



REDICA
Systems

Redica Systems

**DATA DRIVEN INSPECTION
INTELLIGENCE AND CMO
SELECTION**

Is this presentation for me?

Innovator /
Sponsor

Generics/
Biosimilars

CMO

Contents

1. How the magic works
2. Inspection and Enforcement trends: Asia Pacific
3. Warning Letter Trends
4. Top GMP items cited: Asia Pacific
5. CMO Selection and Monitoring: Site Risk Scoring

Decoding regulatory data



Structuring the unstructured

1. Data Acquisition



4. Data Driven Workflows

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

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

The key problem

The same entity being described (very) differently

The image displays a collage of overlapping screenshots illustrating the problem of inconsistent entity descriptions. The screenshots include:

- A letter with a header containing "11630 W. Lenexa, KS (913) 752-4343" and a recipient name "Dan McPherson".
- A document with a header "Establishment Name: Hospira McPherson" and a table.
- A screenshot of the Government of Canada website with the text "Section 40 & 43" and "OFFICIAL".
- A screenshot of a "Drug Inspection" report with the text "Lead Director Hospira 1776 North McPherson Kansas USA." and "Subject: Hospira".
- A screenshot of the "EudraGMDP" compliance portal with a "GMP Compliance Menu" and a search bar.

In the center, a box lists various software logos: Veeva, ORACLE, SAP, IQVIA, TrackWise DIGITAL, Agilent, MasterControl, amazon REDSHIFT, Microsoft X, Microsoft S, and snowflake.

Solution = Redica ID

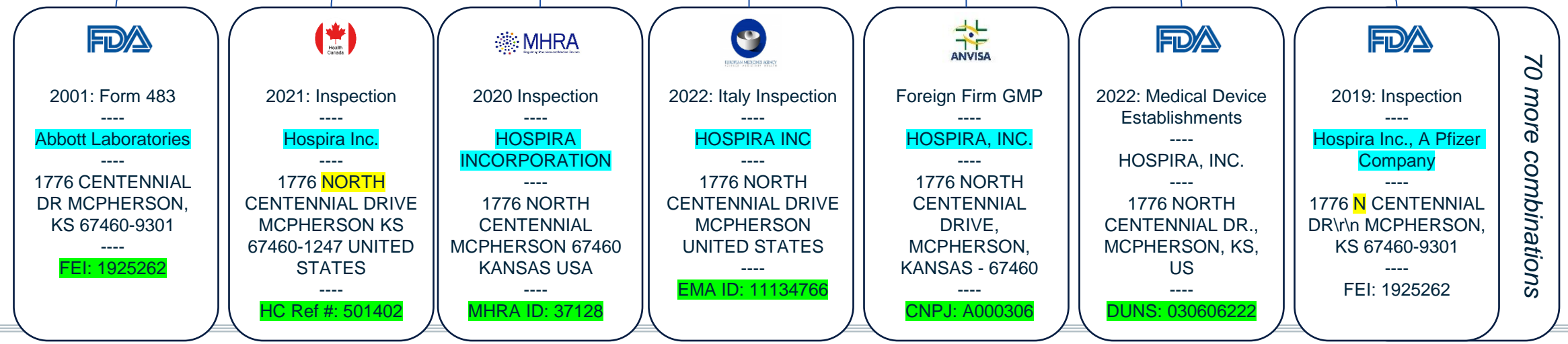


Display Name
Hospira, Inc. [Mcperson / United States of America]
(13 Aliases)

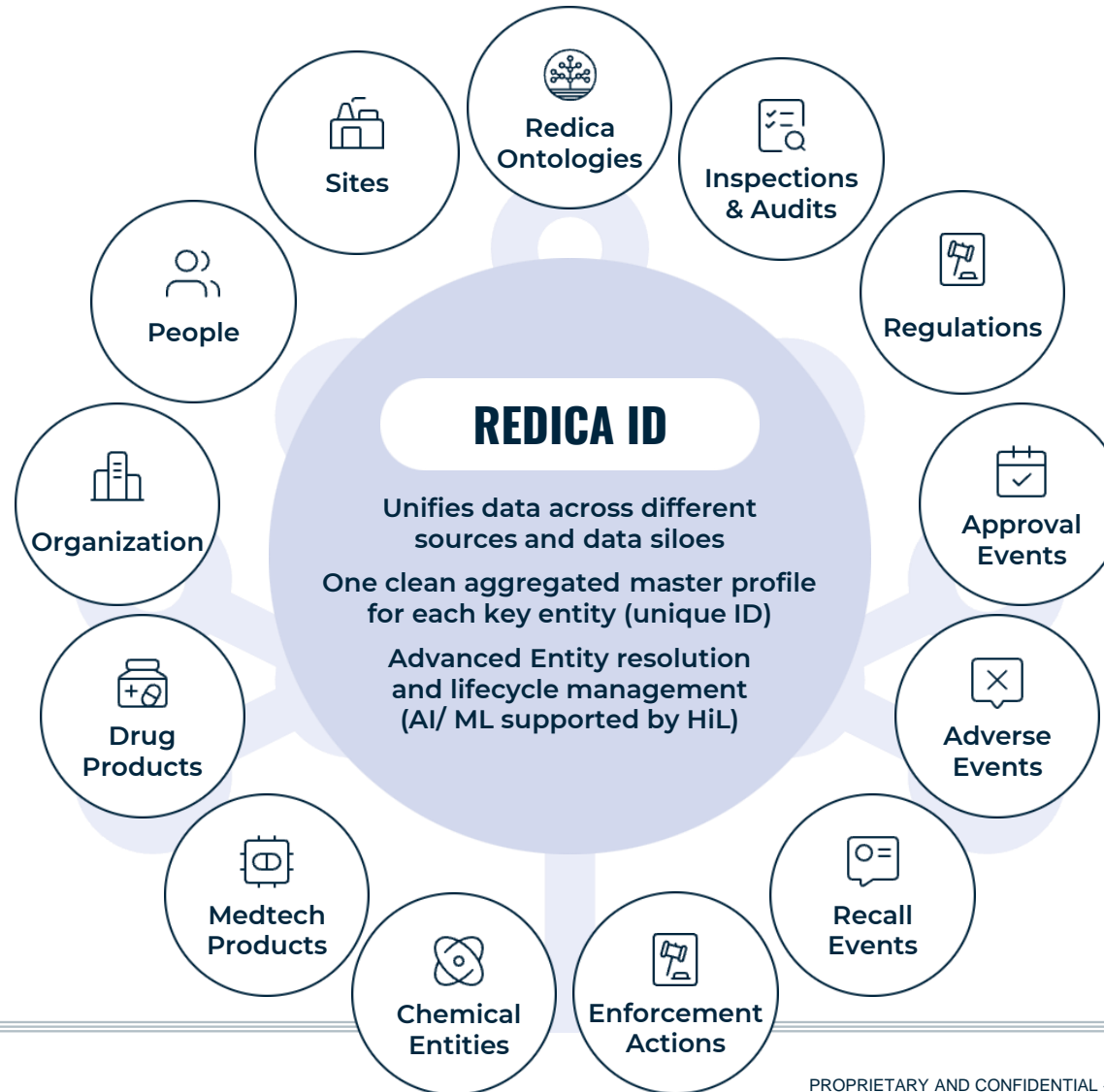
Display Address
1776 NORTH CENTENNIAL DRIVE,
MCPHERSON, KANSAS (KS)
67460, UNITED STATES (USA)
(52 Aliases)

Redica ID: 100027279
(8 Aliases)

- 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

eyJpdil6li80bnZi... 1 / 3 | - 44% +

1

2

3

copy

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
FDA/CDCR
10903 New Hampshire Ave., Bldg 51, RM 4225
Silver Springs, MD 20993
+1-301-796-3334
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
08/25/2022 - 09/02/2022

FBI NUMBER
3001174929

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Serena (NMI) Angius, Site Lead

FIRM NAME
Hospira Australia Pty Ltd

STREET ADDRESS
1-39 Lexia Pl

CITY, STATE AND ZIP CODE
Mulgrave, Victoria, 3170, Australia

TYPE OF ESTABLISHMENT INSPECTED
Sterile Drug Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVES DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OF ACTION WITH THE FDA REPRESENTATIVE DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM & (S) OBSERVED:

OBSERVATION 1
There is a failure to thoroughly review any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed.

Specifically, your firm failed to thoroughly investigate the following discrepancies:

A. Your deviation investigation PR# 6512092, initiated 10-Nov-2021 failed to reference a CAPA for a work order created as a direct result of the investigation into an equipment failure which caused **(b)(4)** but **(b)(4)** to be cancelled during post-set-up activities but just before vial filling commenced. This failure to include appropriate investigation details in the investigation and follow-up contributed to an additional downstream investigation which caused **(b)(4)** Media Fill Trial Batch **(b)(4)** to be terminated due to low yield.

B. Your firm initiated investigation PR# 6562924 on 25-Nov-2021 to capture the termination of **(b)(4)** Media Fill batch **(b)(4)** for low yield resulting in a deviation. The investigation determined the root cause to be "Equipment" but failed to recognize a contributing factor. The contributing factor was that a failure to follow established written procedures and include appropriate investigation details in previous investigation (PR6512092) and work order 400633, that was conducted outside of a CAPA for investigation PR6512092, contributed to the events which caused the low yield for **(b)(4)** Media Fill batch **(b)(4)**. Additionally, investigation PR# 6562924 determined that a gap in written procedure existed as no "formal prompt" existed to remind production operators and fitters, who were responsible for the change-over of filling line equipment to return the alignment of the stopper bowl base to its original position after a non-typical alignment adjustment was previously made to the stopper bowl base under WO# 400633. This procedural gap was not further investigated or addressed as part of the investigation and subsequent CAPA for PR# 6562924.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Michele L. Glendenning S. Dept. of Health and Human Services, Division of Regulatory Operations, Office of Compliance and Inspection Support

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Michele L. Glendenning, Investigator

DATE ISSUED
09/02/2022

FORM FDA 483 (08/01) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 1 of 3

copy

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
FDA/CDCR
10903 New Hampshire Ave., Bldg 51, RM 4225
Silver Springs, MD 20993
+1-301-796-3334
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
08/25/2022 - 09/02/2022

FBI NUMBER
3001174929

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Serena (NMI) Angius, Site Lead

FIRM NAME
Hospira Australia Pty Ltd

STREET ADDRESS
1-39 Lexia Pl

CITY, STATE AND ZIP CODE
Mulgrave, Victoria, 3170, Australia

TYPE OF ESTABLISHMENT INSPECTED
Sterile Drug Manufacturer

OBSERVATION 2
Written procedures are not always followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

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

Michele L. Glendenning

Title

Investigator

[+ Add Investigator](#)

Issued Date

09/02/2022

Document processing - Behind the scenes

Field Review Section Review QSL Review

Search text here 156 %

TO: Serena (NMI) Abgus, Site Lead

FIRM NAME	STREET ADDRESS
Hospira Australia Pty Ltd	1-39 Lexia Pl
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mulgrave, Victoria, 3170, Australia	Sterile Drug Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
 There is a failure to thoroughly review any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed.

Specifically, your firm failed to thoroughly investigate the following discrepancies:

A. Your deviation investigation PR# 6512092, initiated 10-Nov-2021 failed to reference a CAPA for a work order created as a direct result of the investigation into an equipment failure which caused (b) (4) batch (b) (4) to be cancelled during post-set-up activities but just before vial filling commenced. This failure to include appropriate investigation details in the investigation and follow-up contributed to an additional downstream investigation which caused (b) (4) Media Fill Trial Batch# (b) (4) to be terminated due to low yield.

B. Your firm initiated investigation PR# 6562924 on 25-Nov-2021 to capture the termination of (b) (4) Media Fill batch (b) (4) for low yield resulting in a deviation. The investigation determined the root cause to be "Equipment" but failed to recognize a contributing factor. The contributing factor was that a failure to follow established written procedures and include appropriate investigation details in previous investigation (PR6512092)

Document reviewed

Show only 1 Confidence 5 Labels 14

▲ Observation 1 Pg (1-2)

Primary Issue

Reviewed

OBSERVATION 1 There is a failure to thoroughly review any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed.

Quality Unit > Reviews and Approvals > Deviation Investigations
 HDGMP

Medium/High Confidence (0.88) Suggest New

Mark as reviewed

OBSERVATION 1 There is a failure to thoroughly review any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed.

Data Integrity > Accurate
 DI

Medium/Low Confidence (0.61) Suggest New

Reviewed

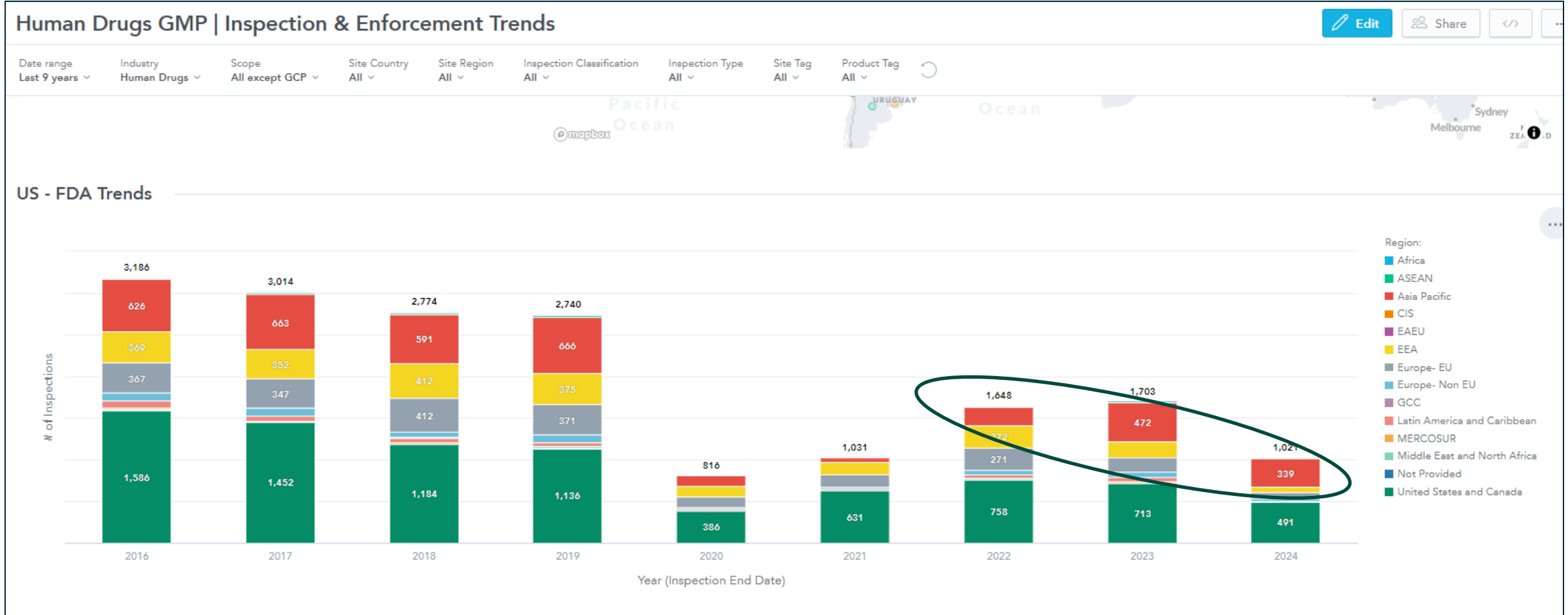
The contributing factor was that a failure to follow established written procedures and include appropriate investigation details in previous investigation (PR6512092) and work order 400033, that was conducted outside of a CAPA for investigation PR6512092, contributed to the events which caused the low yield for Media Fill batch®

Quality Unit > Reviews and Approvals > Deviation Investigations > Inadequate
 HDGMP

High Confidence (Human Edited)

Inspections and Enforcement

FDA Inspections have NOT bounced back since COVID



Human Drugs GMP Inspections – mostly India and China

of Inspections

2,048

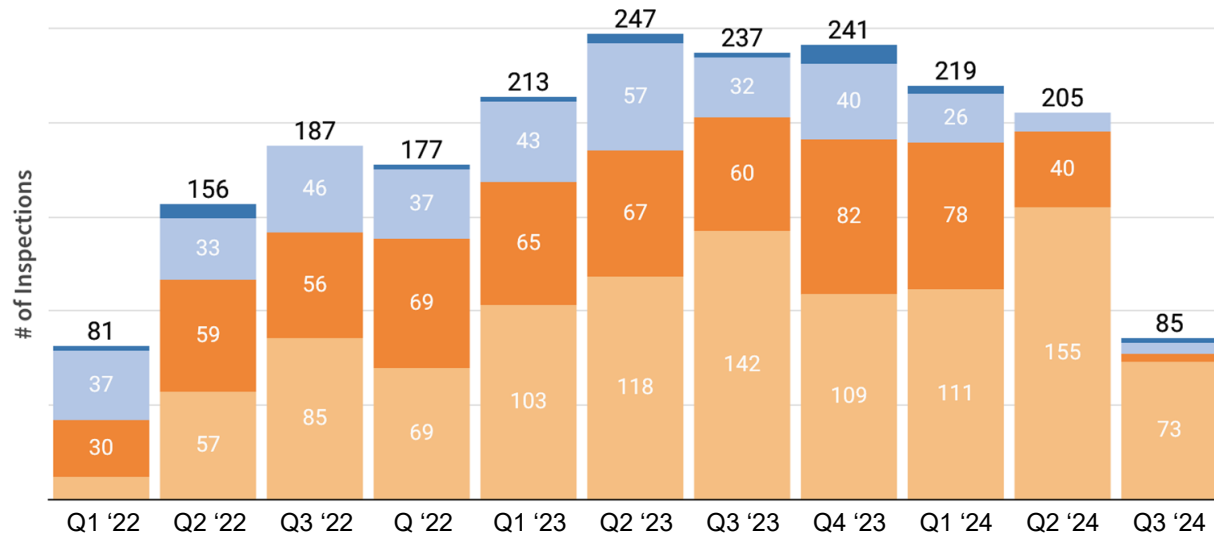
of Sites

1,511

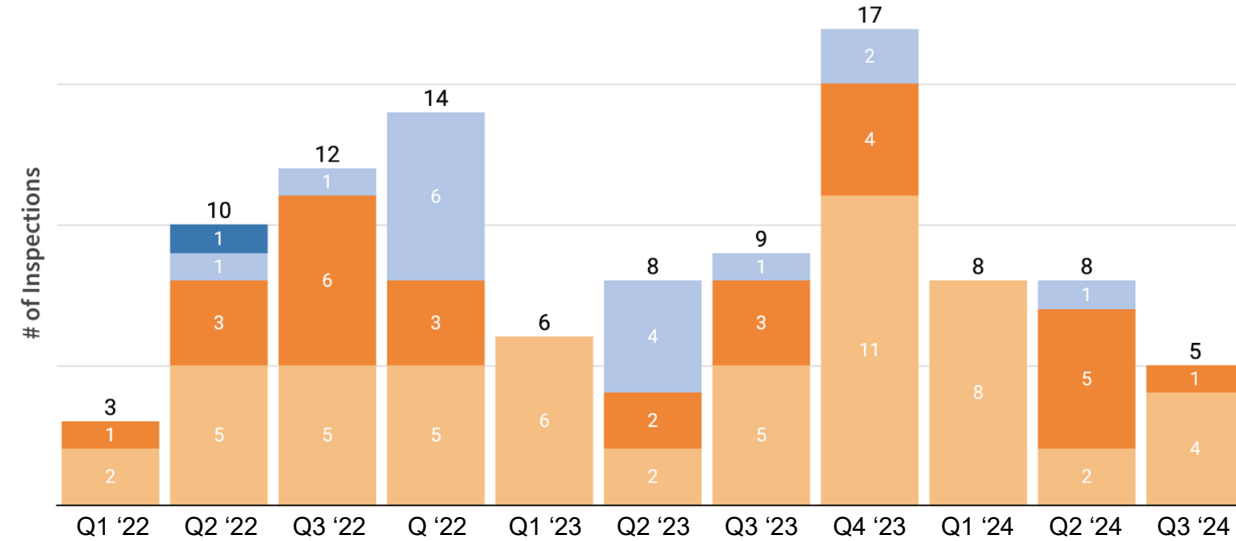


Primarily driven by FDA and EMA

Asia Pacific



South Korea

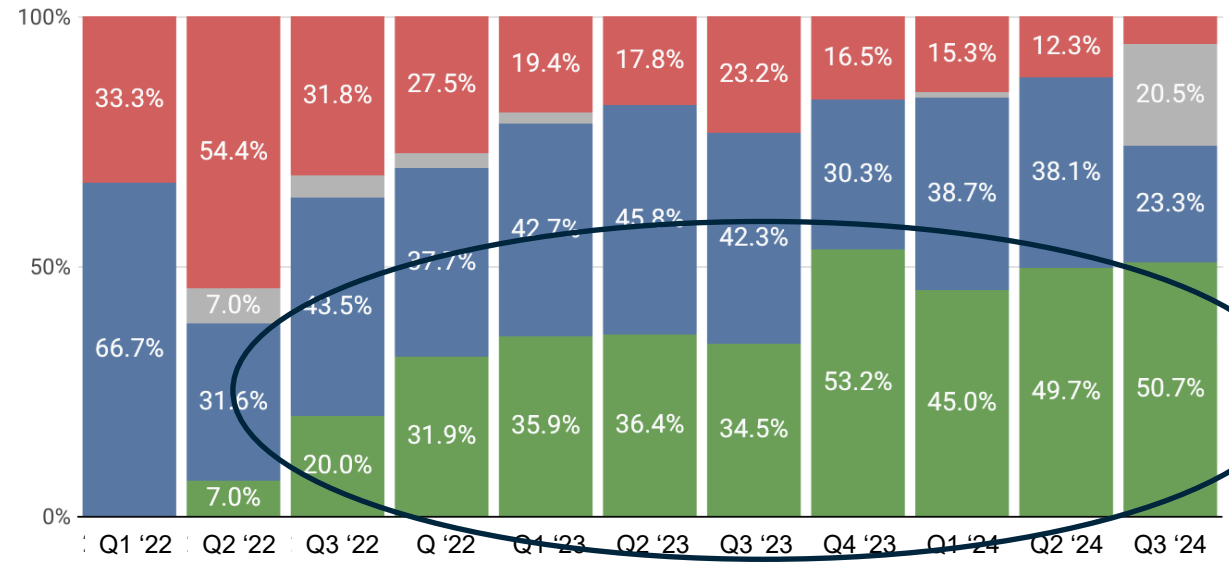
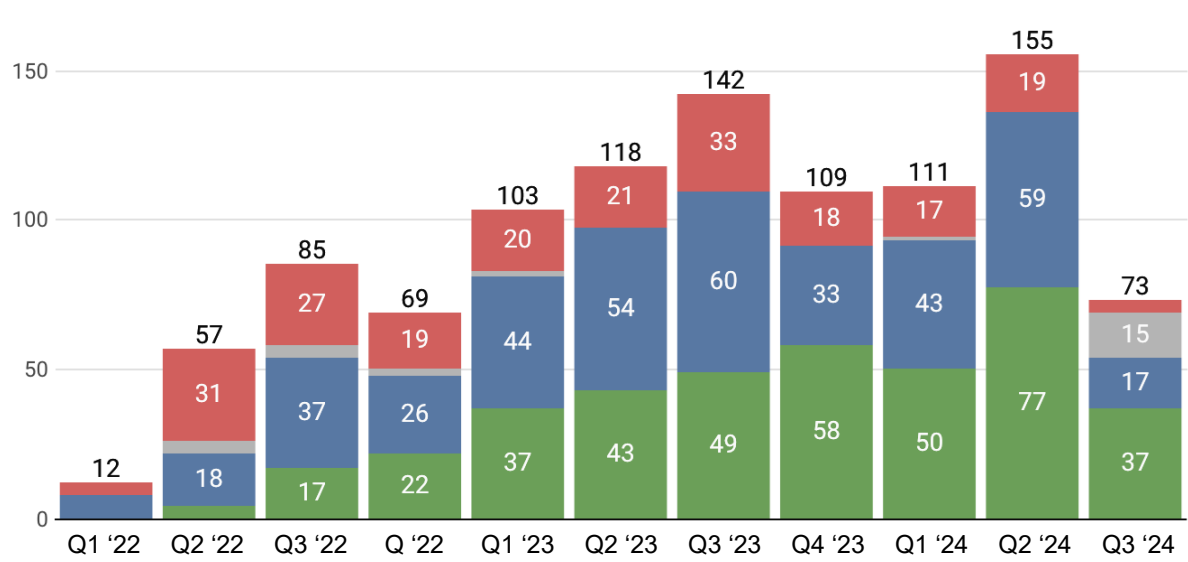


■ MHRA
 ■ HC
 ■ EMA
 ■ FDA



Routine Inspections on the Rise by the FDA since COVID

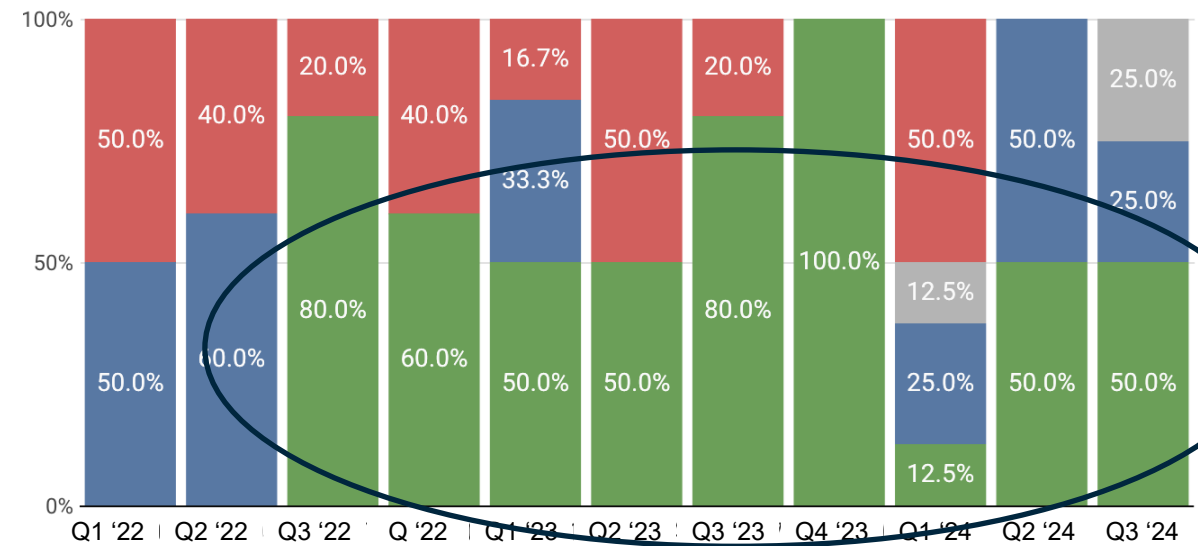
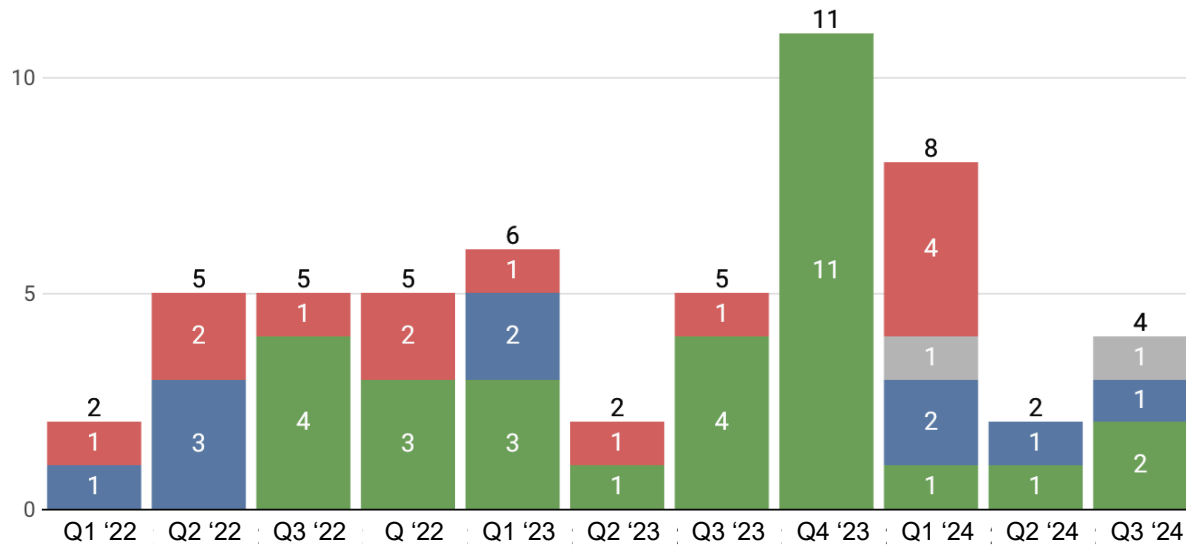
Asia Pacific



For-Cause Not Provided Pre-Approval Routine

...Even more so in Korea

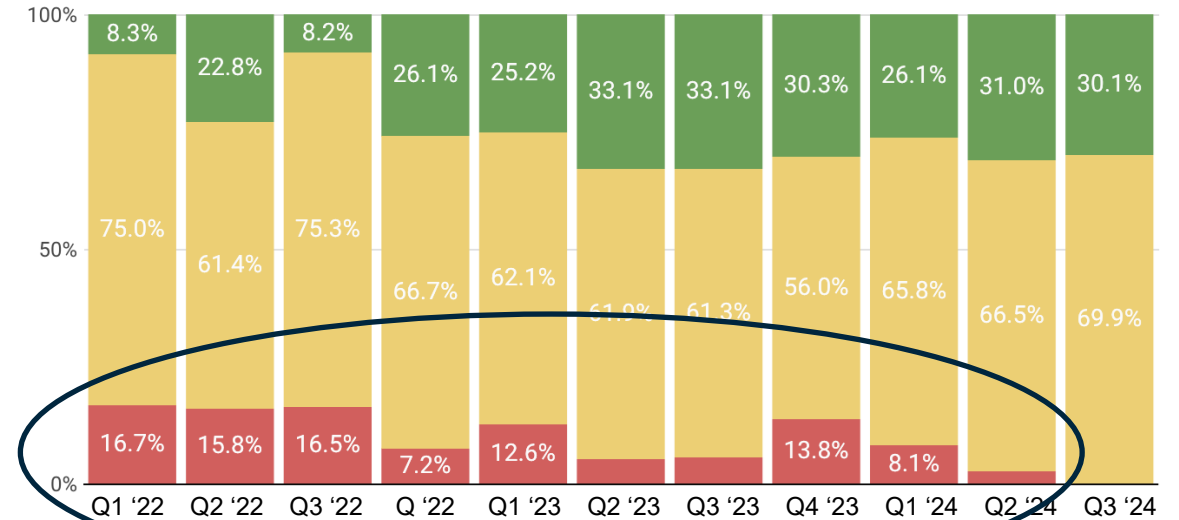
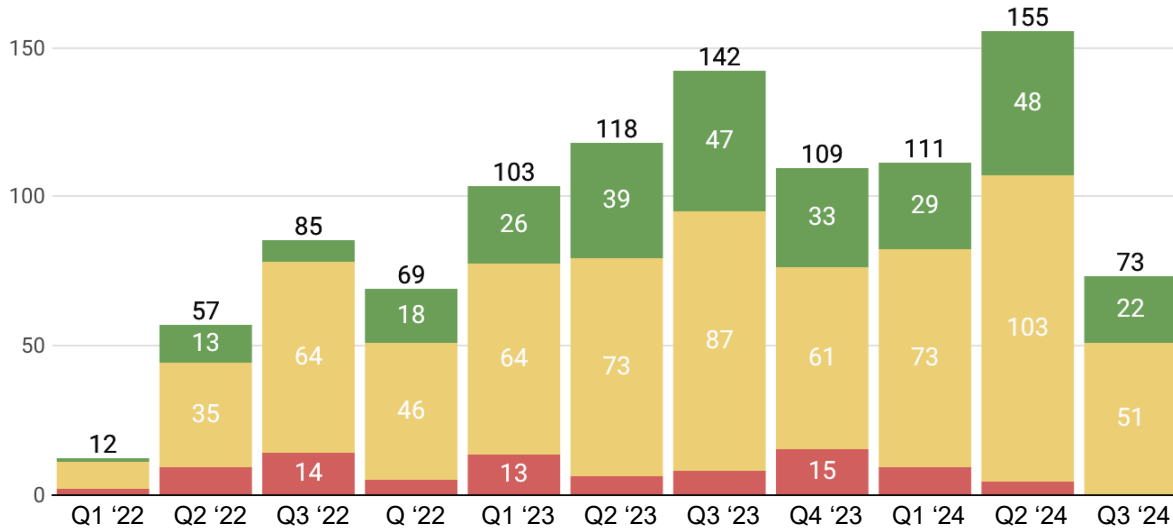
South Korea



■ For-Cause ■ Not Provided ■ Pre-Approval ■ Routine

“Red” inspections dropping a little

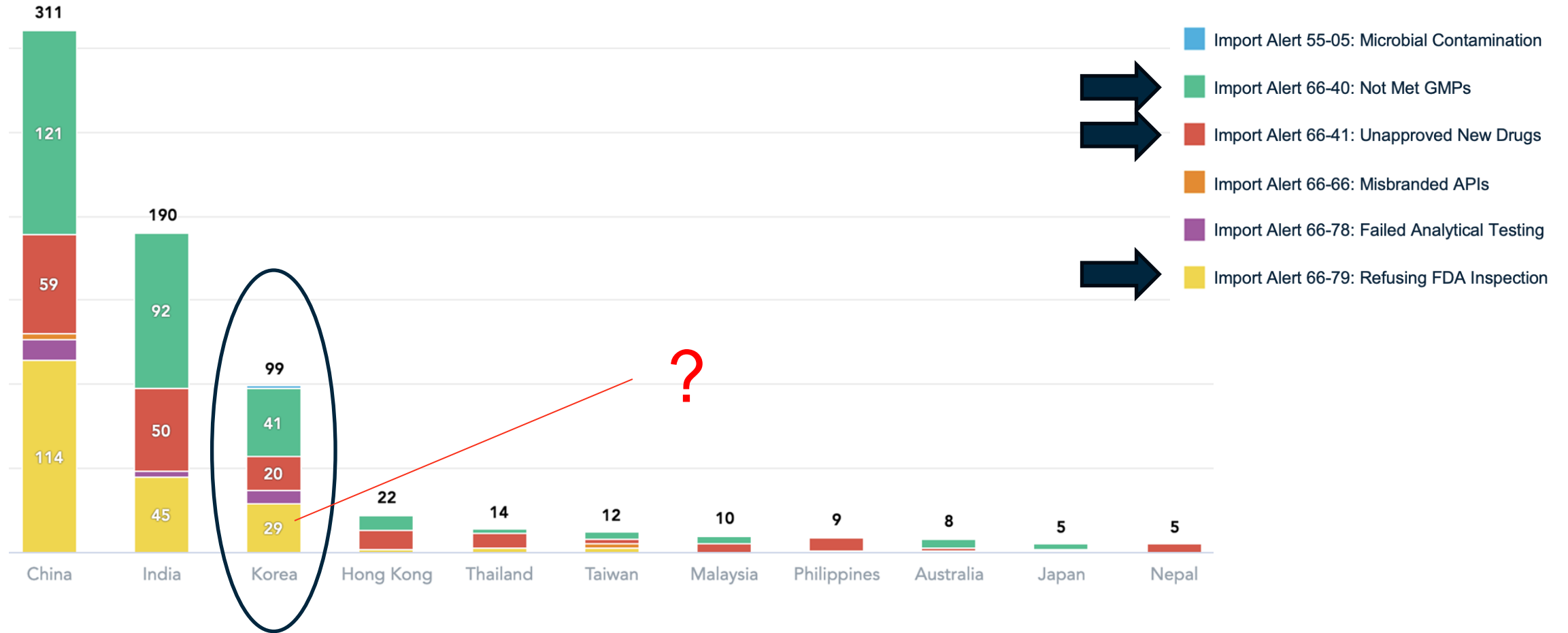
Asia Pacific



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

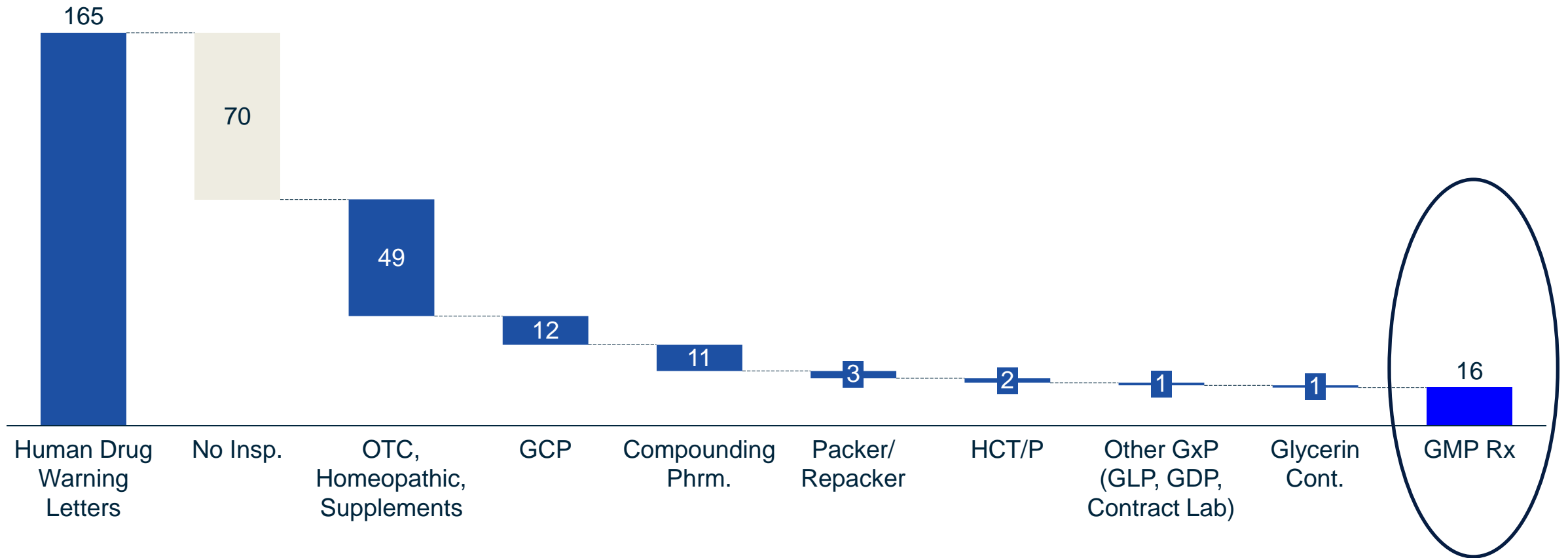
Korea: Surprisingly high number of Import Alerts

Human Drug Import Alerts, 2022-Present, Asia Pacific

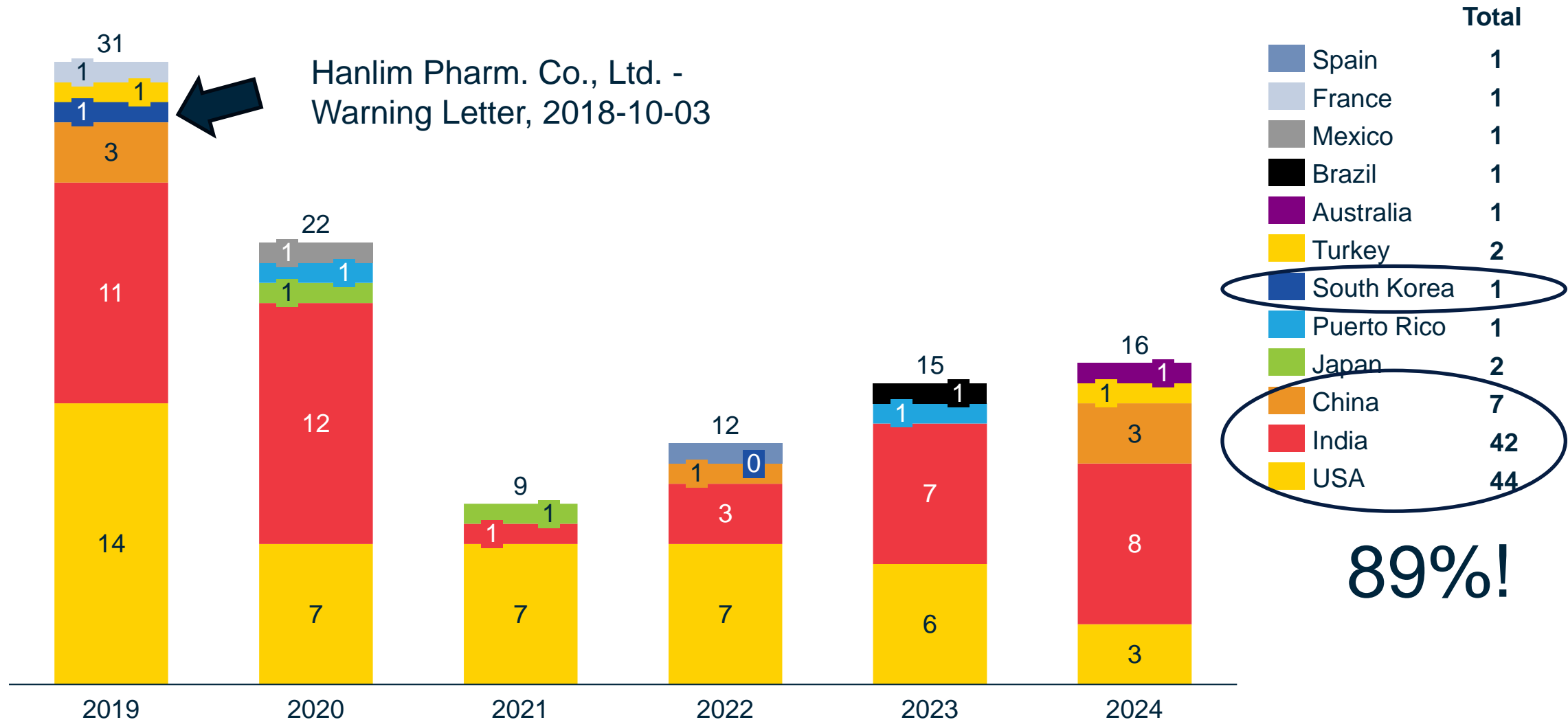


Warning Letters

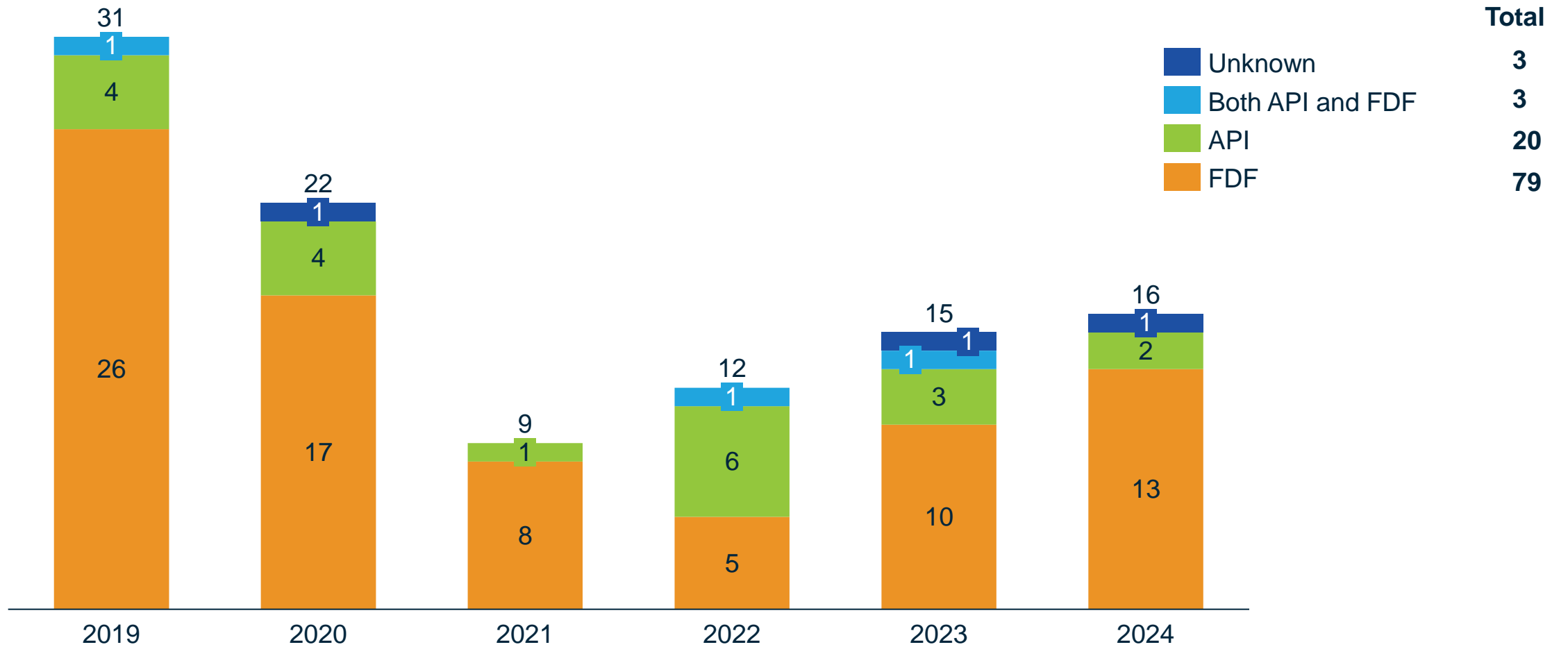
Warning letter waterfall 2024



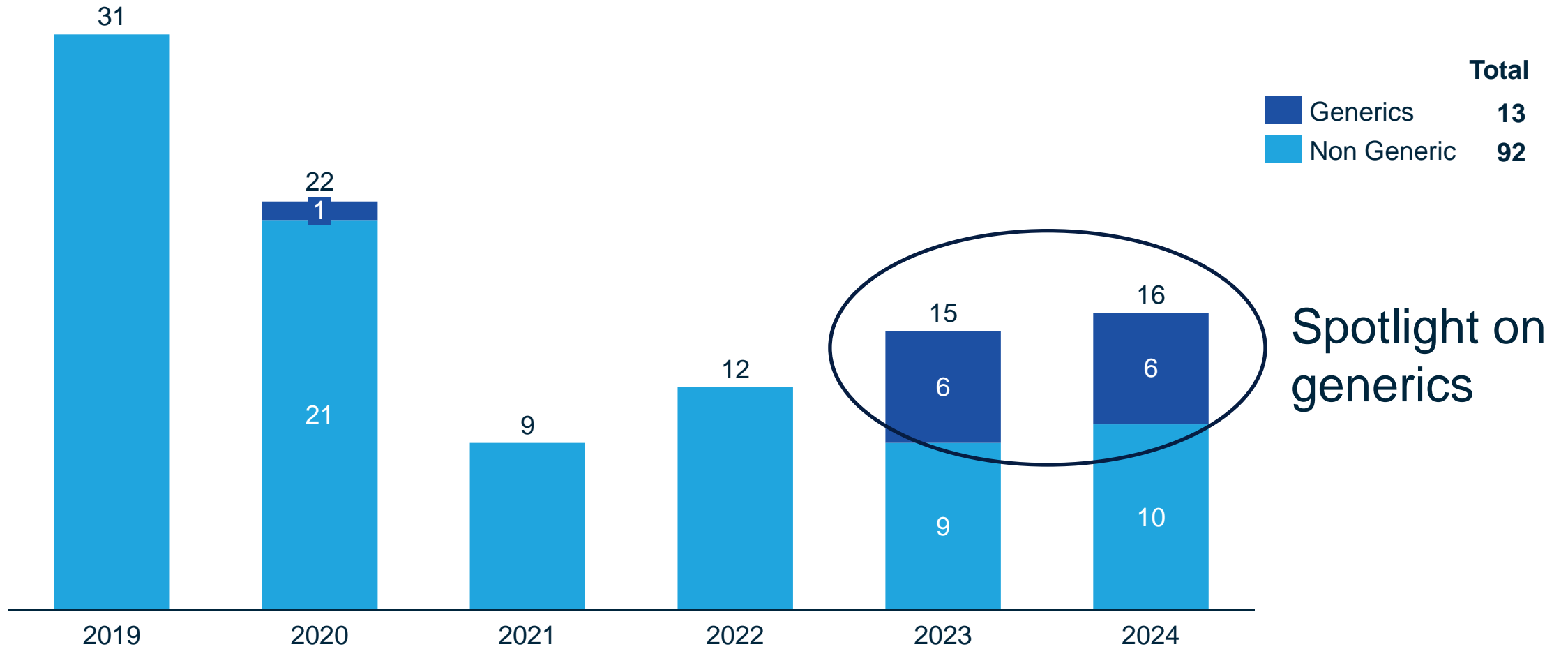
GMP Rx Warning Letters by Country



GMP Rx Warning Letters by Facility Type

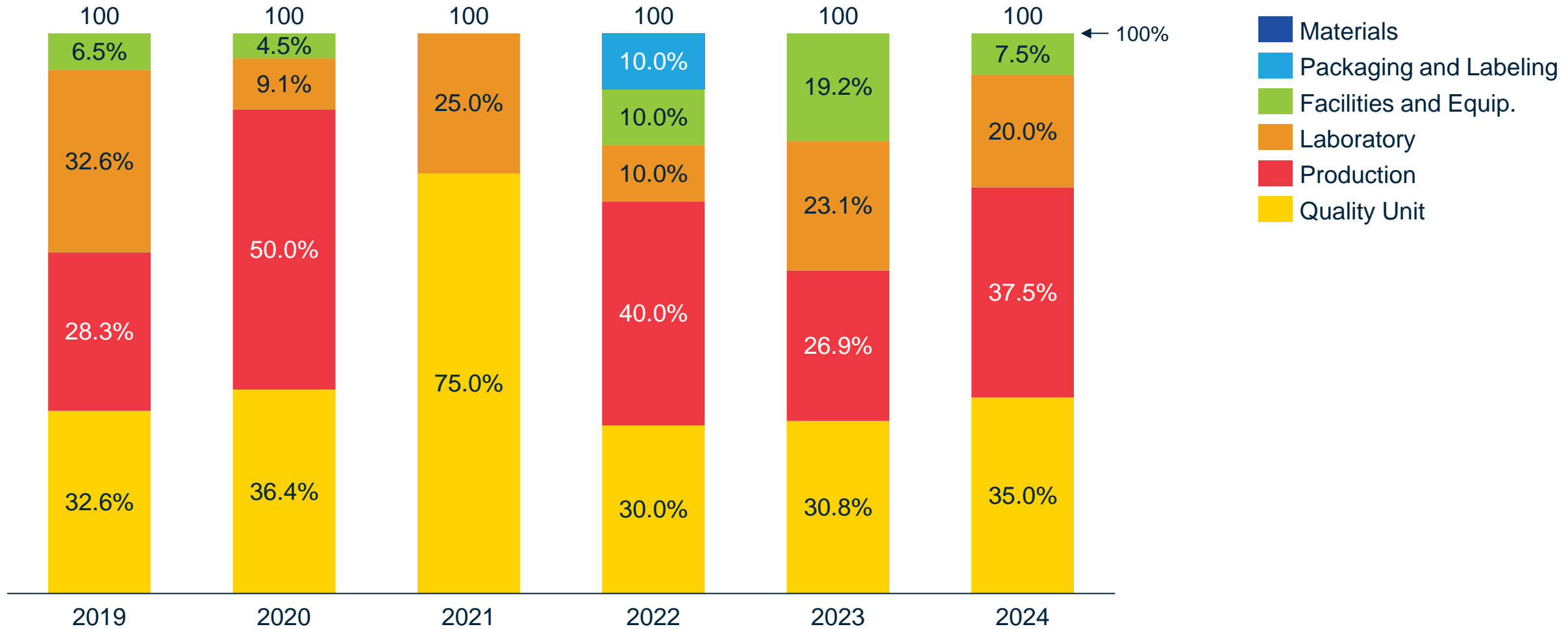


GMP Rx Warning Letters by License Type

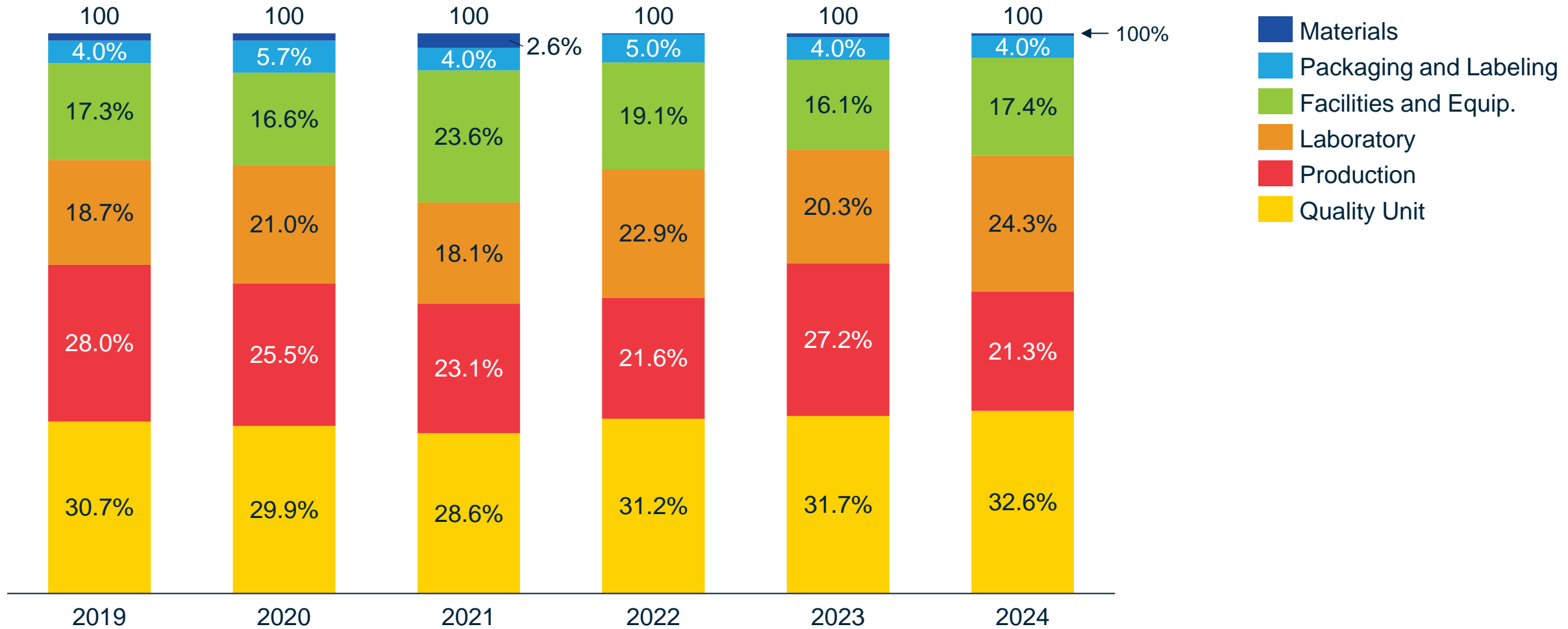


GMP Items Cited

Asia GMP Citation Trends: Warning Letters



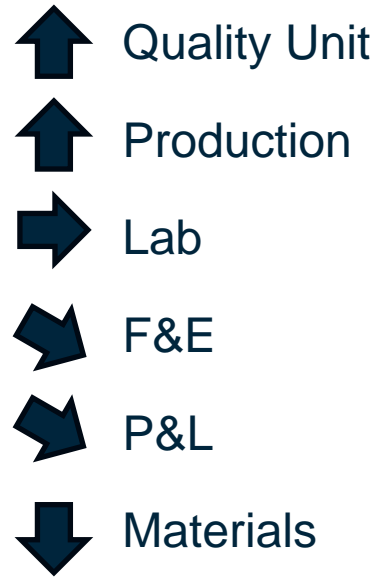
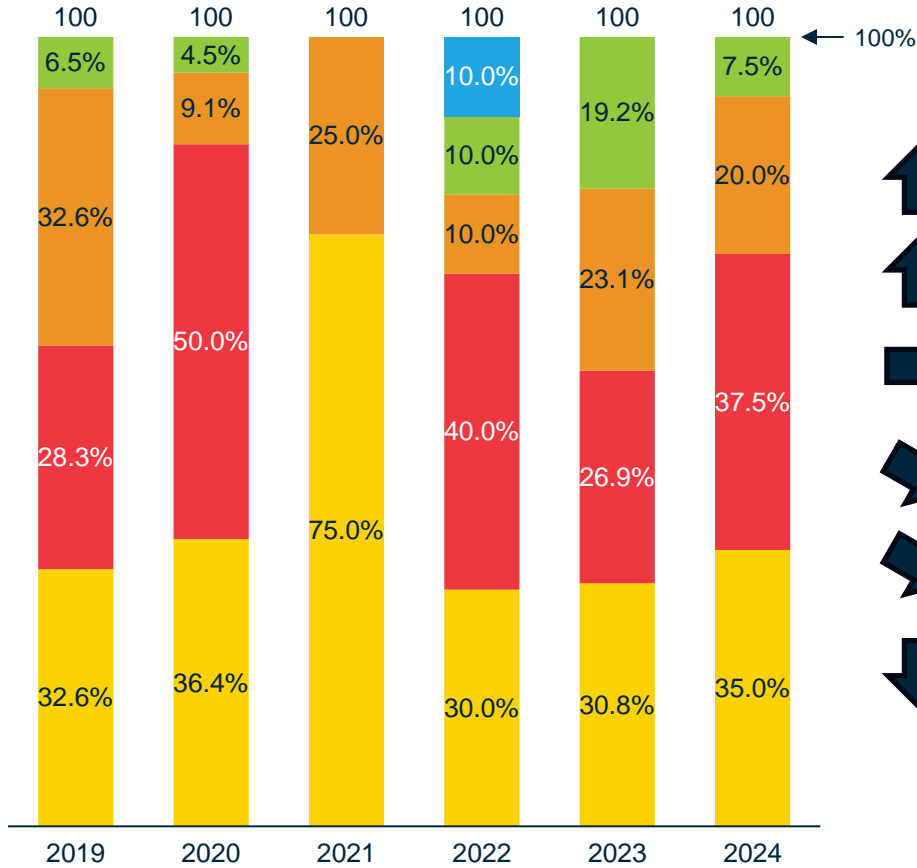
Asia GMP Citation Trends: 483s



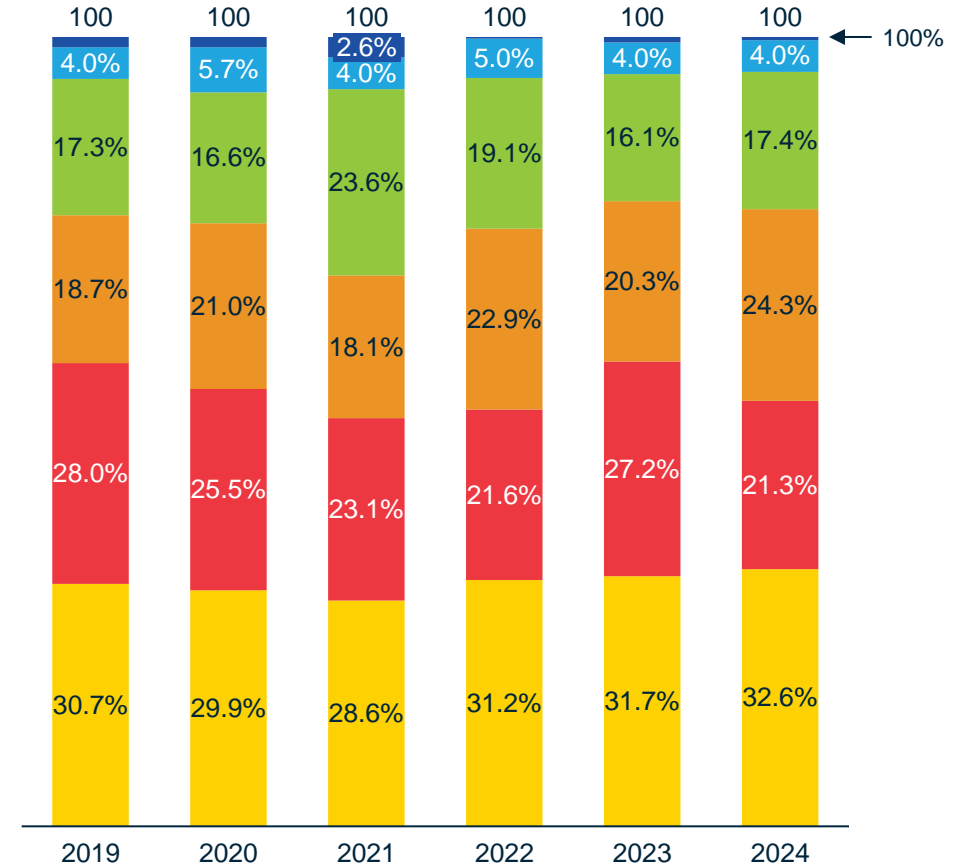
Side by Side



Warning Letters



483s



Double Click : Warning Letters



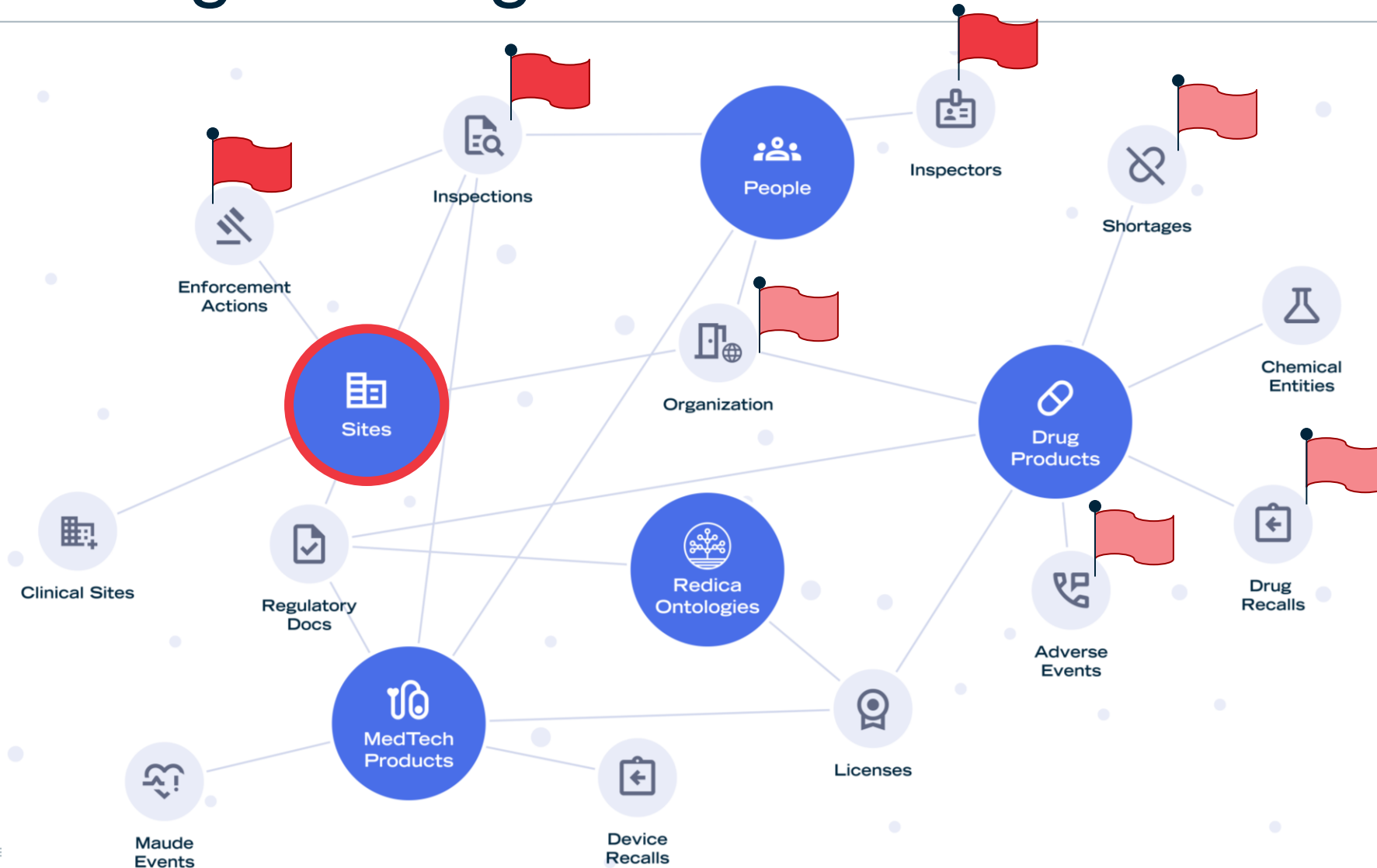
Double Click : 483s

Warning Letter Rankings

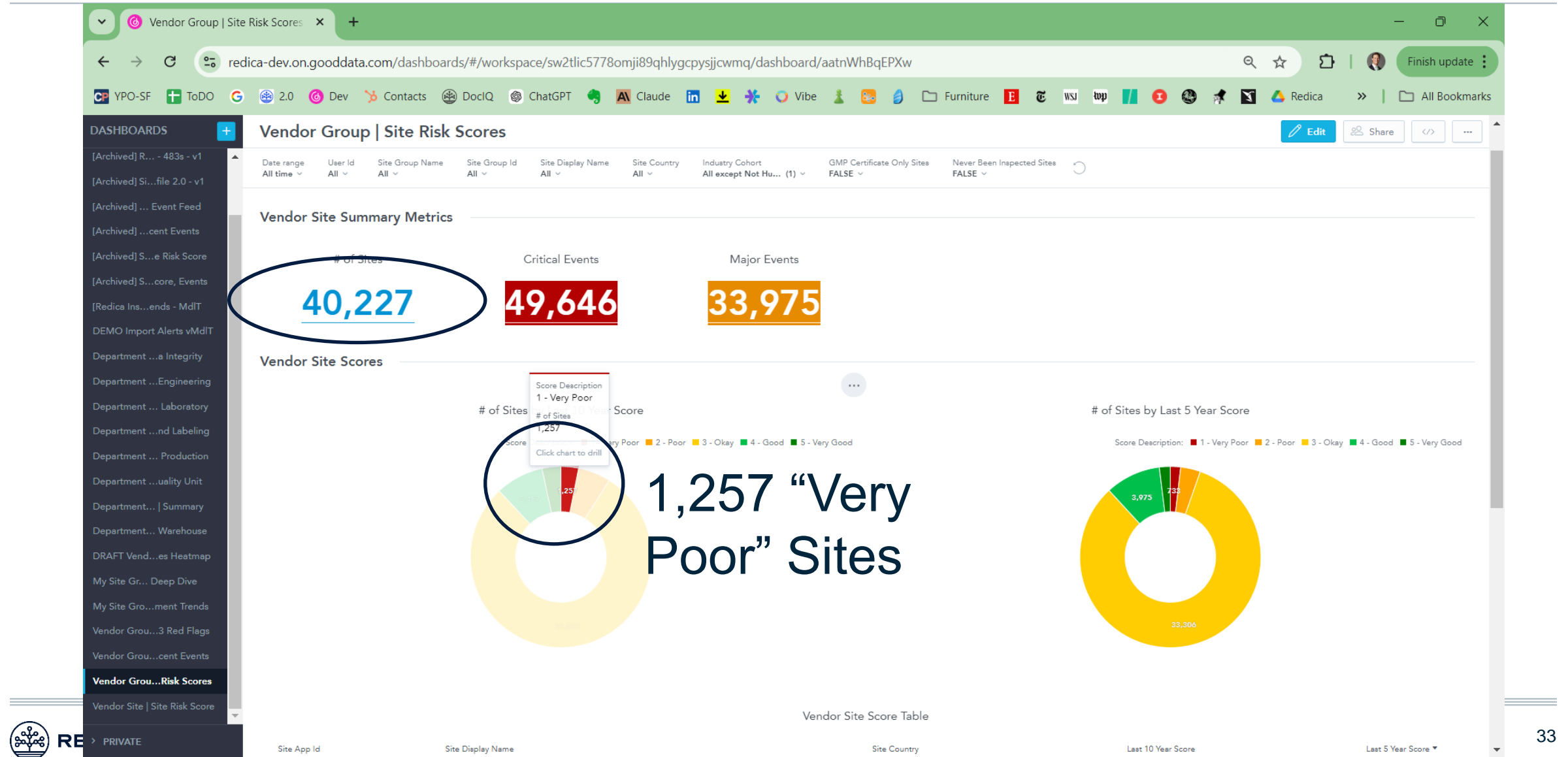


CMO Selection

Connecting red flags to Sites



All Human Drugs Sites



Double Click into individual Sites and Events

Vendor Site | Site Risk Score - G x +

redica-dev.on.gooddata.com/dashboards/#/workspace/sw2tlc5778omji89qhlygpcysjjcwmq/dashboard/aa75JhVdtUJX

YPO-SF + TO DO G 2.0 Dev Contacts DocQ ChatGPT Claude LinkedIn Vibe Furniture WSJ Wp I Redica All Bookmarks

DASHBOARDS + Vendor Site | Site Risk Score Edit Share <> ...

Date range: All time Site Display Name: All Fei: All Site App Id: 100039791

Cumulative Site Score Over Time

Year	Score
2010	7
2011	4
2013	6
2014	5
2015	7
2016	9
2017	-6
2018	16
2019	45
2021	97
2022	146
2024	161

Site Score Over Time by Red Flag Criticality

Year	None	Minor	Major	Critical
2010	0	7	0	0
2011	-3	0	0	0
2013	-3	5	0	0
2014	-9	5	0	0
2015	-3	5	0	0
2016	-3	5	0	0
2017	-14	1	0	0
2018	-6	8	8	28
2019	-3	7	7	20
2021	-3	8	7	40
2022	-6	8	7	55
2024	0	8	7	15

Date (Event End Date)	Red Flag Criticality	Red Flag Type	Red Flag Value	Red Flag Agency	Site Score
2024-02-02	Major	1. Inspection Reason	For-Cause	US - FDA	7
	Minor	2. Inspection Outcome	483	US - FDA	5
			VAI: Drug Quality Assurance	US - FDA	5
		7. Inspection Timing	Long Duration Inspection	US - FDA	1
		8. Inspector	Expert Inspector	US - FDA	2
	None	1. Inspection Reason	Pre-Approval	US - FDA	0
	Critical	2. Inspection Outcome	OAI: Drug Quality Assurance	US - FDA	20
	Major	1. Inspection Reason	For-Cause	US - FDA	7
	Minor	2. Inspection Outcome	483	US - FDA	5
		7. Inspection Timing	Long Duration Inspection	US - FDA	1
		8. Inspector	Expert Inspector	US - FDA	2
	None	1. Inspection Reason	Pre-Approval	US - FDA	0
		2. Inspection Outcome	CFR Citation	US - FDA	0

Vendor Group | 483 Red Flags

Vendor Site | Site Risk Score

> PRIVATE

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	-	-	-	-	-	-	-3	-	-	-6	-	2	-	-	7	9
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

Innovator /
Sponsor

Generics/
Biosimilars

CMO