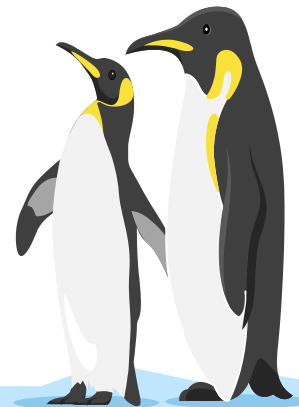




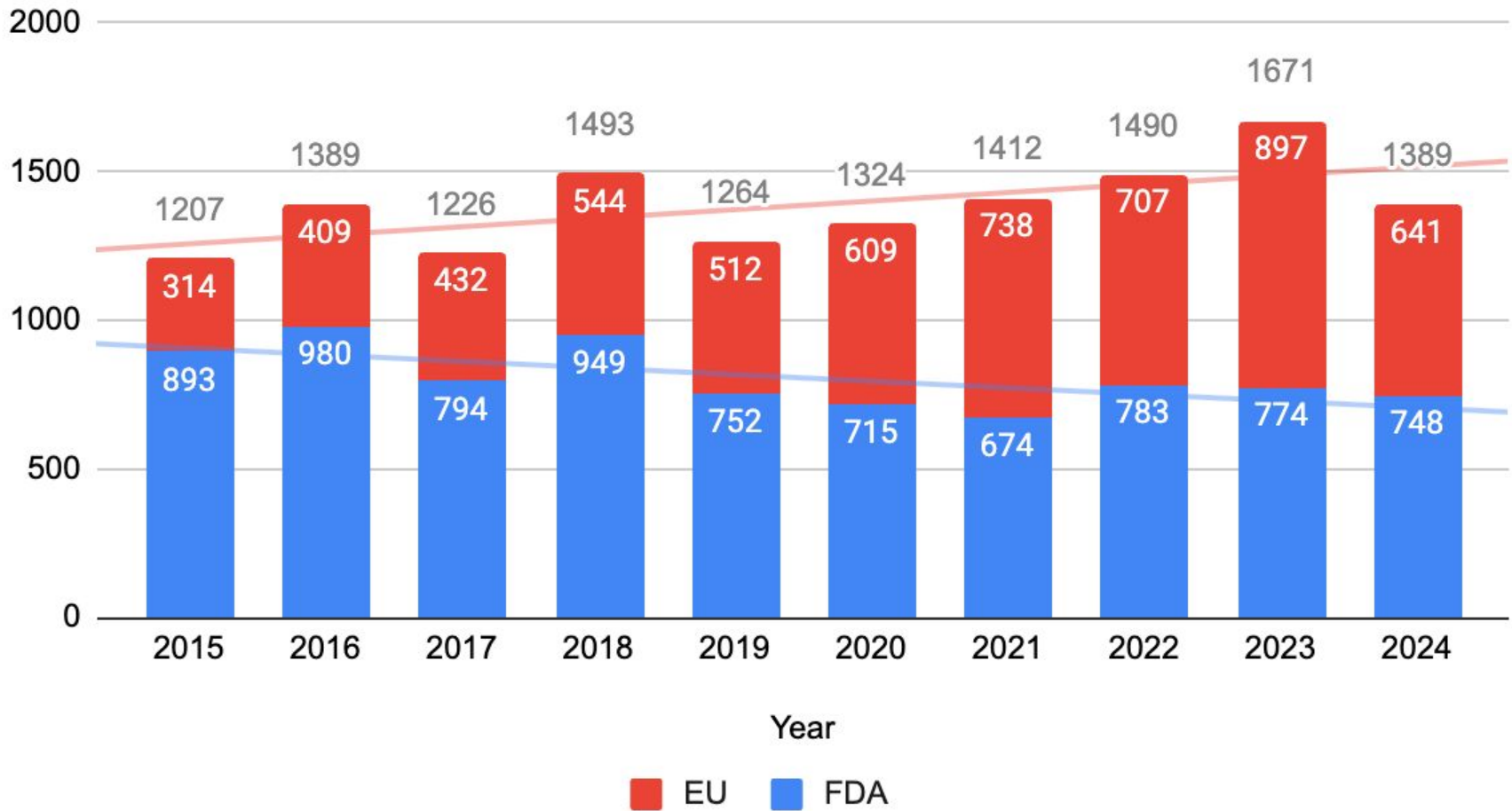
The Future of Regulatory Affairs and How Technology is Shaping Regulatory Compliance



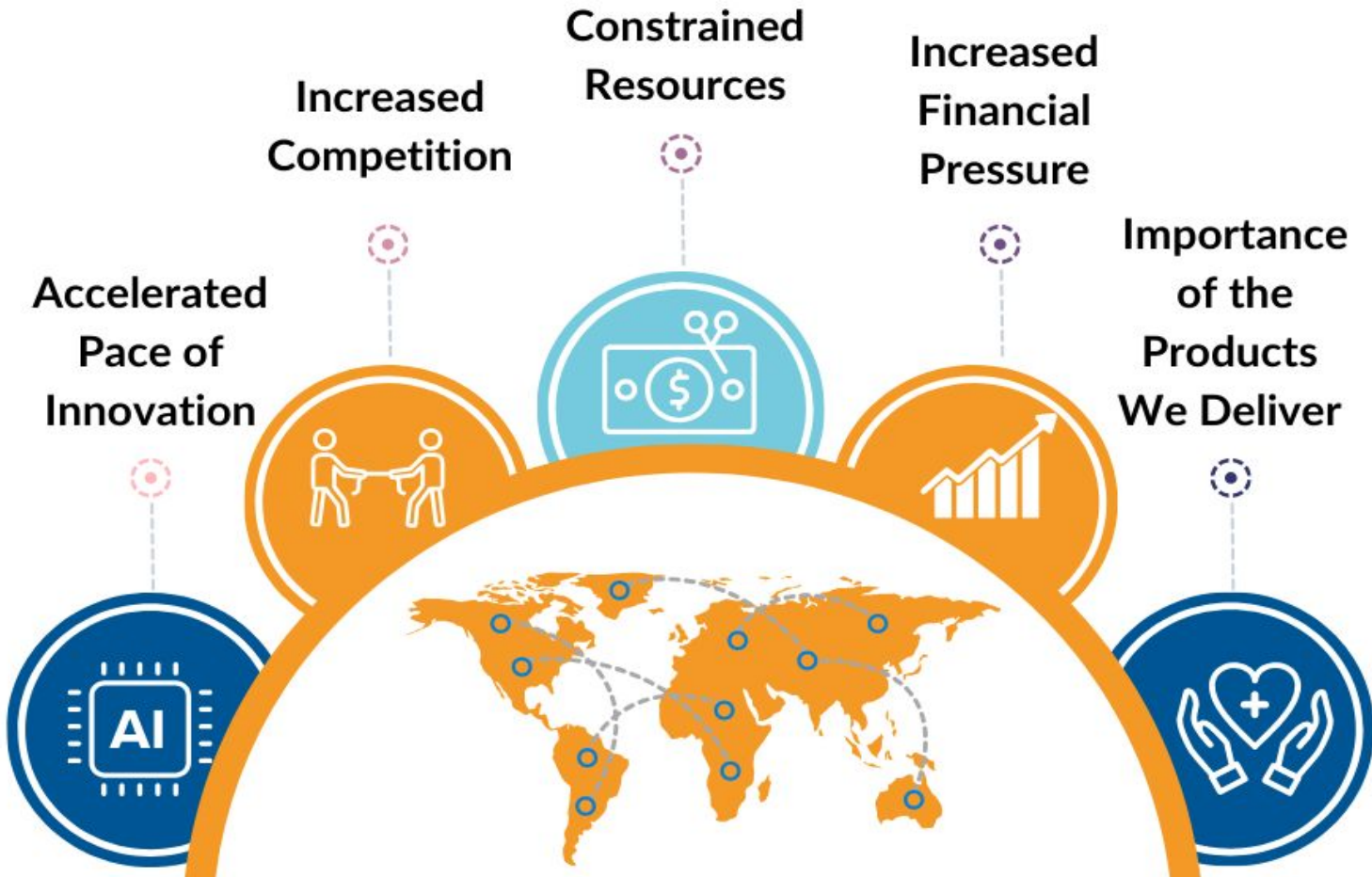
Complexity in regulatory compliance is increasing at a record pace.



FDA and EU Regulations by Year



Market Problem



Accelerated
Pace of
Innovation

Increased
Competition

Constrained
Resources

Increased
Financial
Pressure

Importance
of the
Products
We Deliver

OUR ICEBERG

IS MELTING



Meet Fred, an Emperor Penguin

**Our Iceberg is
MELTING!**

What do I do?



Fred Approached His Boss, Alice

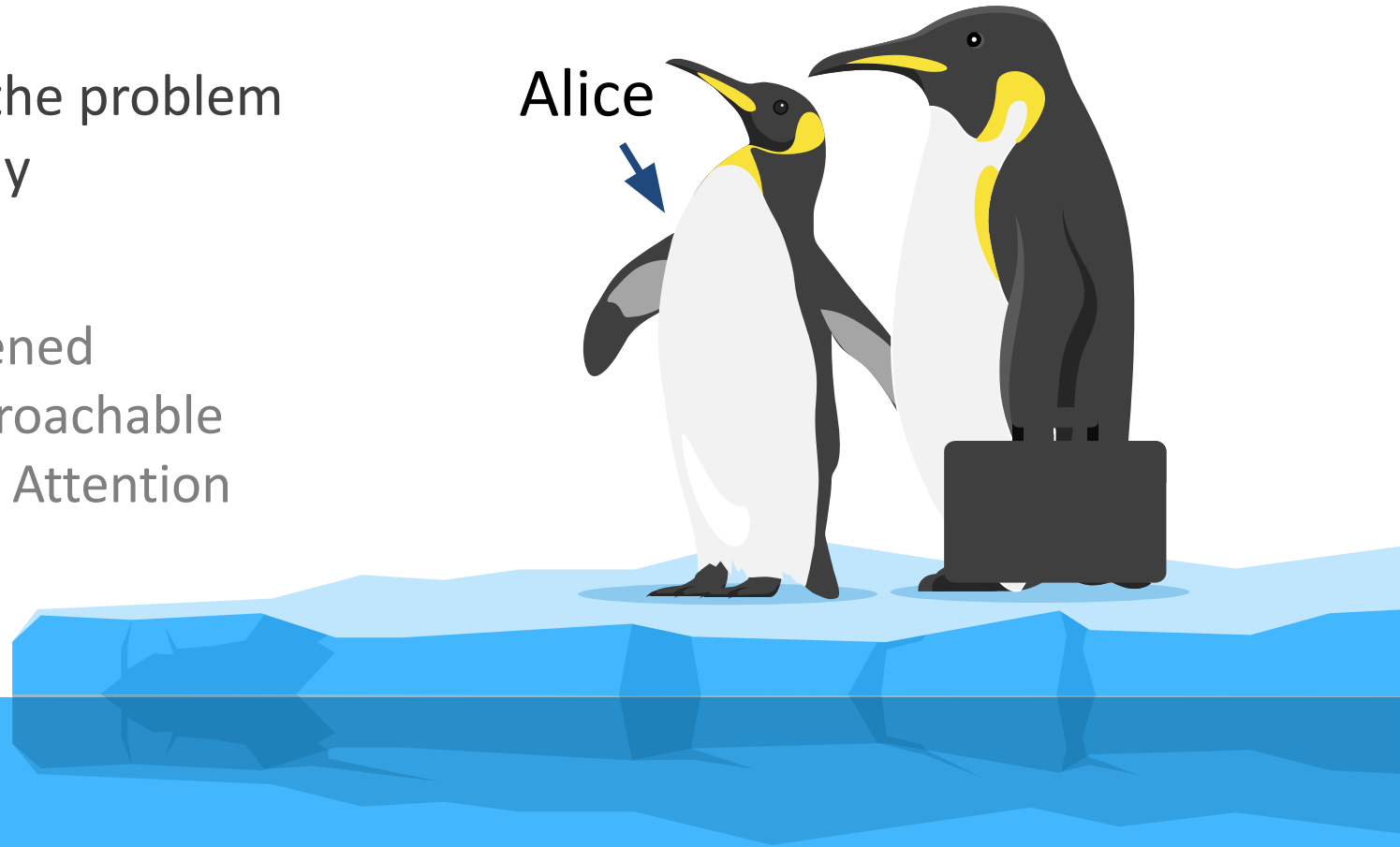
Explained the problem
scientifically

Alice:

Listened

Approachable

Paid Attention



Alice Contacted The Board

Problem? What Problem?

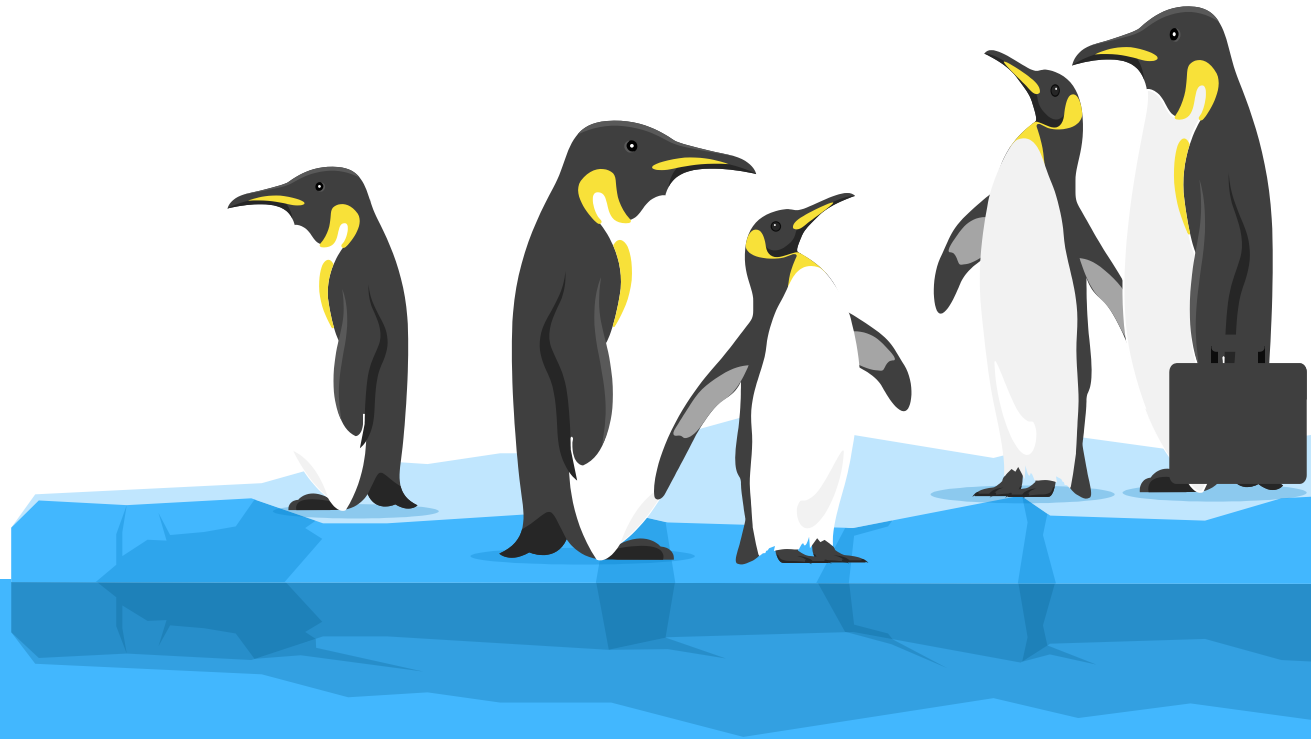
Debated

Some nodded

Defended

Disagreed

Need Evidence!



Challenges Facing Us

An illustration of an iceberg floating in the ocean. The tip of the iceberg is above the water line, while the much larger part is submerged. The iceberg is composed of various shades of blue and grey, with a yellow triangle at its base. The background shows a blue sky with white clouds and a blue sea with small fish and coral. The title 'Challenges Facing Us' is at the top. Four text labels are connected to the submerged part of the iceberg by dashed lines and small white circles: 'Difficult to keep up with changes to Regulations' (top left), 'Time to Build Submissions' (top right), 'Managing Product Changes' (middle left), and 'AI becoming omnipresent' (bottom right). 'Redundancy, Administrative Work, Resources' is written at the bottom left of the image.

Difficult to keep up with changes to Regulations

Time to Build Submissions

Managing Product Changes

AI becoming omnipresent

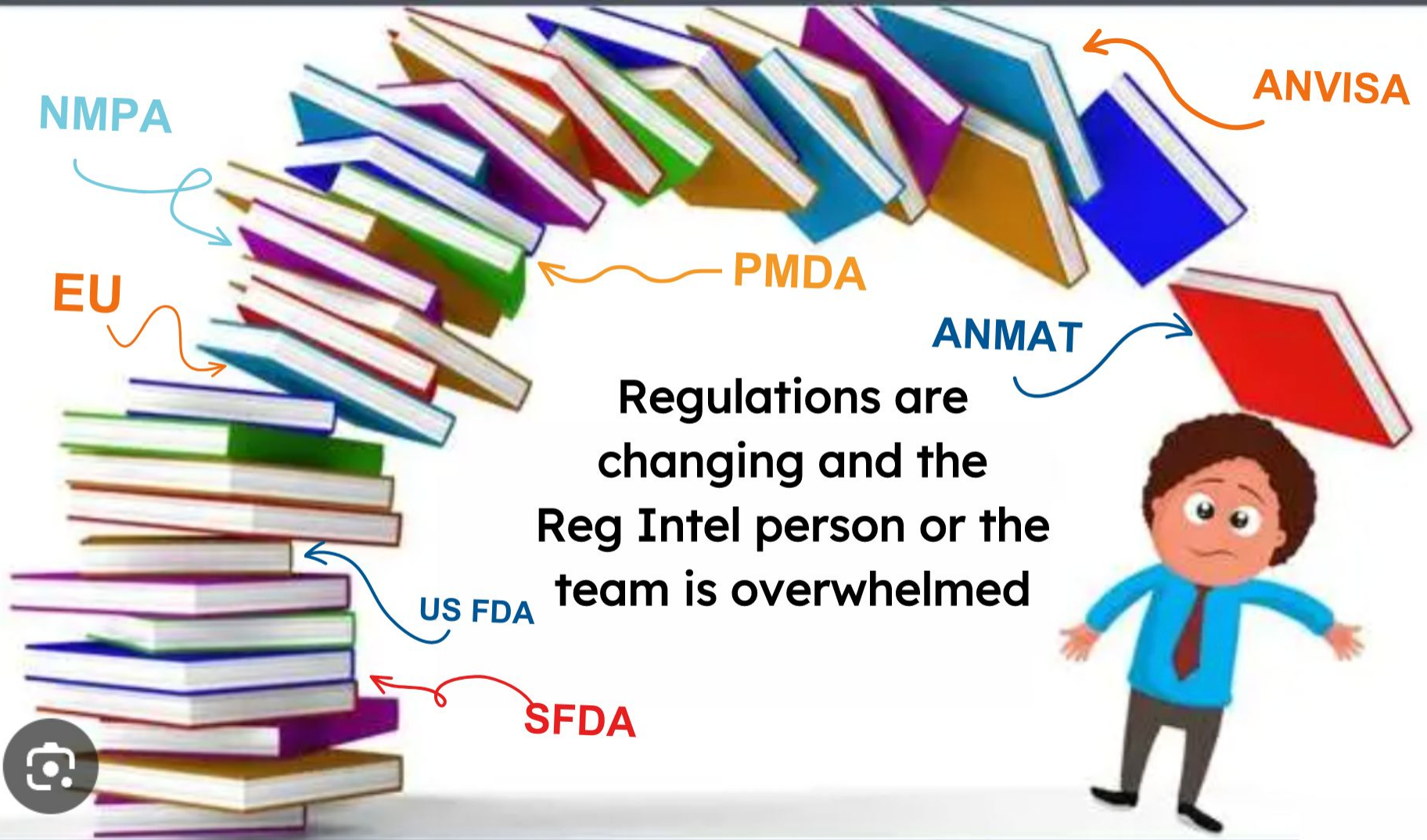
Redundancy, Administrative Work, Resources

Regulatory Intelligence

90 Updates in June

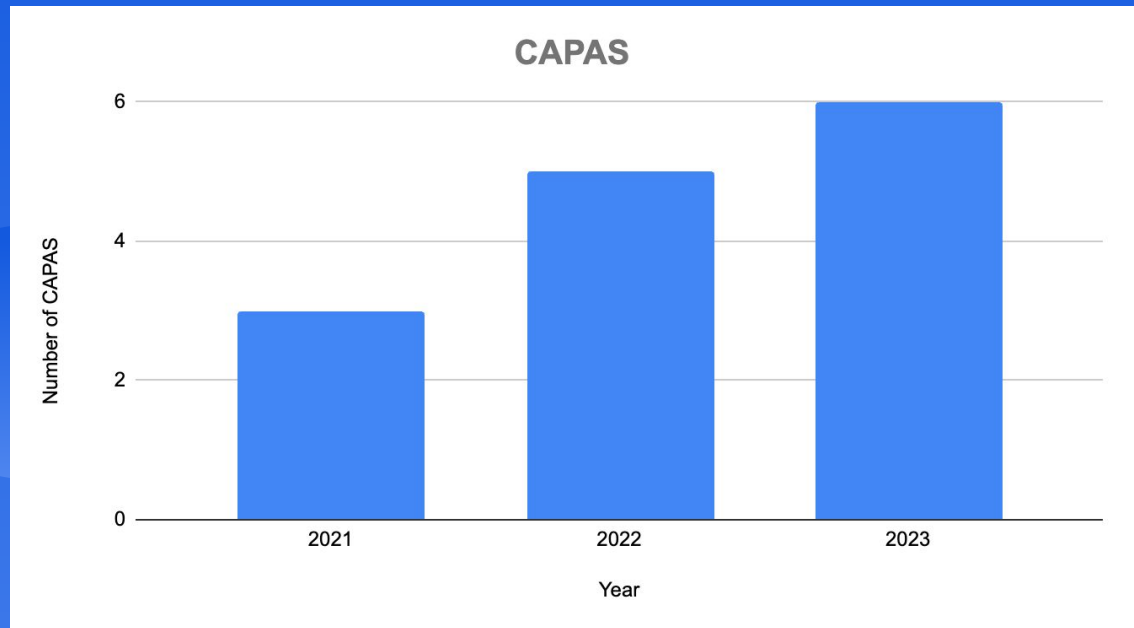


Is Your Team Able to Keep Up?



Case Study

- Mid size IVD Company
- Struggled to keep up with regulatory intelligence
- Non compliant for missing regulatory changes
- Missed risk assessments



Old Way Just Won't Work

Gather RI

1. Distributors
2. Consultants
3. Regional Teams
4. Agency
Newsletters

Disseminate

1. Aggregate RI manually
2. Create report
3. Disseminate

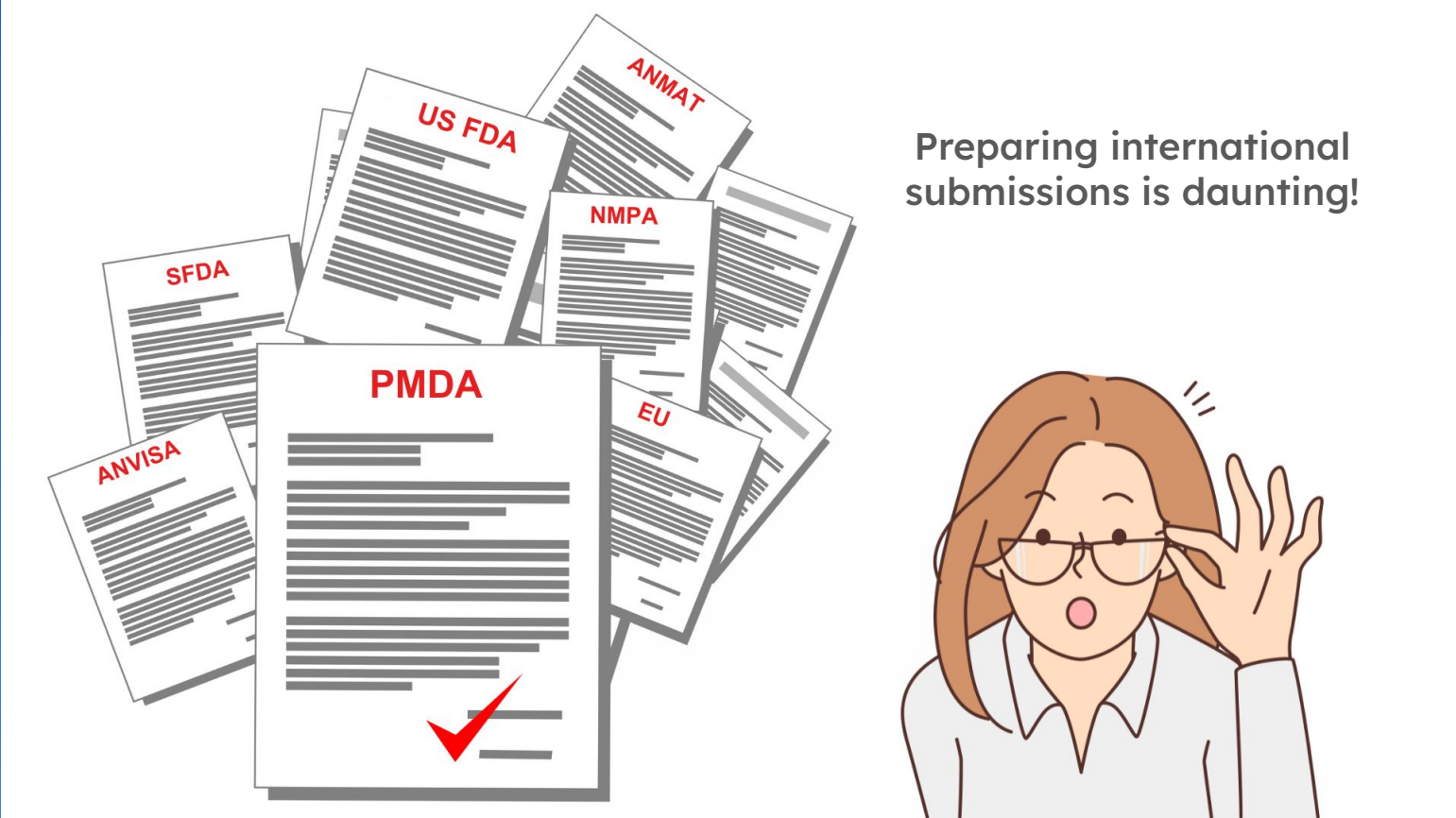
Challenges

1. Resource Heavy
2. Manual —> Errors
3. Compliance Risk

Non compliance can cost a company fees of up to 5% of the revenue.



Building Submissions Continues To Be Challenging



Only Two Paths To Submission Preparation

Internally

Distributor/Consultant



Our Data Shows

Document Shuffling, Rework, and Resources

- Average time to address a single distributor inquiry: **6 - 8 weeks**
- Average time to prepare submissions: **2 - 6 months**
- One RA associate handles: Max **4** applications **per year**
- Frustration obtaining documents (missing/incorrect documents)
- RA teams **lack knowledge** and confidence in preparing **international submissions**
- RA teams report **loss of knowledge** (MDR remediation, turnover)
- Increasingly more difficult to retain talent



Case Study

A Regional Team's Pursuit



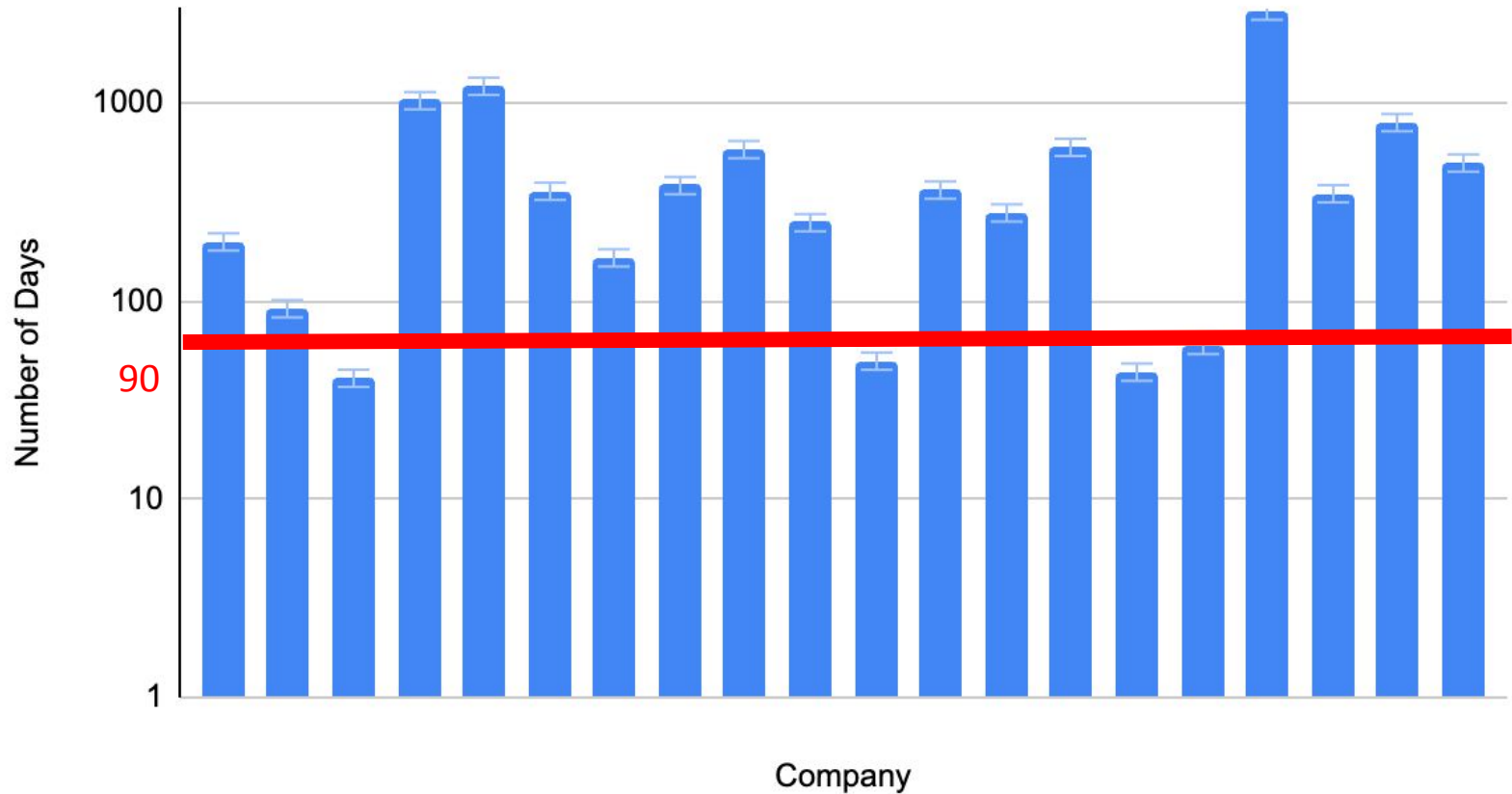
- Enterprise level medtech company
- Latam team based in Brazil
 - Responsible for registration
 - Placed multiple requests to the businesses to share documents
 - Did not have access to the DMS
- Tracked the time it took for businesses to share documents

8 Years Later!



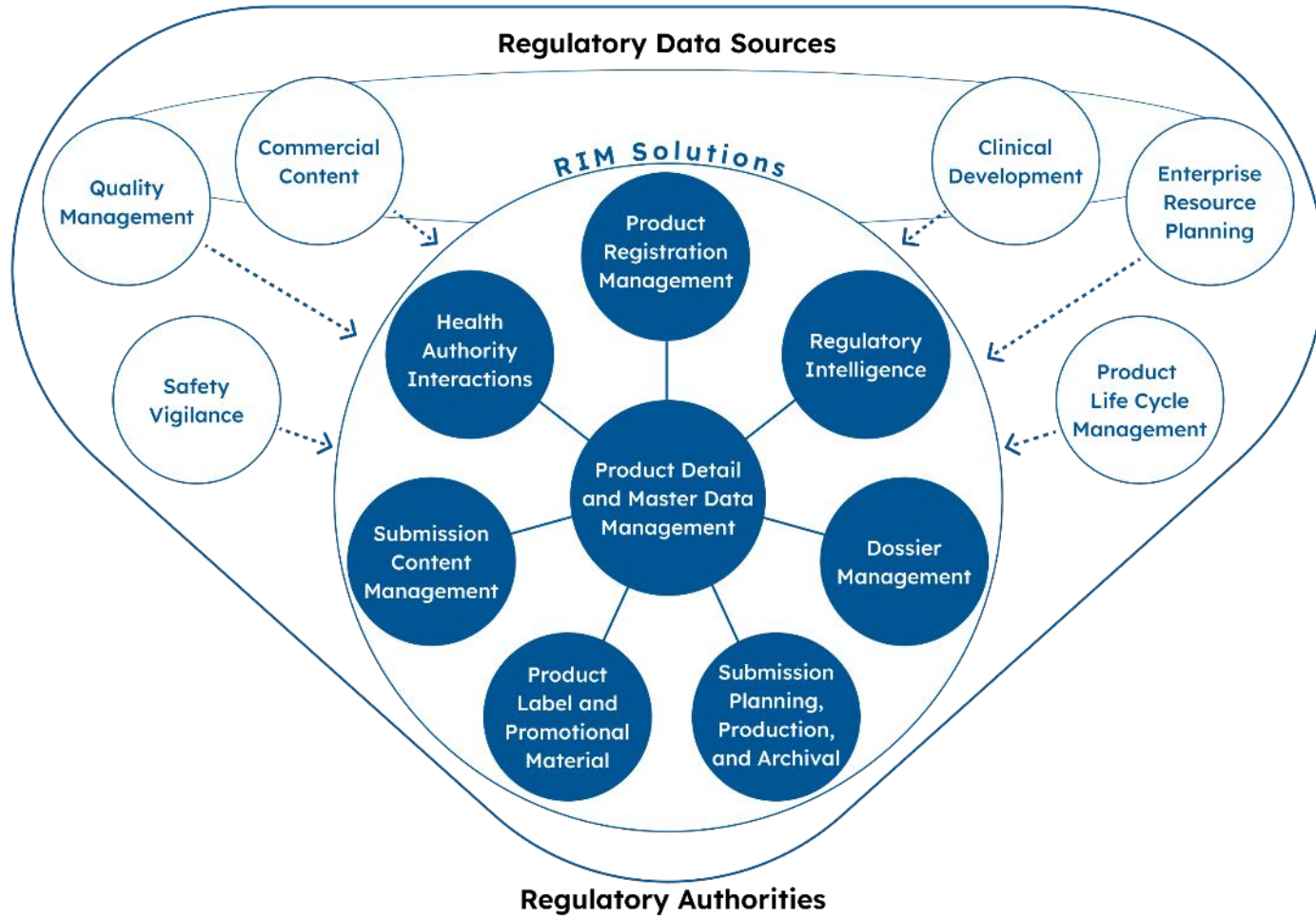
Case Study

Time to Collect Submission Documents

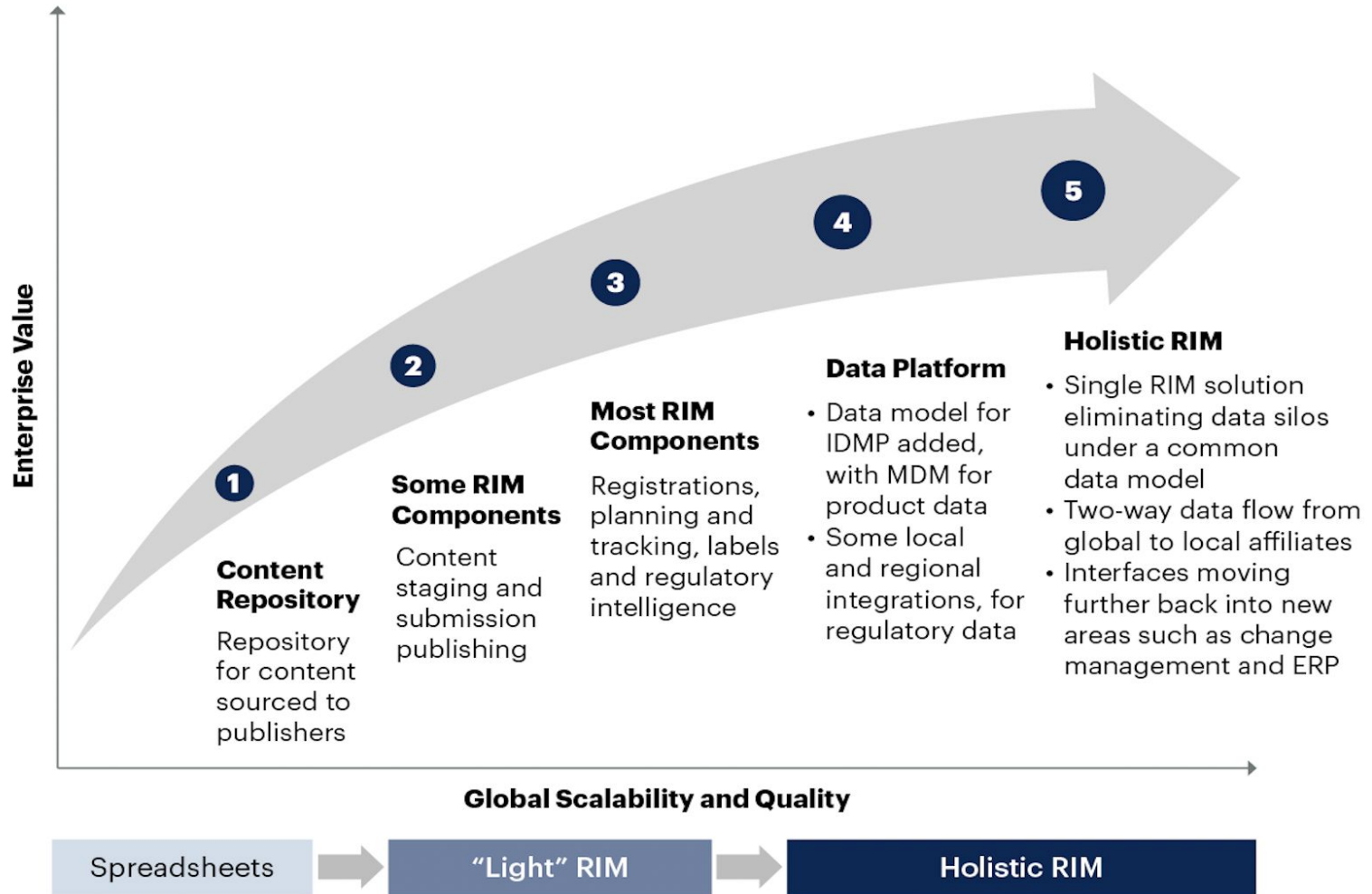


Gartner's Proposed Solution

Holistic RIM



The RIM Platform Progression

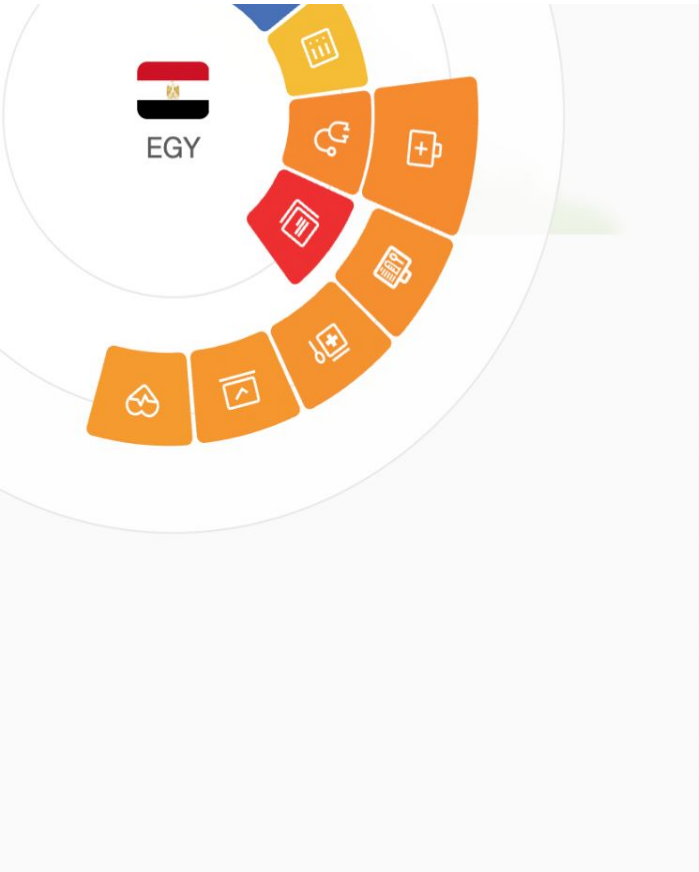


Future of Regulatory Affairs

1. Automation
2. Integrated Workflows
3. AI



Quick Access to RI



[< Back](#)

Class I

[Regulation Data Comparison](#)

- Documents**
32 docs
- Checklist**
5 items
- Procedure**
17 steps
- Fees
\$98 - \$421 USD
- Time
3 - 6 Month
- AR Required
YES
- Dossier Lang...
English or Arabic
- License Validity
10

Documents	Translate	Notary	Legalize	Apostille	Fee	Originals	Copies
Administrative Document (8 docs)							
Application Form	X	X	X	X	X	X	0
Fees Receipt	X	X	X	X	X	X	0
Authorization doc...	X	X	X	X	X	✓	0
Safety/Vigilance ...	X	X	X	X	X	X	0
Letter of Authoriz...	X	X	✓	X	X	✓	0
Commercial Regi...	X	X	X	X	X	X	0
Distribution Agre...	X	X	✓	X	X	✓	0

Daily Alerts

Device Alerts



Search text... Start date ~ End date Search a country name

- Global
- North America
- South America
- Africa
- Europe
- Asia
- Oceania





Work Smarter & Faster

- 1. Cover Letter 100%
- 2. Device Description 100%
- 3. Labeling 100%
- 4. Design and Manufac... 100%
- 5. General Safety and ... 100%

1. Cover Letter



General information about the device

1. Cover Letter* ? N/A Off

- Certificate # reference(s) (if known)
- The type of review (new product, design change, shelf life extension, etc.)
- Brief product description, including model numbers involved, etc.
- Notified Body Ref. #) for any other relevant submissions (for example, concurrent applications which may affect the submission)
- An explanation of:
 - what has been submitted and how it demonstrates compliance and, for changes to existing certification:
 - what is affected (packaging, material change, sterilisation, etc.)
 - what is not affected (along with appropriate justification)

Select from DMS

Overview



Product: Surgical cap
Country: EU
SKU: 1234584-55845 [✎](#)
Application Type: New Registration
Product Type: Medical Device
Classification: Class IIb
Template Version Name: EU_BSI_MAY_2020
Template Version Number: 1.00
Attribute: Not Set [✎](#)
Latest Update: 16 OCT 2024
Creation Date: 12 SEP 2022

Add New Application

Enter Application

Please, enter application name



Confirmation

You are about to create a new application with the following information:

Name: India Submission 3

Product: Surgical cap

SKU: [SKU List](#) ▾

Country:  India

Application Type: New Registration

Product Type: Medical Device

Classification: Class C

Template Version Name: REG_MDR2017_2023

Template Version Number: 1.00



Eliminate Redundancy



Application autofill completed. Open

Server time
22:32:06 26 NOV 2024 v4.1

Applications

1. Application Form
0%

2. Power of Attorney
100%

3. AR Details
0%

4. Plant Master File
75%

5. Device Master File
66%

6. Regulatory Declarati...

1. Application Form

Form MD-14

1. Application Form* N/A Off

1. To request a license or loan license to manufacture for sale or distribution, as the case may be, of a **Class C** or **Class D** medical device, an application shall be made to the Central Licensing Authority through an identified online portal in **Form MD-7** or **Form MD-8**, respectively.
2. To request a license or loan license to manufacture for sale or distribution, as the case may be, of a **Class C** or **Class D** medical device, an application shall be made to the Central Licensing Authority through an identified online portal in **Form MD-9** or **Form MD-10**, respectively, after *satisfactory Inspection Report*.
3. An *authorized agent* with a license to manufacture for sale or distribution or a wholesale license for sale or distribution shall apply for a grant of *import license* for a medical device through an identified online portal in **Form MD-14** for obtaining a license.

Select from DMS

For example:

The form can be found here: [FORM MD-7 Application License Class C and D](#)

Overview

Product: Surgical cap

Country: IND

SKU: [SKU List](#)

Application Type: [New Registration](#)

Product Type: [Medical Device](#)

Classification: [Class C](#)

Template Version Name: [REG_MDR2017_2023](#)

Template Version Number: [1.00](#)

Attribute: [Not Set](#)

Latest Update: 26 NOV 2024

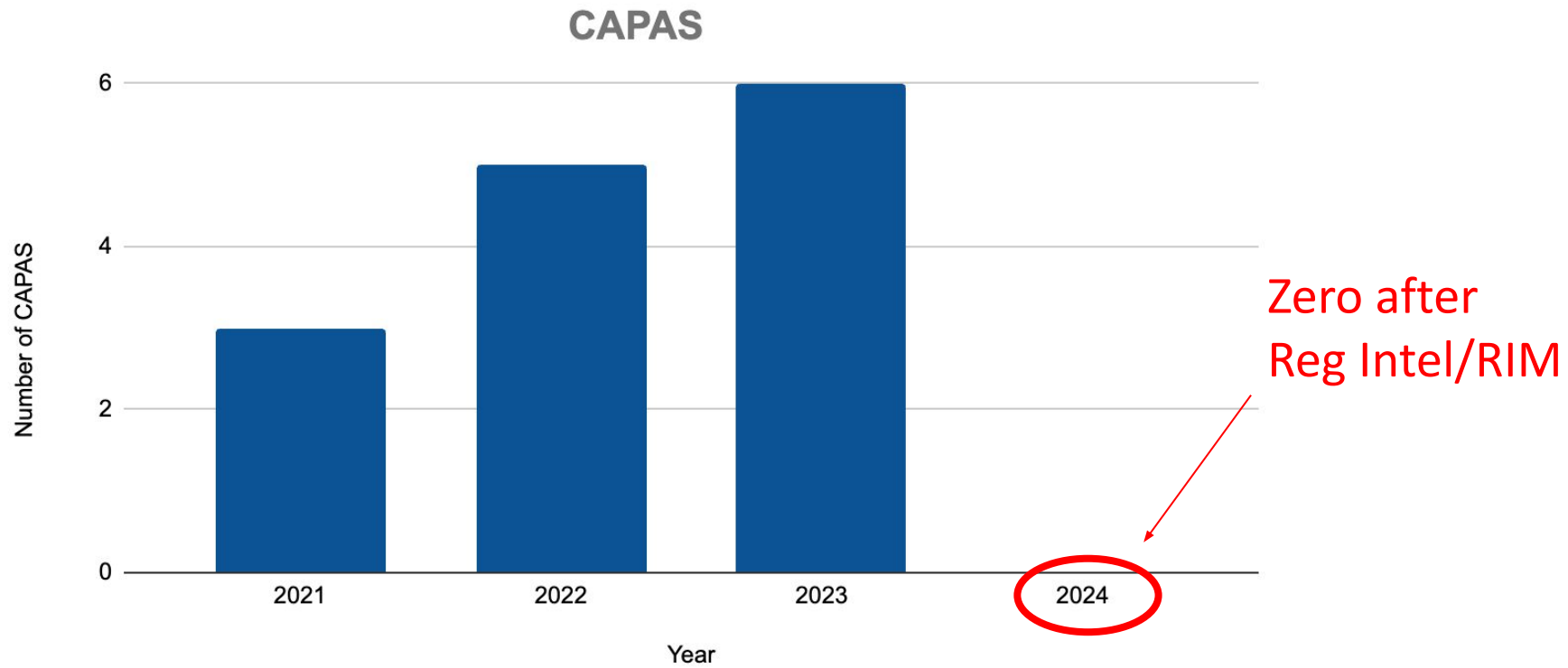
Creation Date: 26 NOV 2024

Owner: [RegDesk](#)

Overall Progress: 65%

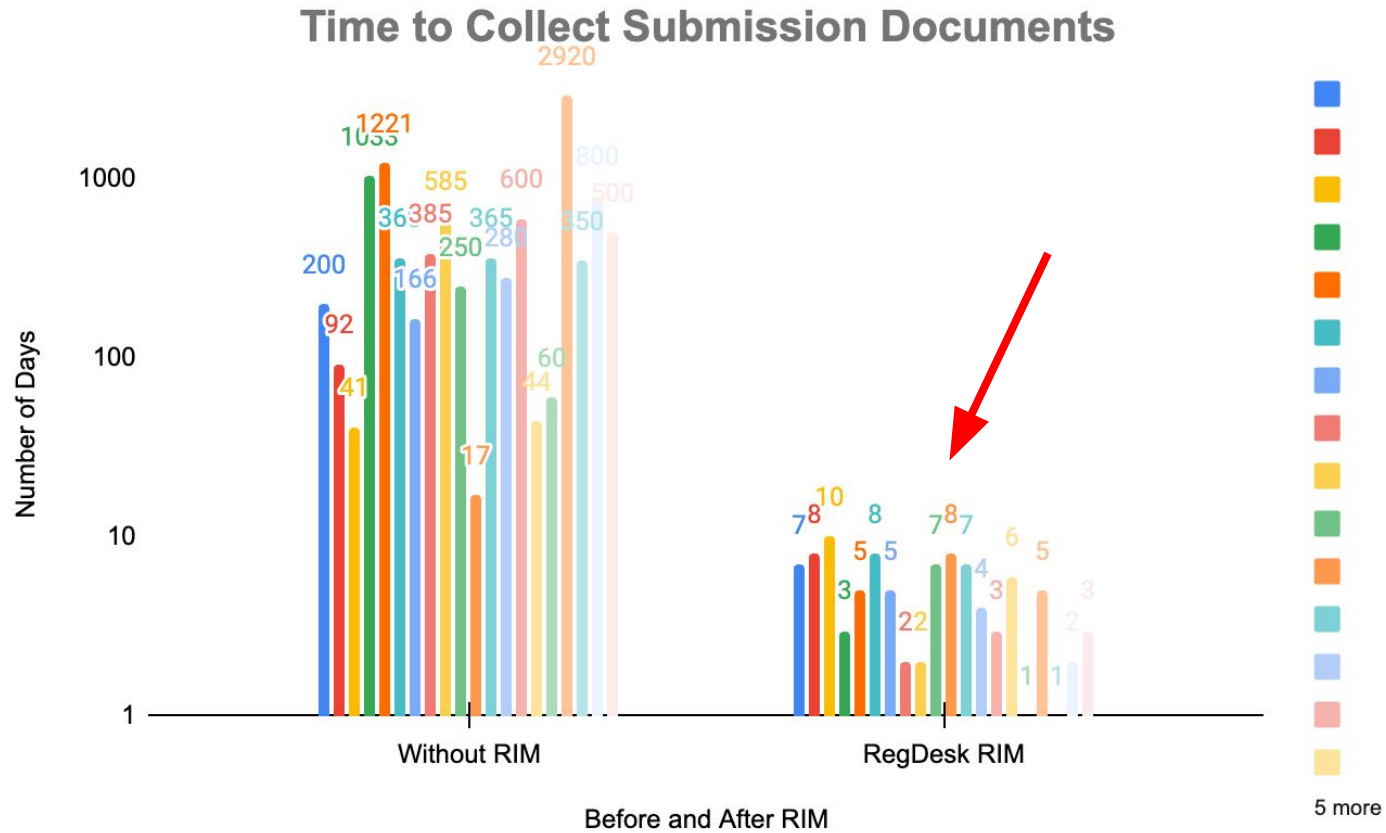
65%

Significant Reduction in CAPAS





Significant Reduction in Time With RIM



How Will You Adapt?

- **AI-Enabled RIMS**
- Automated Workflows
- Digitization of Processes
- Smarter & Integrated Regulatory Intelligence



How To Select A RIM

1.	Draft User Requirements
2.	Select a Holistic System
3.	Integrated Regulatory Intelligence
4.	Workflows
5.	Allows Collaboration with External Partners
6.	Integrates with external key systems such as ERP, eDMS, PLM

Life Sciences companies that adopted holistic RIMS platform saw a reduction of 20% in operational expenses. - Gartner





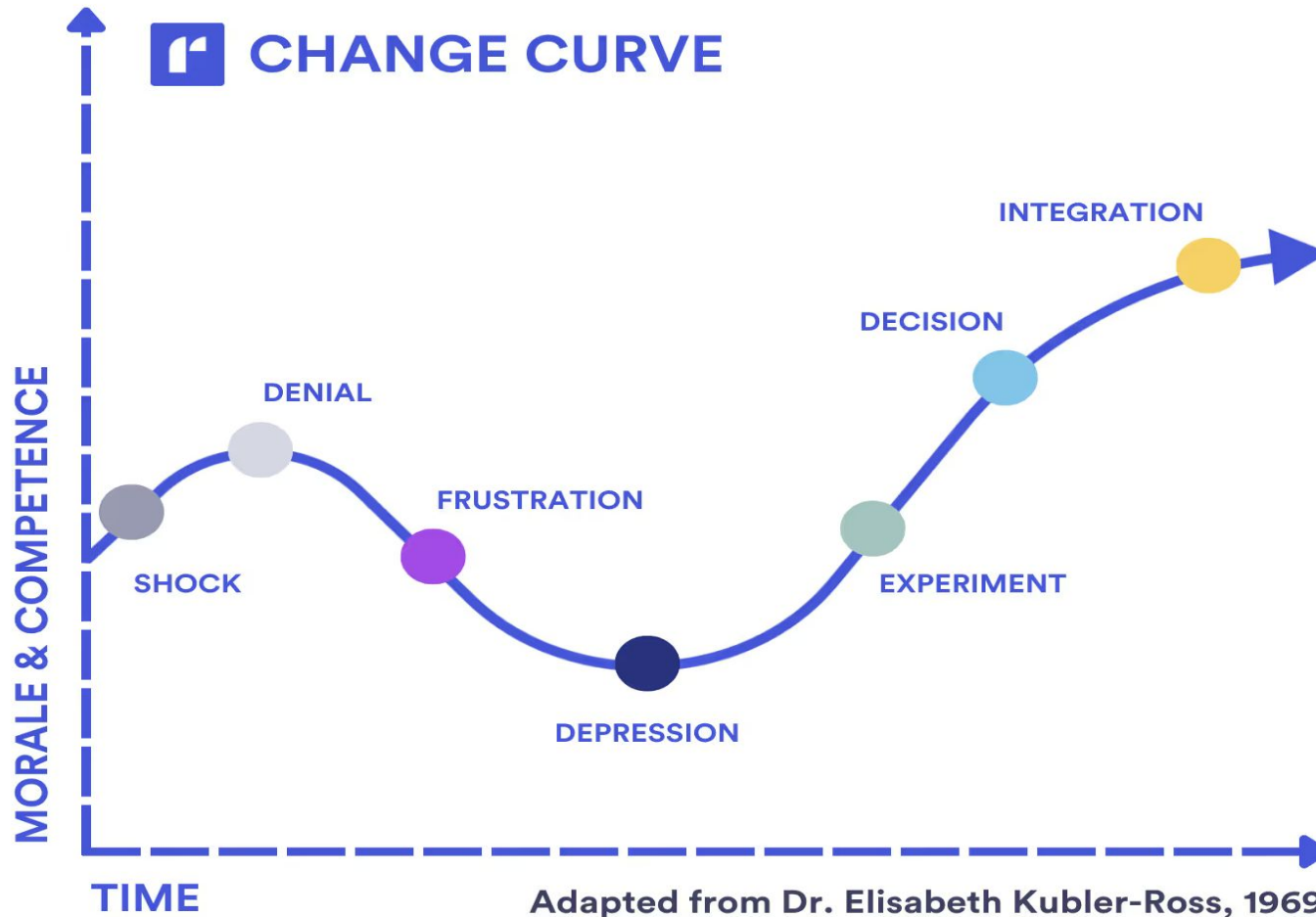
Experiment

Filled glass bottle with ice and water.

Proof

bottle broke, proving the iceberg would break as well.

Adapting to Change is Hard But **A MUST**





Our Iceberg Is Melting

A story that teaches us how to **identify** and **adapt to change**. **NOT TO OVERLOOK IT.**

*Only possible with good leadership, taking calculated risks, and communication.



Will you let your Iceberg Melt?

