# pharmaREADY USER GROUP

## Future ready regulatory operations with regulatoryREADY

**Innovation. Intelligence. Compliance.**

27 August 2026 | 10:30 – 13:00 IST

Website LinkedIn

# WELCOME TO THE pharmaREADY USER GROUP VIRTUAL MEETING

This is a **recorded event**

To ensure the best audio experience for you, **all audio lines have been muted**

If you would like to ask a question or make a comment, **please use the Q&A chat window**

The Q&A box will appear on the bottom right-hand side of the screen, and **you can type in your question or comment and click 'send'**

Questions will be answered at **the end of the call if time permits**, otherwise we will respond offline.

If you are experiencing technical difficulties, please reach out to:
support.pharmaready@navitaslifesciences.com

If you would like to get in touch, please email
support.pharmaready@navitaslifesciences.com

# AGENDA

1

## WELCOME

**10:30 – 10:40**

Opening remarks, current and future plans for Regulatory at Navitas

2

## regulatoryREADY PRODUCT ROADMAP

**10:40 – 11:00**

Product roadmap inline to meet agency mandate and futuristic AI needs

3

## CUSTOMER'S VOICE

**11:00 – 11:15**

**Dr. Pratik Vora**, Associate Executive VP at **Intas**

4

## pharmaREADY eCTD 4.0

**11:15 – 11:45**

Navitas' readiness and rollout plans for eCTD 4.0 and prototype walkthrough

5

## CUSTOMER'S VOICE

**11:45 – 12:00**

AGM – Global IT Quality at a global pharmaceutical manufacturing company

6

## OUR END-TO-END SERVICES CAPABILITIES

**12:00 – 12:15**

Explaining technology-enabled services from Navitas Life Sciences

7

## OUR AI CAPABILITIES

**12:15 – 12:30**

Regulatory intelligence and AI features in **regulatoryREADY**

8

## AI DRIVEN labelREADY

**12:30 – 12:50**

**labelREADY** PACKX powered by AOTM – benefits and solution walkthrough

# MEET THE NAVITAS LIFE SCIENCES TEAM FOR TODAY'S SESSION…

**Marty Boom**
Global Head of Regulatory and Safety

**Sivanandam B**
Senior VP – Customer Success and Business Growth

**Malli R**
Senior VP – Regulatory Affairs and Technology

**Sathish S**
VP – Product Development

**Senthil Chidambaram S**
Director – Customer Success and Business Growth

**Ganapathy Raman S**
Solution Architect

**Mohan Raj**
Associate Director – Business Analyst

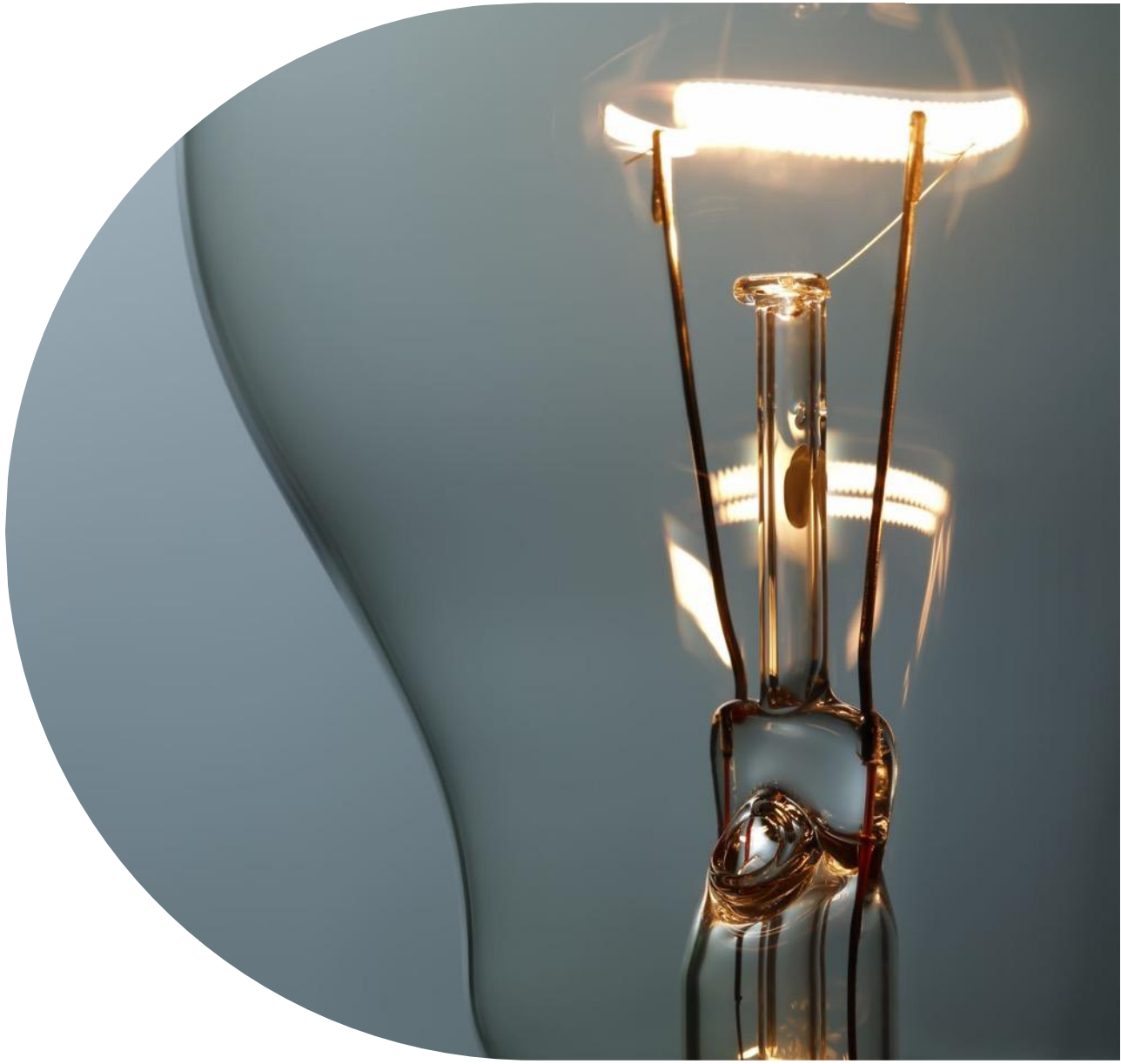
# WELCOME ADDRESS


## Marty Boom

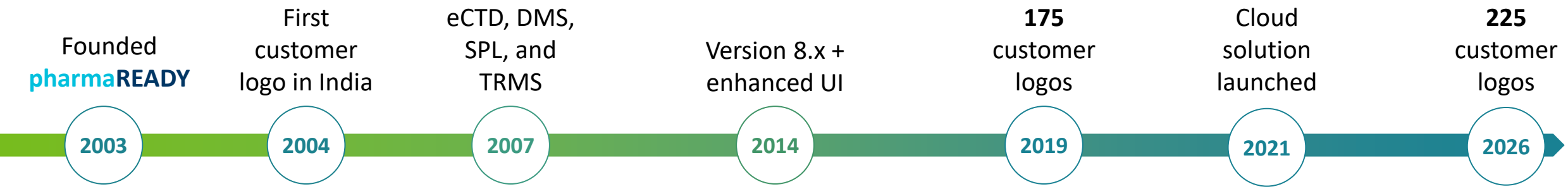
Global Head of Regulatory and Safety

Navitas Life Sciences


Website LinkedIn



# THE pharmaREADY® JOURNEY…
## KEY MILESTONES




- **14+** agency submissions
- **17,000+** users
- **1.7m** documents handled
- **2.75m** submissions
- **1.1m** SPL managed

- **24/5** support by our dedicated team, handling **~3,000** support tickets per annum

- Two decades of product evolution, customer growth, and regulatory scale

# regulatoryREADY PRODUCT ROADMAP AND FUTURISTIC AI PLANS


Sathish S

VP Product Development

Navitas Life Sciences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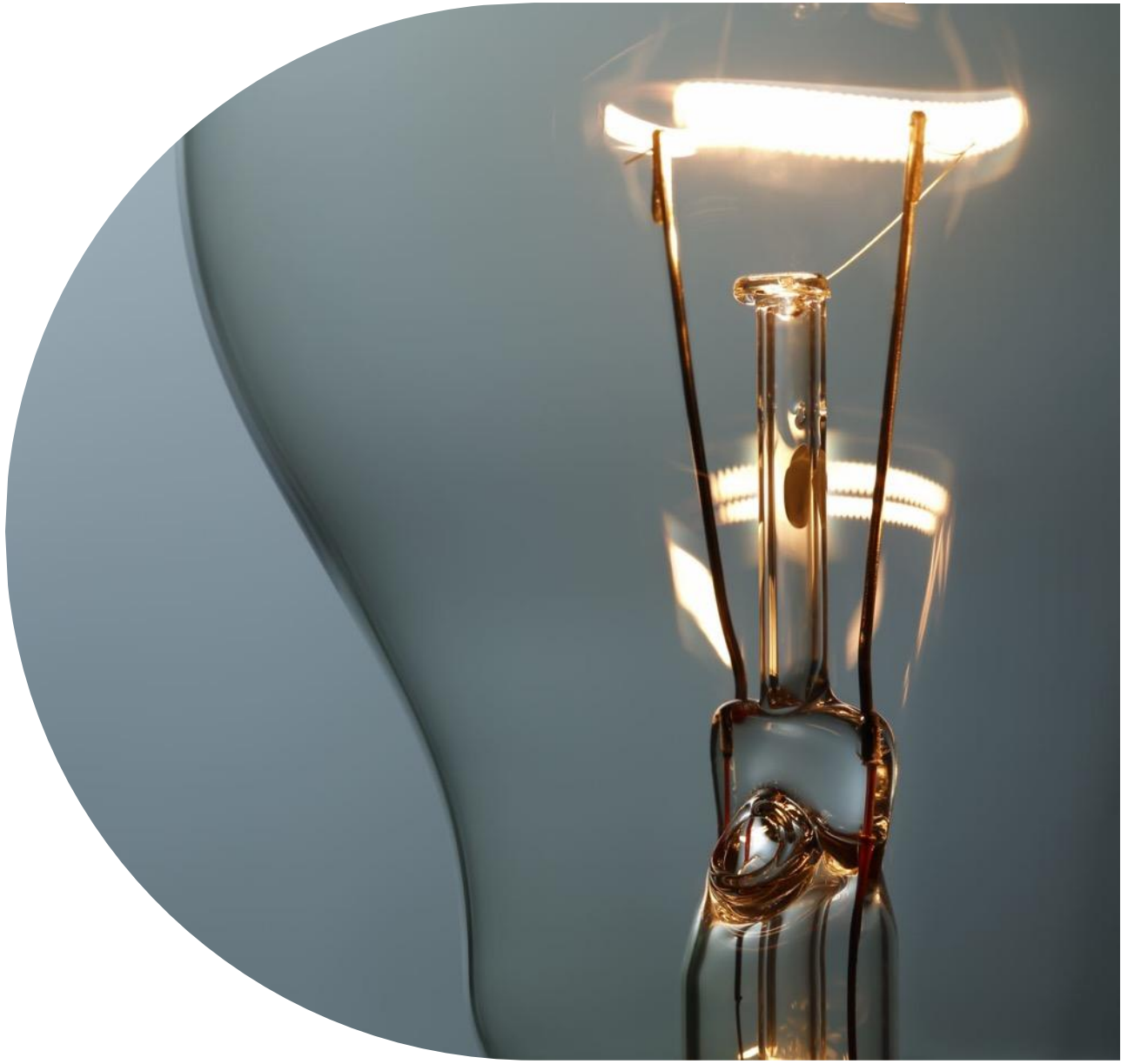
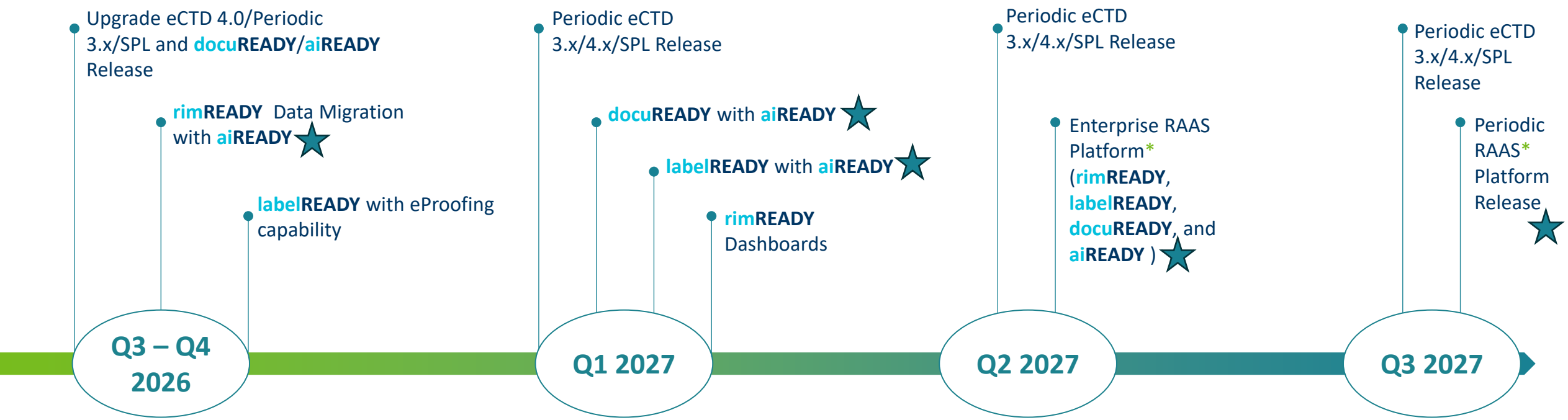


# regulatoryREADY | UPCOMING RELEASES 2026 - 2027




**Stay Compliant. Stay Ready for What's Next.**

- Meet regulatory requirements and agency mandates
- Leverage the Navitas **aiREADY** platform across key regulatory workflows
- Deploy specialized AI agents: **docuREADY**, **rimREADY**, and **labelREADY**
- Access integrated Regulatory Services and Technology through the Enterprise RAAS Platform.

*__Enterprise RAAS__: A unified SAS platform combining Regulatory Services and Technology subscriptions.

# ROADMAP RELEASE HIGHLIGHTS | TWO-QUARTER DELIVERY TIMELINE

## REGULATORY MANDATES + RIM + LABELING + ENTERPRISE DMS CAPABILITY EXPANSION

**Q4 2026**
**6** planned releases

**Q1 2027**
**5** planned releases

### Regulatory and Analytics

1. **eCTD | NMPA China specification, active documents highlights in latest view**
   DTD v1.1 + Validation Criteria v1.1
2. **eCTD/SPL | WHO PQT validation, Agency folder specific preview issue**
   Validation Criteria v1.1, compiled output, Agency-specific view capability, SPL document-type-based preview
3. **eCTD | eCTD 4.0 CAP Submissions (RPS enablement)**
   AI assisted legacy migration from eCTD 3.x to eCTD 4.x
4. **rimREADY | AI-assisted RIM solution, comprehensive packaging components**
   RIM metadata extractor, primary, secondary, tertiary and other components; product/pack/vendor/ variation links; usage reports
5. **rimREADY | Analytics and Dashboards**
   Enhanced analytics and dashboard capability
6. **labelREADY | Labeling workflow with AI capabilities and eProofing**
   End-to-End labeling workflow from CR to label implementation along with Artwork eProofing

### RIM Master Data and Life Cycle

1. **rimREADY | Fill volume data**
   SKU/pack attributes: strength, nominal volume, overfill and MA number
2. **rimREADY | RUP submission type**
   DCP/MRP/RUP fields, member states, wave, approvals and procedure dates
3. **rimREADY | API site enhancements**
   ASMF/CEP revisions, validity dates and Variation ↔ API Site relationship
4. **docuREADY | AI-assisted Enterprise DMS**
   Enterprise Level DMS along with AI capabilities on interactive search, AI assisted drafting, document comparisons
5. **eCTD | eCTD 4.0 updates**
   Priorities arrived based on agency milestones

NAVITAS LIFE SCIENCES and INTAS

# CUSTOMER VOICE

## Dr. Pratik Vora

Associate Executive VP – Regulatory Affairs

Intas Pharmaceuticals

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# Transforming Regulatory Submission Management : Our pharmaREADY eCTD Experience and Readiness for eCTD v4.0

Regulatory Affairs and Business Continuity

**Dr. Pratik Vora, Associate Executive VP**

**50+ Countries**
Global Presence

**Multi-Region**
FDA · EMA · Health Canada

**eCTD Compliant**
v3.2.2 & v4.0 Ready

August 2026

NAVITAS LIFE SCIENCES

Platform Selection

**Why pharmaREADY**

5 criteria that defined the decision to select a single integrated regulatory platform

Submissions managed on platform to date

**50K+**

INTAS

## Platform Selection Rationale

# Why Intas has chosen pharmaREADY for 20 years

*Intas needed a platform that would scale globally, integrate end-to-end, and deliver first-time-right submissions without adding headcount.*

### End-to-End Integration

Covers DMS and eCTD publishing in one unified platform — no stitching of point solutions.

### Multi-Agency Readiness

FDA, EMA, Health Canada, Swiss Medic, TGA, GCC, Tunisia and more — supported out of the box.

### First-Time-Right Design

Built-in validation engine catches errors before submissions reach the health authority — reducing rework cycles.

### Cost Efficiency

Lower total cost of ownership vs. modular point solutions; standardized processes reduce operational overhead across all markets.

### Expert Service Layer

Regulatory professionals with deep eCTD expertise support execution — not just software deployment.

# pharmaREADY eCTD — How it works for Intas

*The platform creates a structured, validated submission pipeline from document authoring through final dossier delivery to health authorities.*

INGEST ASSEMBLE VALIDATE TRACK DELIVER

1

Ingest

### Document Ingestion and Management

DMS with full version control and audit trails ensures every document is traceable and governance-ready from the outset.

2

Assemble

### Drag-and-Drop eCTD Assembly

Automated granularity and file placement logic eliminate manual structuring errors during dossier assembly.

3

Validate

### Comprehensive Validation Engine

Agency-specific rule checks run before submission leaves the organization — catching errors at source.

4

Track

### Submission Roadmap Tracking

IND, NDA, and post-approval filings monitored across the full product lifecycle — a single system of record for all agencies.

5

Deliver

### Dossier Delivery to Health Authorities

Compliant, validated dossiers delivered to US FDA, EMA, Health Canada, and other agencies via proven submission infrastructure.

**50,000+ submissions managed on the platform to date — proven reliability at enterprise scale**

US FDA EMA Health Canada + More

Workflows **Standardized** | First-Time-Right **Improved** | Lifecycle **Unified** | Audit Readiness **Enhanced** | Scalability **Operational** | Collaboration **Cross-Functional**

# Benefits and Outcomes Realized Through the Implementation

**pharmaREADY** *transformed Intas' submission operations from reactive, error-prone publishing into a governed, scalable compliance function.*

Efficiency

### Standardized Publishing Workflows

Consistent processes across all therapeutic areas and target markets, eliminating internal variation in eCTD assembly.

Compliance

### Stronger Audit Readiness

Complete document history and electronic audit trails enable confident responses to regulatory inspections.

Quality

### Improved First-Time-Right Rates

Fewer agency queries and resubmission cycles — built-in validation catches errors before dossiers reach health authorities.

Growth

### Operational Scalability

Growing submission volume managed without a proportional increase in headcount — platform absorbs complexity.

Governance

### Unified Lifecycle Management

Amendments, supplements, and labeling updates tracked in a single system of record across the full product portfolio.

Teamwork

### Successful Training with New Country addition

Easily adapts to the addition of new countries and ensures successful training and onboarding for each newly added country.

**Key Result**

*pharmaREADY enabled Intas to scale its global submission function with* **greater speed, consistency, and compliance confidence** *— establishing a foundation for eCTD v4.0 readiness.*

# Intas' Strategy and Preparedness for the eCTD v4.0 Transition

*Approaching v4.0 as a structured program — anchored in three pillars: people, process, and platform.*

## People

- Training regulatory teams on The eCTD v4.0 standard message structures and controlled vocabularies.
- Upskilling teams on new validation criteria and metadata-centric submission logic.
- Building internal expertise to reduce dependency on external publishing support over time.

## Process

- Redesigning submission governance workflows to accommodate metadata-driven document organization.
- Integrating lifecycle operators for amendments, supplements, and post-approval changes into updated SOPs.
- Forward compatibility planning for migrating existing v3.2.2 product lifecycles once agency guidance is finalized.

## Platform

- Leveraging pharmaREADY's v4.0 readiness roadmap for system upgrades and configuration.
- Participating in FDA sample submission process and EMA testing phases to validate readiness before mandatory deadlines.
- Phased rollout: prioritizing new MAAs to US and EU first, then extending to other agencies per regional deadlines.

**Program Readiness Meter** — 72% Complete

Team Training · SOP Redesign · Platform Config · FDA/EMA Testing · Full Go-Live

*Strategic intent: v4.0 transition managed as a governance program — not a reactive format change — with phased market rollout and continuous agency engagement.*

# Future Expectations from AI-driven regulatory technologies and digital transformation


*AI is moving from proof-of-concept to operational accelerator — and v4.0's structured data architecture makes AI integration substantially easier*

### Regulatory Intelligence

Real time updates on guidelines and country requirements. End-to-end workflow automation & content reuse.

### Predictive Compliance

eCTD models flagging potential deficiencies before submission, informed by historical agency feedback patterns.

### AI-Assisted Authoring

Automated generation of CTD sections, gap analysis against agency expectations, and intelligent document versioning — reducing manual authoring burden.

### Cross-Border Harmonization

Richer metadata and controlled vocabularies enable single-source submission packages adaptable to multiple agency formats.

**Intas' Expectation**

A regulatory platform that evolves continuously with AI capabilities — reducing cycle times, increasing first-time-right rates, and freeing regulatory professionals to focus on strategy rather than publishing mechanics.

Speed Quality Strategy

# pharmaREADY eCTD 4.0

## Our readiness and preparation for eCTD 4.0


Mohan Raj

Assoc. Director – Business Analyst

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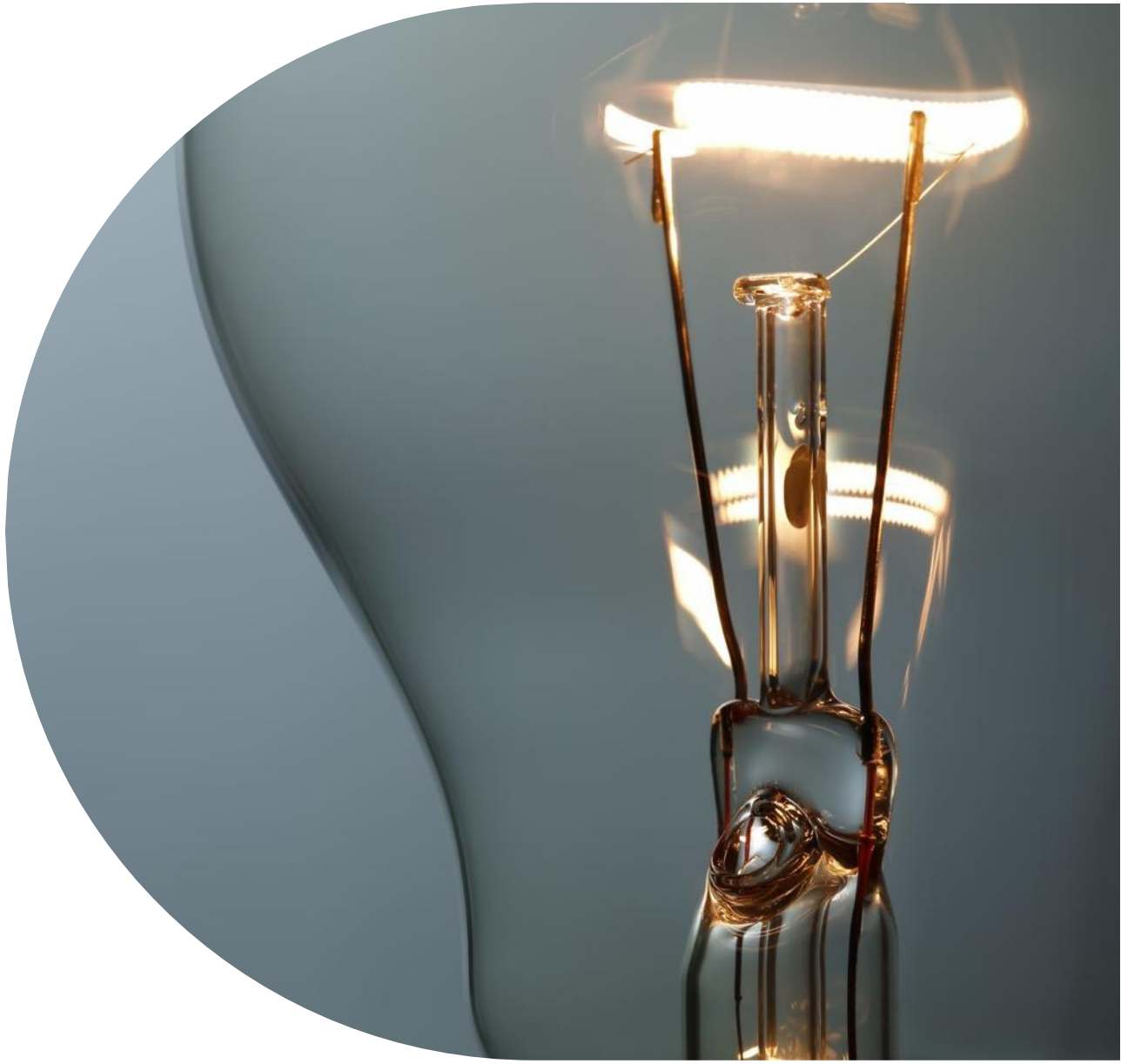


# eCTD 4.0

## CURRENT GLOBAL IMPLEMENTATION STATUS


**US FDA**
- Accepting eCTD 4.0 since September 16, 2024
- Mandatory by 2029


**EMA**
- Voluntary in 2025 (CAPs)
- Mandatory - TBC


**PDMA (Japan)**
- Voluntary since 2022
- Mandatory by 2026


**Health Canada**
- Voluntary in 2026
- Mandatory by 2028


**TGA (Australia)**
- Technical pilot in Q3, 2025
- Voluntary in 2026

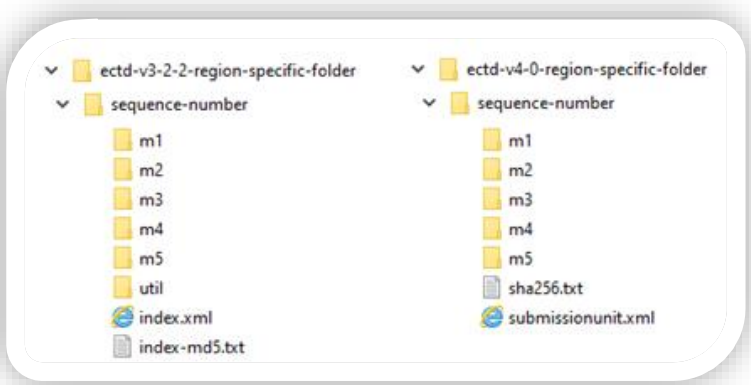
# eCTD 4.0: FROM NEW REQUIREMENTS TO NEW OPPORTUNITIES

| eCTD 4.0 CHANGE | | WHAT IT ENABLES | | BUSINESS BENEFIT |
|---|---|---|---|---|
| New XML Schema | → | More structured submission content | → | Streamlined submissions |
| Document Reuse | → | Reduced duplication and improved consistency | → | Greater efficiency |
| Controlled vocabularies | → | Standardized metadata and terminology | → | Improved data quality and compliance |
| Two-way communication | → | More dynamic interaction with agencies | → | Faster, clearer regulatory communication |
| Enhanced Life Cycle Management | → | More flexible content and document management | → | Improved submission life cycle management |
| Global Harmonization | → | Consistent approach across regions | → | Greater global consistency |

# KEY TECHNICAL CHANGES IN eCTD 4.0

## ECTD 4.0 INTRODUCES A MORE FLEXIBLE AND STREAMLINED SUBMISSION STRUCTURE

| eCTD v3.2.2 | eCTD v4.0 |
|---|---|
| **Multiple XML files**<br>• Index, Regional, and STF XMLs | **Single Submission Unit XML** |
| **Limited Life Cycle Operations**<br>• New, Append, Replace, Delete | **Enhanced Life Cycle Management**<br>• New, Suspend, Replace |
| **1:1 File Replacement**<br>• One file can replace one file | **Flexible File Management**<br>• One-to many or many-to-one |
| **Sequence Numbering**<br>• Starts at 0000 or 0001 | **Simplified Sequence Numbering**<br>• Starts at 1 |




**A simpler XML backbone with greater flexibility in how submission content is managed**

Global Pharmaceutical Manufacturing Company

# Regulatory Digital Transformation Journey

From dossier publishing to connected regulatory lifecycle management

pharmaREADY eCTD

rimREADY RIMS

August 2026

# Why we began the journey

Growing regulatory complexity required a connected and controlled digital backbone.

## Our starting point

- Regulatory information distributed across products, markets, applications and teams
- Submission publishing already supported through **pharmaREADY**
- Broader planning and lifecycle tracking required a connected platform

## What the business needed

- Structured product and application information
- Submission planning and task ownership
- Correspondence, query and commitment tracking
- Better reporting and lifecycle visibility

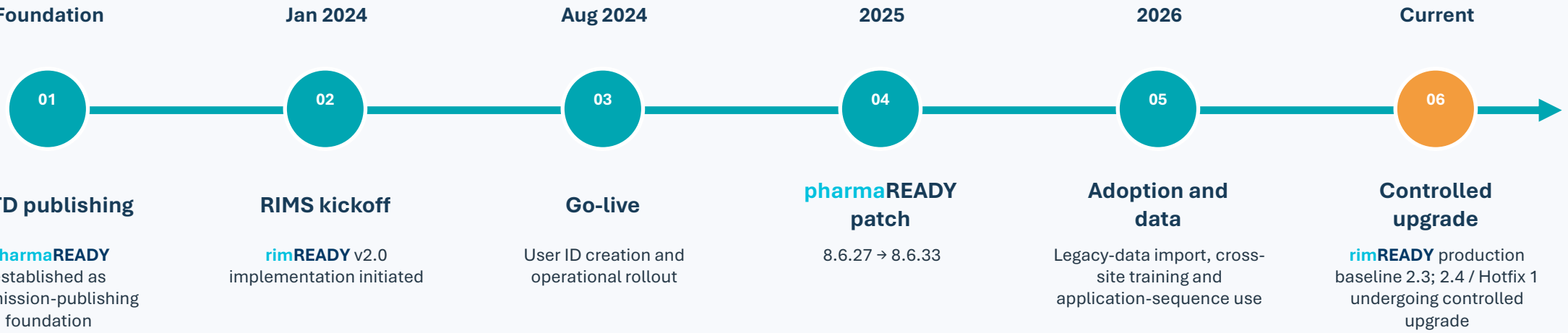
## How Piramal framed it

- Implement across Development, Validation and Production
- Integrate with **pharmaREADY** eCTD
- Validate the platform and establish controlled operations

**Our ambition was to connect information, planning, execution and submission publishing across the regulatory lifecycle.**

# Our journey and application versions

A progressive transformation managed through controlled releases and validation.




**Version statement for presentation: pharmaREADY 8.6.33 | rimREADY production baseline 2.3 | 2.4 / Hotfix 1 controlled upgrade in progress**

# One regulatory ecosystem

Information, planning, publishing and governance connected through a common operating model.

## pharmaREADY eCTD

- Submission content and sequence assembly
- eCTD publishing and validation activities
- Established publishing foundation

## rimREADY RIMS

- Product, manufacturer and application information
- Submission planning, tasks and lifecycle events
- Correspondence, queries and commitments

## Piramal governance

- Business-owned master data
- Quality IT, QeC and CSV oversight
- Dev, Val and Production controls
- Role-based access, e-signatures and audit trail

**Technology provides capability. Piramal's operating model converts capability into controlled business value.**

# Benefits realized

Observed operational outcomes, presented without unsupported numerical claims.

### Structured information base

Legacy product and application information imported into **rimREADY**, enabling structured regulatory use.

### Transition from manual tracking

Users started creating application sequences in the system; some manual activity remains during stabilization.

### Lifecycle visibility

Product, application, submission plan, task, renewal, correspondence, query and commitment information connected.

### Planning-to-publishing continuity

**rimREADY** lifecycle activities linked with the existing **pharmaREADY** eCTD publishing process.

### Control and audit readiness

Role-based access, e-signatures, audit-trail review and validated environments support controlled operation.

### Analytics foundation

Potential use cases include DMF LOA customer notifications and reporting on repeated correspondence questions.

**The shift is from document-centric execution toward information-centric lifecycle management.**

# Challenges faced and our response

The hardest work was data, workflow, validation alignment and adoption, not installation alone.

| Challenge area | What Piramal experienced | How Piramal responded |
|---|---|---|
| **Legacy data readiness** | Different source formats, duplicate or inconsistent master data | Structured templates, Development checks and controlled import batches |
| **Workflow and integration maturity** | eCTD push and user-mapping issues during end-to-end testing | Joint troubleshooting before completing publishing and gateway steps |
| **Product maturity and upgrades** | Frequent fixes, release-note gaps and compatibility dependencies | Formal addenda, impact assessment and controlled environment progression |
| **Validation-document alignment** | Retrospective revisions and detailed traceability expectations | UFRS, FRA, CS, OQ, PQ and RTM revisions through controlled review |
| **Adoption and process transition** | Training did not immediately eliminate paper and manual activities | All-site training, user guides, governance and utilisation follow-up |
| **Shared infrastructure dependency** | **pharmaREADY** and **rimREADY** downtime needed coordinated communication | Both applications included in maintenance communication and planning |

# Our implementation principles

What converted a technology deployment into a controlled transformation journey.

01

## Business ownership

Regulatory teams own information quality and process decisions.

02

## Quality IT partnership

Platform lifecycle, architecture and operational governance remain connected.

03

## Risk-based CSV

Impact assessment, traceability and test evidence focus on intended use and risk.

04

## Environment discipline

Changes progress through Development, Validation and Production controls.

05

## Cross-functional governance

Regulatory Affairs, Quality IT, QeC and CSV work as one team.

06

## Adoption by use

Usage and operational outcomes matter more than training completion alone.

**Technology establishes the platform. Trusted data, ownership and governance create sustainable value.**

# From implementation to value realization

The platform foundation is in place; the next phase is adoption, data quality and insight.

## CURRENT STATE

- pharmaREADY 8.6.33 provides the eCTD publishing foundation
- rimREADY operational with imported legacy data and trained users
- Application-sequence creation has started in the system
- 2.4 / Hotfix 1 managed through controlled upgrade and compatibility work

## NEXT HORIZON

- Complete and stabilize the controlled rimREADY upgrade
- Increase adoption and monitor utilization
- Expand reporting for correspondence, renewals and commitments
- Strengthen master-data ownership and periodic data-quality review
- Use portfolio information to support proactive decisions

**Our next phase is to convert a validated platform into a consistently adopted, insight-led regulatory operating model.**

# Thank You

Trusted regulatory information.
Controlled execution. Better lifecycle visibility.

# OUR END-TO-END REGULATORY CAPABILITIES


Malli R

Senior VP – Regulatory Affairs and Technology

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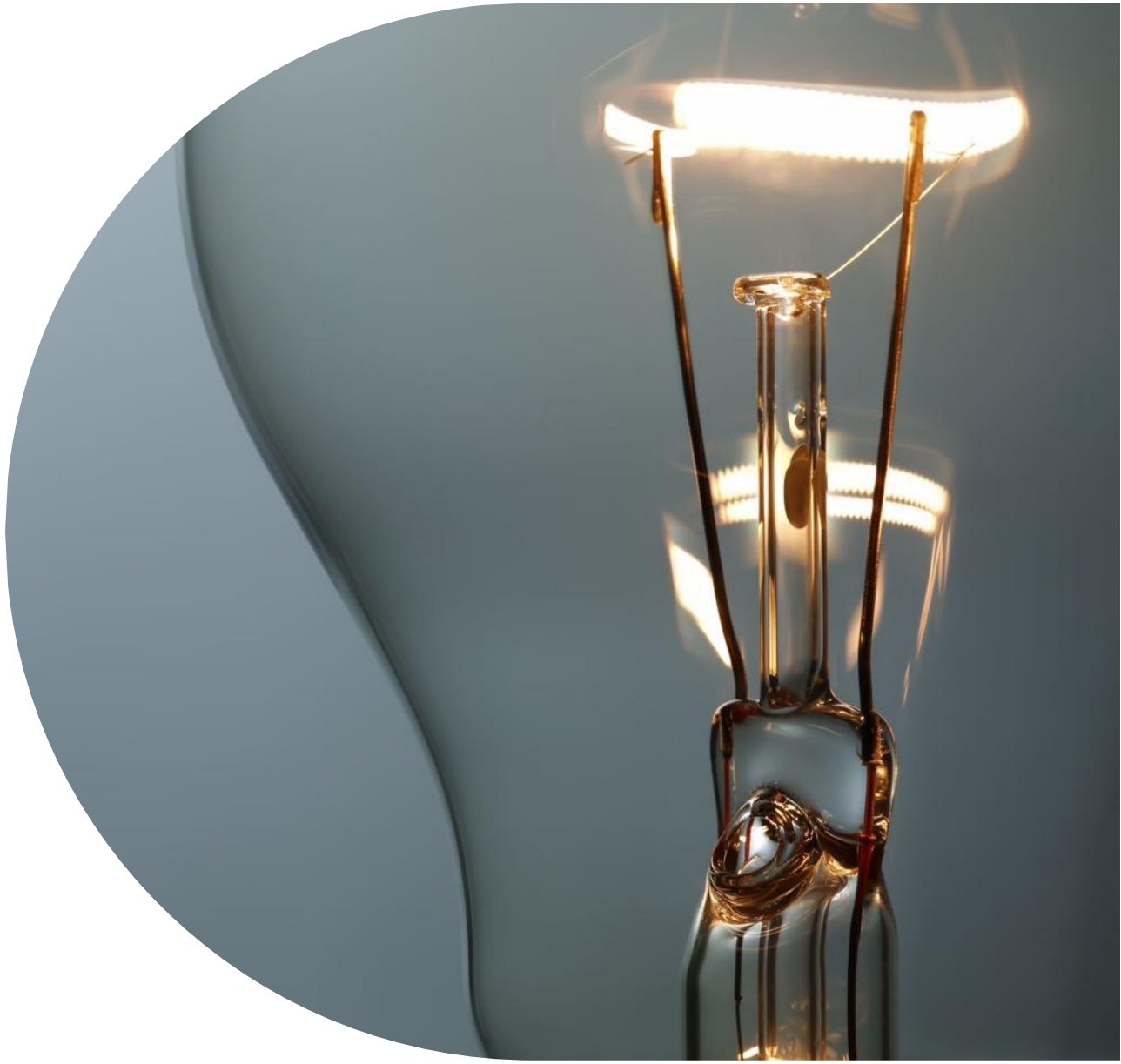


# AN END-TO-END REGULATORY SERVICES PARTNER, ACROSS THE SPECTRUM

## DEEP EXPERTISE, LATEST TECHNOLOGY, IMPECCABLE COMPLIANCE RECORD

### Regulatory Strategy and Advisory Services

Regulatory pathway identification | Approval acceleration | Global strategy and HA liaison | Process improvement and standardization, Operating Model, AI strategy, and roadmap

### Publishing and Submission Management

Submission publishing (eCTD/CTD/paper), validation | HA filing and archival

### Product Life Cycle Management

License renewal | Submission of supplements, amendments, variations (CMC, Safety, Labeling) | Annual reports

### CMC Management

CMC authoring | Gap analysis and remediation | Application maintenance | Change control management | HA responses

### Labeling Management

CCDS and labeling justification | Labeling documents and country-specific labels | Structured product labeling (SPL) | Artwork design and life cycle management

### Medical Writing and Document Management

Pre-submission publishing | Scientific advice | AdPromo | DVD creation and dispatch | Guidance documentation

### Database Management and Tracking

HA commitment tracking | Correspondence management | Dossier submission and EVMPD tracking

### RA Data Governance and Stewardship

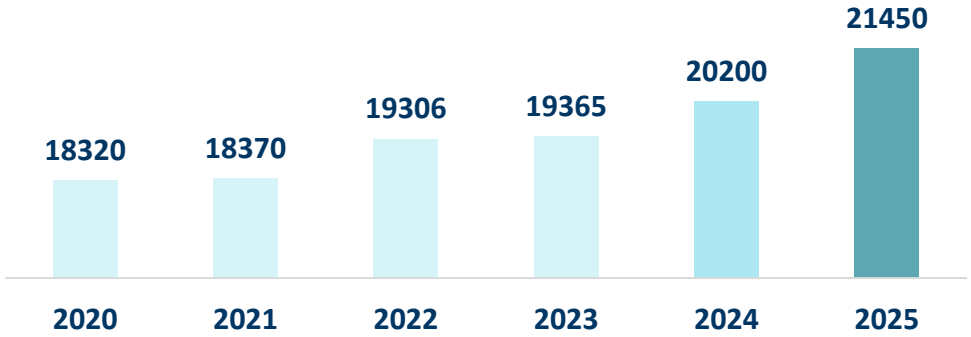
Data Governance, Management and Migration, validation, standardization, analytics, and stewardship | across all platforms

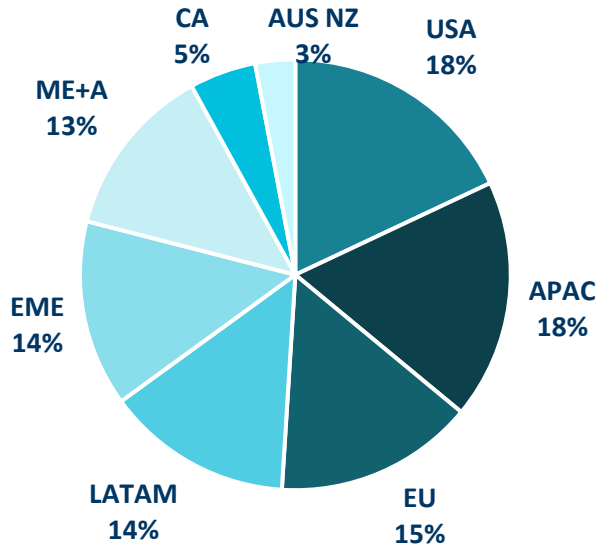
### RA Technology and Automation

regulatoryREADY® tools and Integration with Third Party Tools for workflow automation

# ABILITY TO MANAGE HIGH VOLUMES OF SUBMISSIONS
## ACROSS GEOGRAPHIES AND THERAPEUTICS AREAS

### Proven high submission volumes



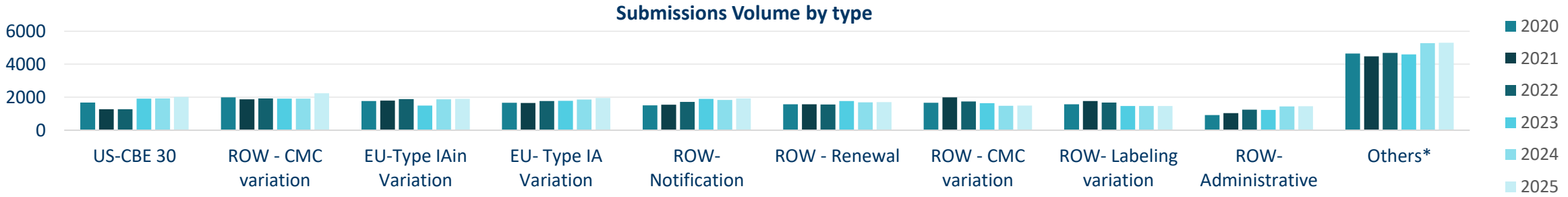




Geographic Split

### Across a range of therapeutic areas…

| Dermatology | Rheumatology | Cardiology | ENT | Gastro (GI) | Ophthal | Nephrology | OB/GYN | Infectious | Others |
|---|---|---|---|---|---|---|---|---|---|
| 14% | 12% | 11% | 10% | 8% | 8% | 8% | 8% | 6% | 15% |

### Covering all types of submissions.




**Includes: CA-CMC variation, US-CBE 0, CA-Query response, AUSNZ-Category 1, US- PAS, EU-Type IB Variation, EU-Type II Variation, Initial, AUSNZ-Category 3, US- Annual report, US – PADER, US – AdPromo, CA-Labeling and CA-Administrative.*

# AI AND GENERATIVE AI CAPABILITIES IN REGULATORY OPERATIONS

## ALREADY REAPING PRODUCTIVITY GAINS, WITH OTHERS READY TO SCALE

### DEPLOYED

**Delivering value today**

- ✓ Submission Planning + Quality Review and Predictive Analytics
- ✓ Document Classification and Metadata Extraction
- ✓ Labeling and Artwork Development + QC
- ✓ Regulatory Data Quality and Stewardship

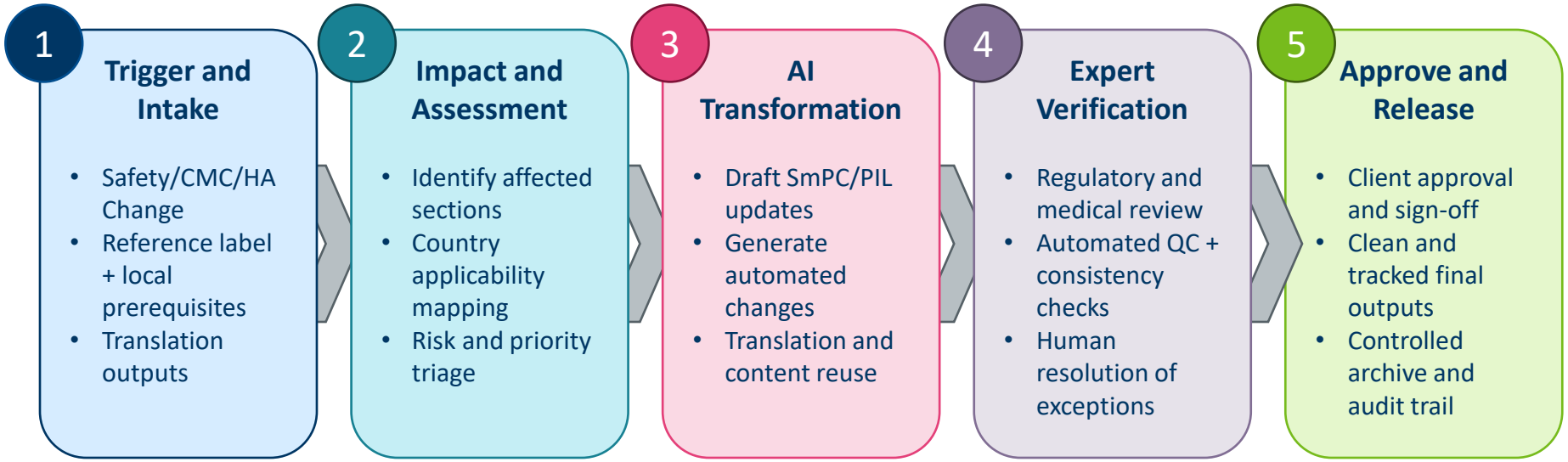
### PILOTED

**Validated for targeted use cases**

- ✓ Regulatory Intelligence and Impact Assessment
- ✓ Health Authority Query Response Support
- ✓ Content Search and Knowledge Retrieval
- ✓ Labeling Content Comparison + Translation

# AI-ASSISTED SmPC CHANGE MANAGEMENT

## ACCELERATING AND SIMPLIFYING THE MANAGEMENT OF EU COUNTRY SmPC UPDATES




**BENEFITS**

1. **Faster cycle time**
   Parallel assessment, drafting, translation, and review
2. **Right-first-time quality**
   Automated completeness and cross-document consistency checks
3. **Compliance by design**
   Country rules, approved sources, and human approval embedded
4. **Scalable delivery**
   Reusable content and standardized workflow across markets

**EFFICIENCY**

Reduced manual review and rework through reuse and automation

**QUALITY**

Consistent SmPC, PIL, artwork text, and market outputs

**SPEED**

Earlier impact visibility and parallelized execution

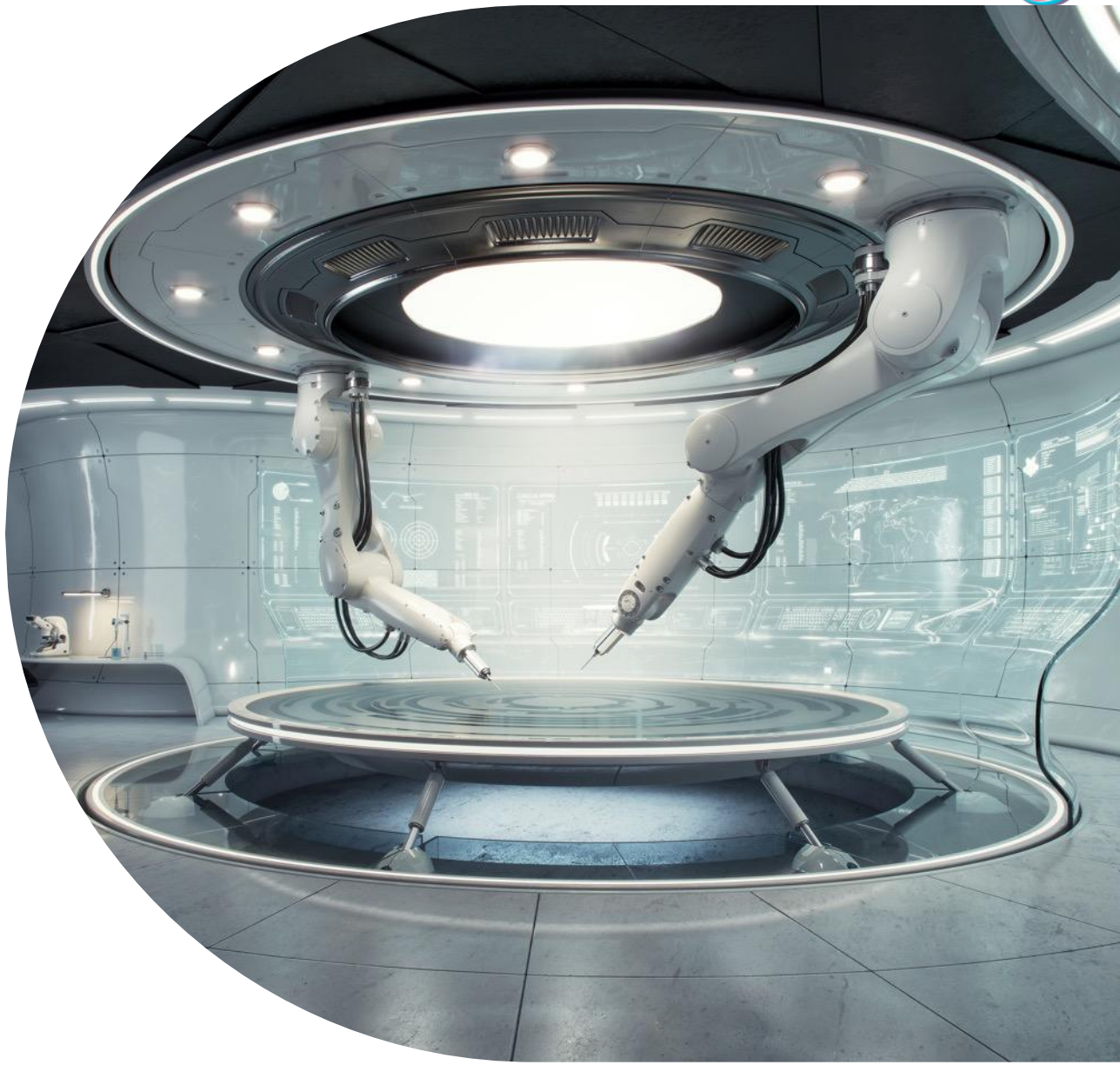
**Three AI agents. One controlled workflow. Human oversight at every critical decision point.**

# Our AI Capabilities

## Regulatory intelligence and AI features in regulatoryREADY

**Ganapathy Raman S**
Solution Architect

Website LinkedIn



# OUR AI PLATFORM: SPECIALIZED AI FOR REGULATORY WORKFLOWS

## ONE PLATFORM. FOUR AI AGENTS. MULTIPLE HIGH-VALUE USE CASES

| **Navitas Life Sciences AI Platform**<br>**AI-enabled regulatory intelligence, content, and workflow automation** | | | |
|---|---|---|---|
| **docuREADY**<br>(with **aiREADY**) | **pharmaREADY eCTD**<br>(with **aiREADY**) | **rimREADY**<br>(with **aiREADY**) | **labelREADY**<br>(with **aiREADY**) |
| • Interactive search | • Document assembly | • RIM metadata extraction | • Label comparison |
| • Document comparison | • eCTD legacy – RPS migration | • Query response patterns | • Impacted markets analysis |
| • AI-assisted drafting | • Regulatory intelligence alerts | • CR impact assessment | • Deviation analysis |
| **One AI Platform. Multiple Specialized Agents. Practical Use Cases Across the Regulatory Life Cycle.** | | | |

NAVITAS LIFE SCIENCES

# labelREADY

Powered by AOTM PACKX



## Gopal Chandra Shekar

Senior Vice President – Creative Excellence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# Traditional vs AI-Powered Process

## TRADITIONAL MANUAL PROCESS

1. Manual input validation of briefs
2. Manual/semi-automated artwork creation
3. Manual proofing & validation

### 4 – 8 HOURS per artwork

- High cost of poor quality
- Longer lead times
- Delayed product launches
- Reputational risk from errors

## AOTM PACKX – AI PROCESS

Single Agentic AI Solution

Automated end-to-end with HITL verification

21 CFR Part 11 & Annex 11 compliant

### 4 – 8 MINUTES per artwork

- Reduces cost of poor quality
- Increases efficiency by 80%
- Faster product launches
- Automated regulatory compliance

# How we solve it: right-first-time

Smart automation across the complete packaging lifecycle

## 01 Smart Briefing

- Validates inputs for accuracy
- Standardizes data for layout
- Extracts styles & fonts
- Extracts colors per brief

## 02 Artwork Automation

- Canvas preview before finalize
- Generates 2D codes
- Braille & special requirements
- PDF sent for proofing

## 03 Intelligent Proofing

- AI content & pixel proofing
- Technical validation checklist
- Regulatory content checks
- HITL for 100% compliance

## 04 Controlled Release

- Stakeholder approval process
- Patient safety assurance
- Full audit traceability
- Print-ready file delivery

GxP Compliance: Full audit traceability aligned with 21 CFR Part 11

# One platform consolidates the entire artwork tool chain

## What is currently used for creating artworks

Adobe Illustrator

Pantone swatches

Barcode applications — Agamik or equivalent

Artwork designer — equipped with laptops / desktops

Proof readers — equipped with laptops / desktops with printer connectivity

## New Gen labelREADY
**powered by AOTM PACKX**

One platform, end to end. No handoffs.

Authoring ·DSX Editor, Barcodes · Braille
Proofing · Print-ready output

labelREADY Powered by AOTM

# Features & capabilities: artwork creation & generation

**KEY DIFFERENTIATOR** **DSX Editor with Pantone Color Capability— native, online artwork editing Platform**

No reliance on third-party design tools. No waiting time, correct instantly and resend for proofing. Authoring, correction

### Barcode Generation & Validation

Generation and validation of industry-standard barcode symbologies: QR Codes, Data Matrix (ECC 200), EAN-13, EAN-8, UPC-A, UPC-E, Code 39, Code 128, GS1-128, GS1 DataMatrix, HIBC, PDF417, ITF-14, Codabar and other standard formats.

### Die Line Measurement & Validation

Verifies dimensions, clearances, bleed, safety margins, and object placement against the die line.

### AI-Generated Artwork Information Panel

Automatically extracts and displays key artwork metadata, specifications, and artwork attributes.

### Comprehensive Reports & Audit Trail

Detailed validation reports, proofing summaries, execution logs, and complete audit history.

### AI-Powered Proofing

Content, layout, and artwork comparison with detailed reports.

### Braille Generation

Supports compliant Braille generation for pharmaceutical packaging.

### Canvas Preview & Pre-Edit Workspace

Review and edit layouts before artwork generation.

**Output Generated with Editable file and also PDF/X-4 Compliant Output**

# What you get: 5X ROI, 80% efficiency gain, 100% critical-element accuracy

## 5X ROI

Return on investment across the packaging artwork lifecycle

**50%**
**Cost reduction**

**5X**
**Productivity**

**2X**
**Delivery speed**

**80%**
**Efficiency gain**

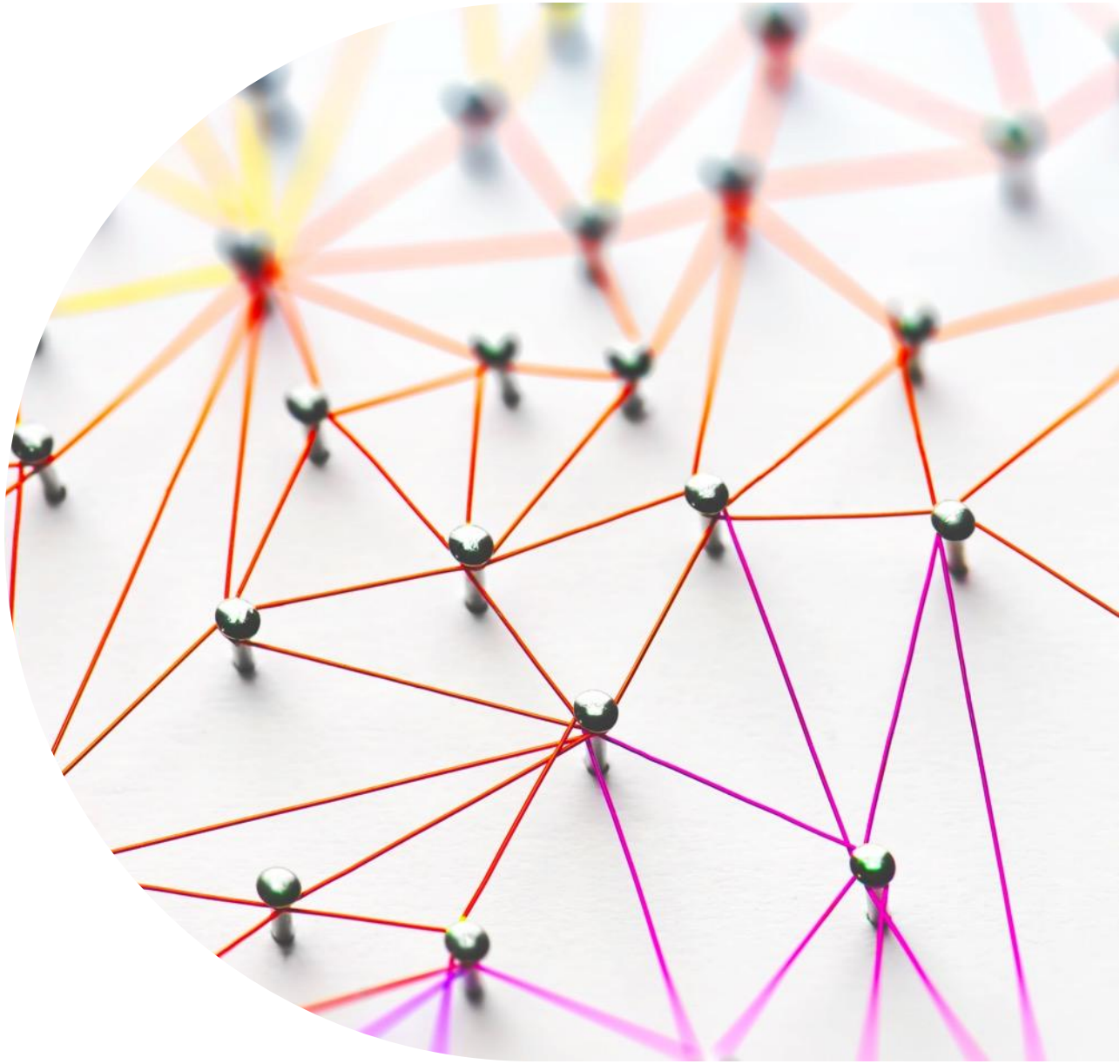
**99.99%**
**Quality**

**100%**
**Critical elements accuracy**

**> 98%**
**Non-critical elements accuracy**

# COMMUNITY PORTAL

A knowledge portal for our pharmaREADY customers



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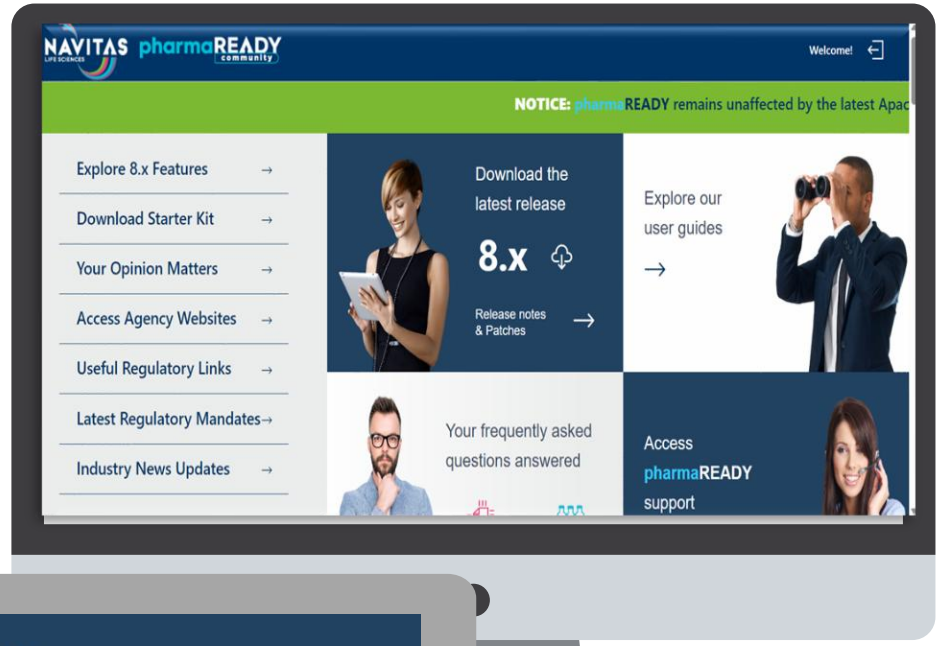
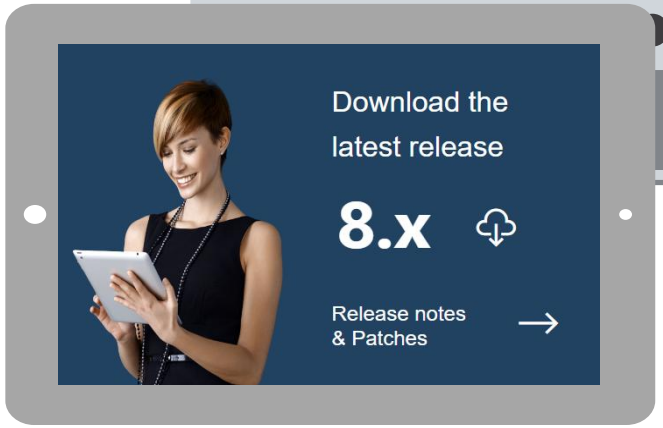
# DO YOU HAVE ACCESS TO COMMUNITY PORTAL?

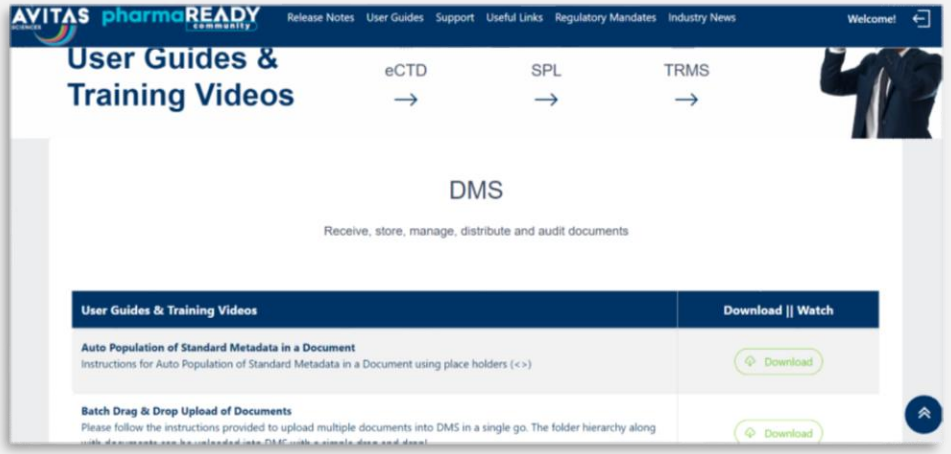
"Access to **pharmaREADY** assets" *https://community.pharmaready.com/*



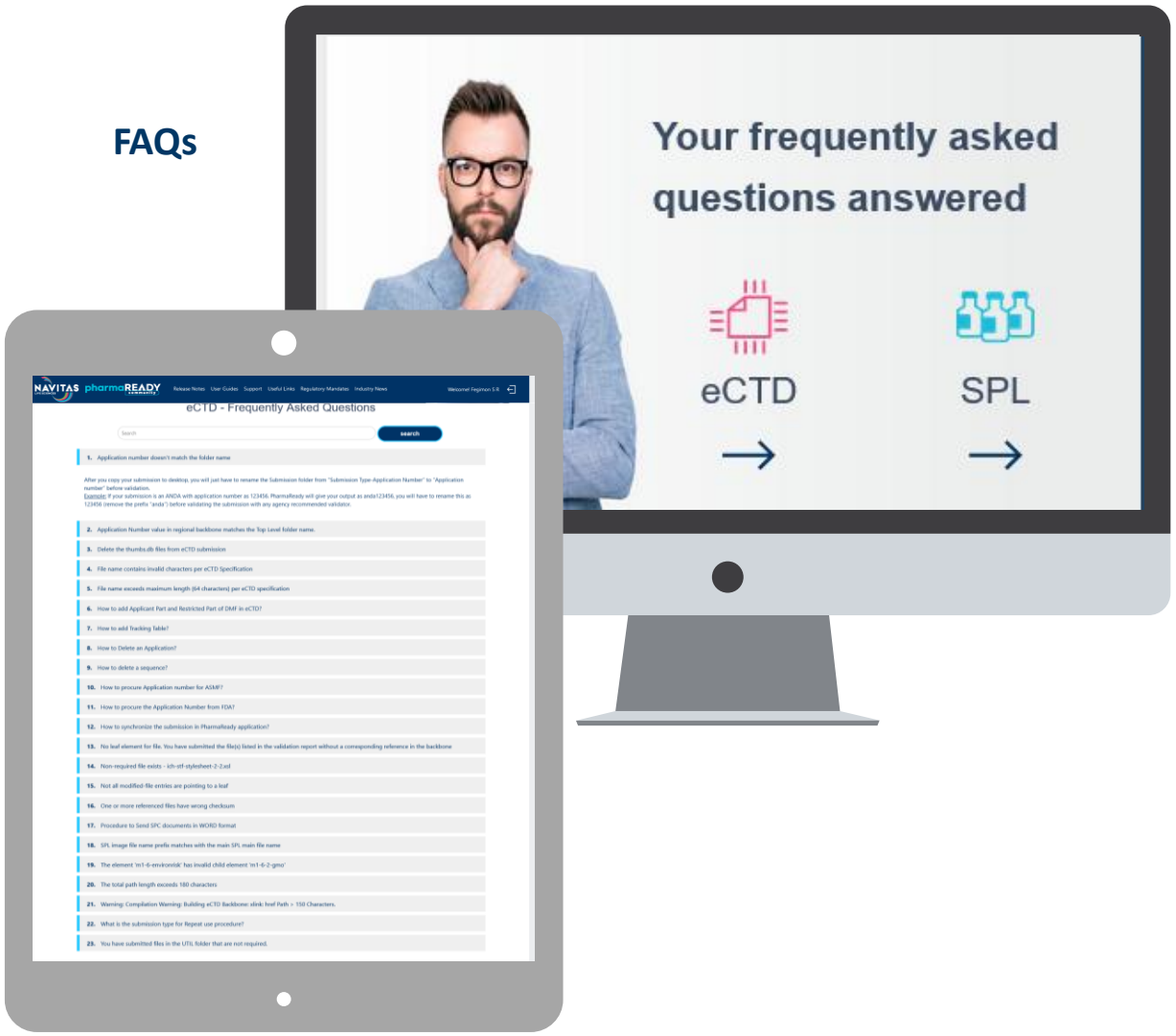

**To download the latest version and stay tuned for the latest industry updates**

**Access to user manuals and Training videos**




# DO YOU HAVE ACCESS TO COMMUNITY PORTAL?

## FAQs




## Periodic agency related updates


# Q&A

Your opportunity to ask any questions using the Q&A feature

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