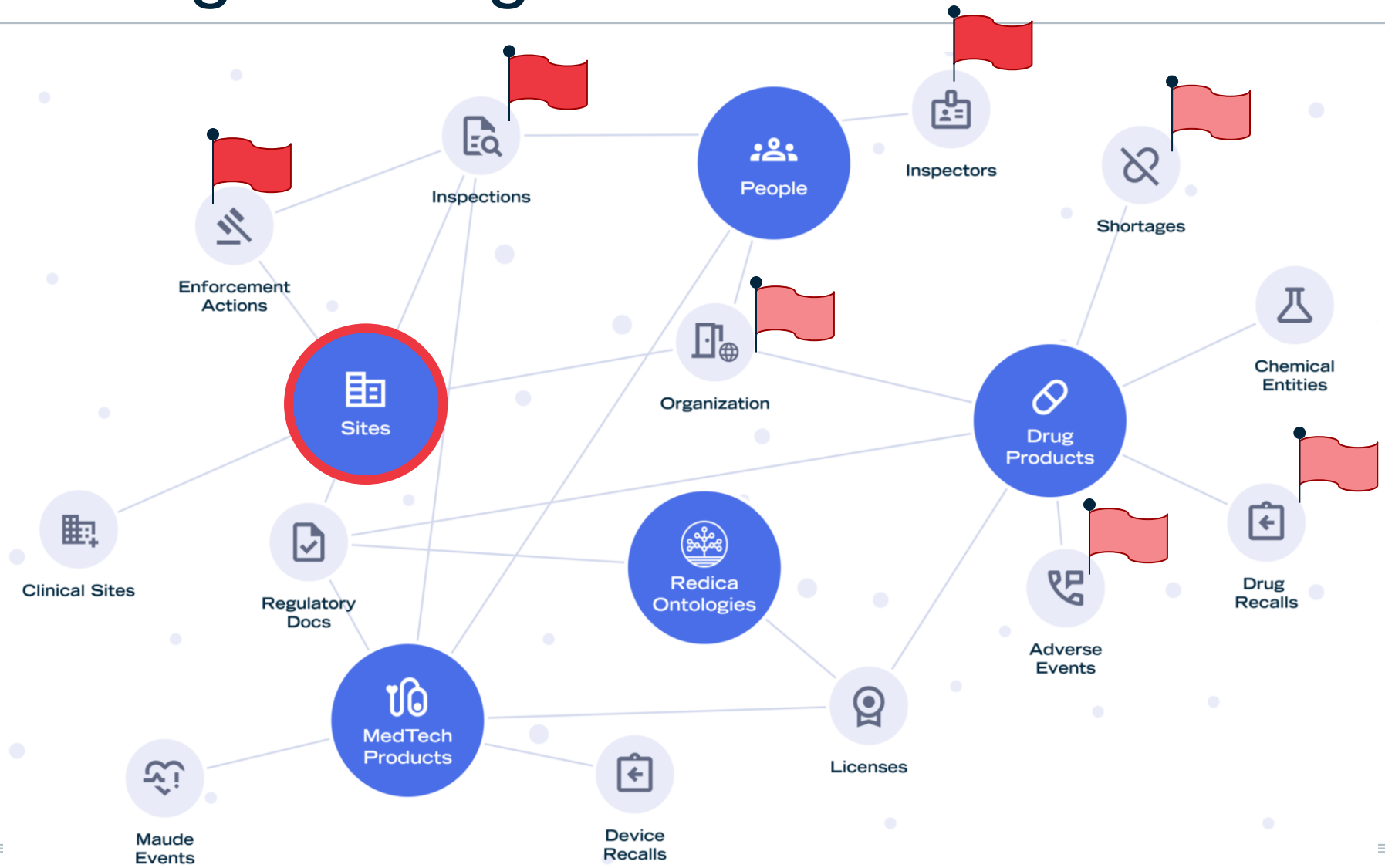
Double Click : Warning Letters

Double Click : 483s

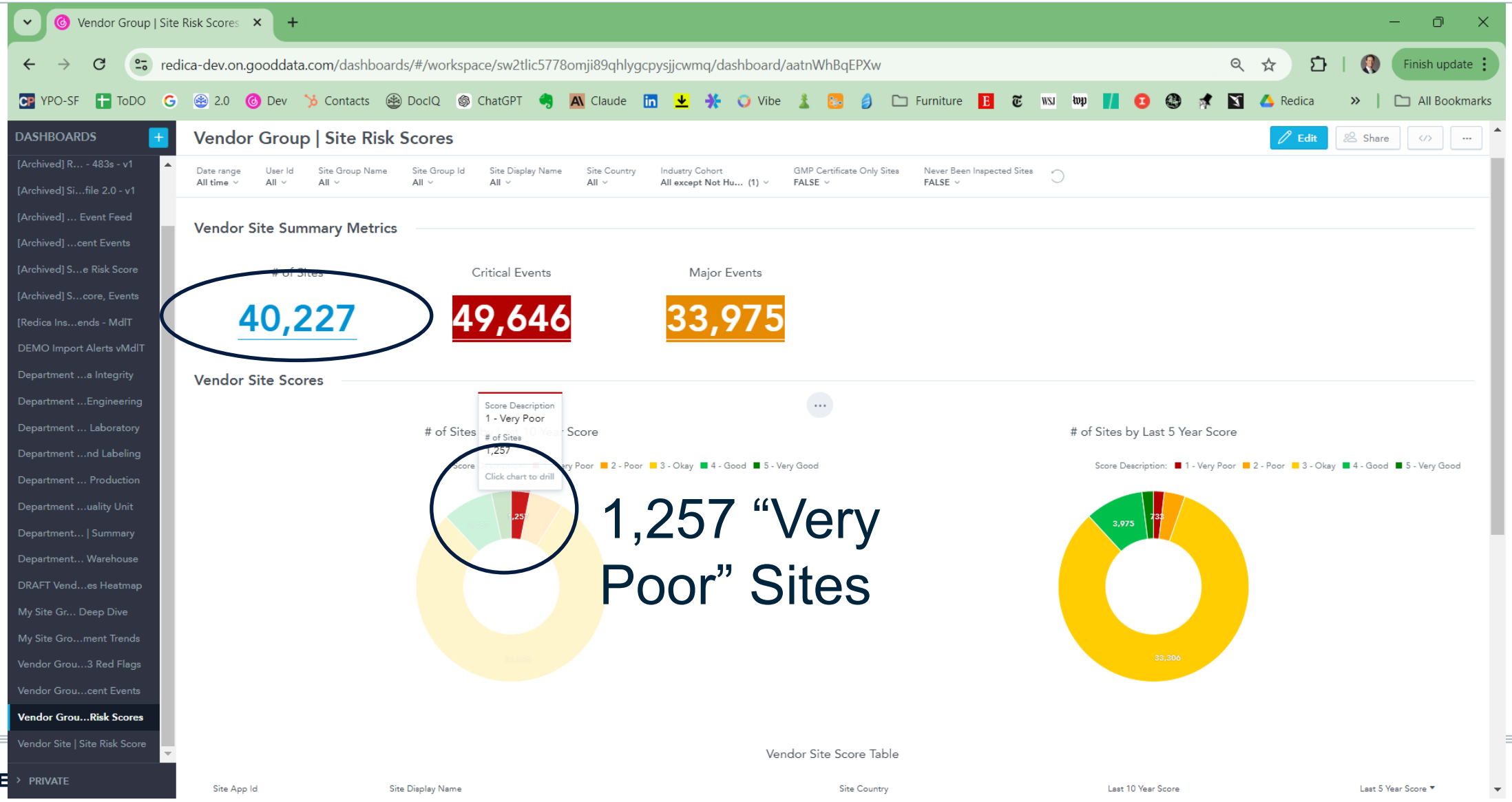
Warning Letter Rankings
#10
8
5
1
24
-
14
-
-
13
-
-
18
33
-

CMO Selection

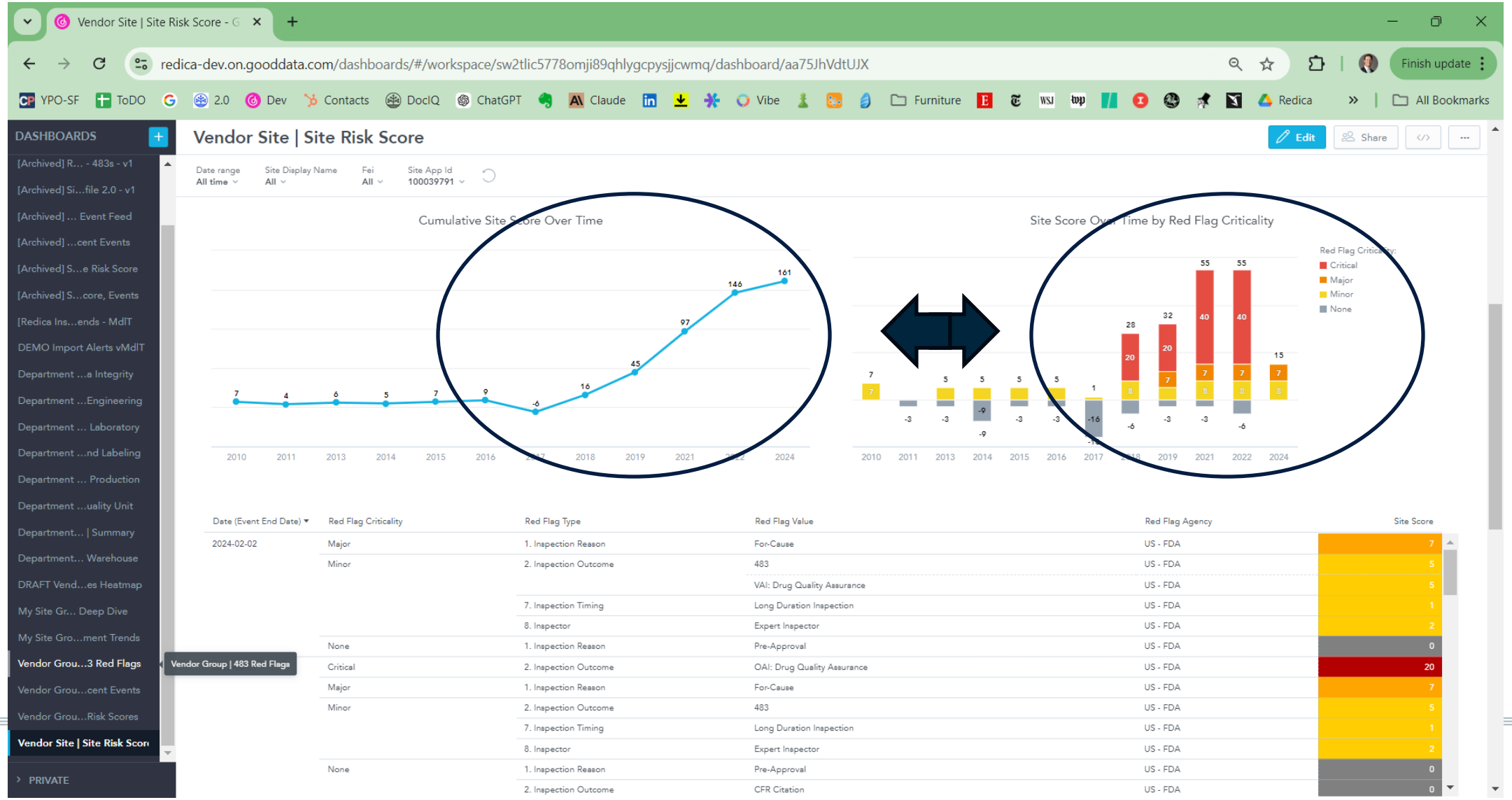
Connecting red flags to Sites



All Human Drugs Sites



Double Click into individual Sites and Events



All Sites in Asia

359 of the “Very Poor” Sites are in Asia

Site Names Redacted

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Site Score
India	-	-8	22	-	38	10	33	10	15	37	10	10	55	7	-	239
China	5	-	-	5	-	80	74	-	35	-	-	-	20	-	-	219
India	-	8	6	15	0	6	26	9	23	22	32	7	72	-12	-	214
South Korea	-	-	-	-	-	20	-	11	40	-	20	40	40	40	-	211
India	-	6	28	35	5	15	35	2	56	-	-	-	20	-	-	202
India	-	-	-	45	31	-	-	51	-	55	-	-	20	-	-	202
India	9	3	5	13	11	56	14	35	-10	38	3	-3	20	-3	-	191
India	5	-	5	2	58	4	23	65	0	-2	-3	-	20	-	14	191
India	-	-	88	-6	54	-	-3	35	-	-	-	-	17	-	-	185
China	-	-	-	-	-	-	115	-	-	-	-	20	40	-	-	175
South Korea	-	-	-	-	-	-	-	60	-	20	-	20	20	54	-	174
South Korea	-	-	-	-	5	-	20	46	-	-	20	20	20	-	40	171
Hong Kong	-	60	47	-	20	-	-	-	-	-	-	-	40	-	-	167
India	-	-	40	5	-	20	-	27	55	-	-	-	20	-	-	167
India	7	-3	-	2	-1	2	2	-15	22	29	-	52	49	-	15	161
India	-	-8	-	-	-	67	5	-	34	-	34	-	20	8	-	160
India	-	-	-10	-	-	108	40	-	-	-	-	-	20	-	-	158
India	34	-	9	4	2	3	8	26	-	-1	2	-	15	56	-3	155
India	-	-	-	-	20	20	-	-	-	-	20	20	54	-	20	154
India	-10	-	-3	83	10	40	23	-	-	6	-	-	-	-	-	149
India	-1	-	10	-	46	-	5	-	-	51	-3	2	20	14	-	144
India	-	-	-	2	-	-	-	45	55	-	-	20	20	-	-	142
Singapore	-	-	-	5	-	-	28	-	-	54	-	-	55	-	-	142
India	-	-	5	12	-	2	30	22	12	20	-	-	39	-	-	142
India	-	-	-	5	-	-	34	-	34	-	54	-	-	14	-	141
India	7	-	-	12	-	67	-	-	-	-	-	-	20	-	34	140
China	-	-3	-10	-	-3	68	-	34	-3	32	-	-	-6	34	-3	140
China	-	-	40	-	40	20	-	-	-	-	-	20	20	-	-	140
India	-	-	-	52	2	35	-	49	5	-	-	-	-3	-	-	140
India	-	7	-9	17	2	-3	29	-6	41	14	-	-	-	32	14	138
India	-	28	-3	10	-6	-	25	1	-3	5	29	-	35	14	-	135

CMO Sites in Asia

Site Names Redacted

Country	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Site Score
South Korea	-	-	-	-3	2	-5		39	8	6	-6	-	-3	-	12	50
South Korea	-	-	-	-	-	-10	5	4	10	14	-3	-9	-2	12	8	29
Australia	-	-	-	-	-	-	-	-	-	-	2	-	-	12	2	16
Singapore	-	-	0	5	2	5	-1	-10	2	18	-	-3	-3	-3	-	12
South Korea	-	-	-	-	-	-	-	-8	12	-10	-9	7	10	-1	8	9
China	-	-	-	-	-	-	-	-	-	-	-	-	-	7	2	9
China	-	-	-	-	-	-	-3	-	-	-6	-	2	-	-	7	0
China	-	-	-	-	-	-	-	9	-	0	-3	-3	-6	6	-3	0
China	-	-	-	-	-	-	-	-	-	2	-	-3	-	-	-	-1
South Korea	-	-	-	-	-	-	-	-7	-	-	-	-	-	-	-	-7
China	-	-	-	-	-	-	-	-	-	-	-	-	-	-8	-	-8
China	-	-9	-	-	-	-	-	-	-	-	-	-	-	-	-	-9
Australia	-3	-9	-	2	-	-	-	-	-	-	-	-	-	-	-	-10
China	5	-	-	2	-3	-3	4	-	-15	-	-	-	-	-	-	-10
China	-	-	-	-	-	-	-	-	-	-6	-	-6	-	-	-3	-15
China	-	-	-	-	-	-	-	-	-	-8	-	-	-	-	-10	-18
China	-	-10	-	-9	-	-	-	-	-	-	-	-	-	-	-	-19
India	-	-	2	-	-3	-13	-	-13	13	6	4	-	-9	-	-10	-23
China	-	-	-	-13	3	-	-13	-	1	-6	-	-	-	-	-	-28

Wrapping up