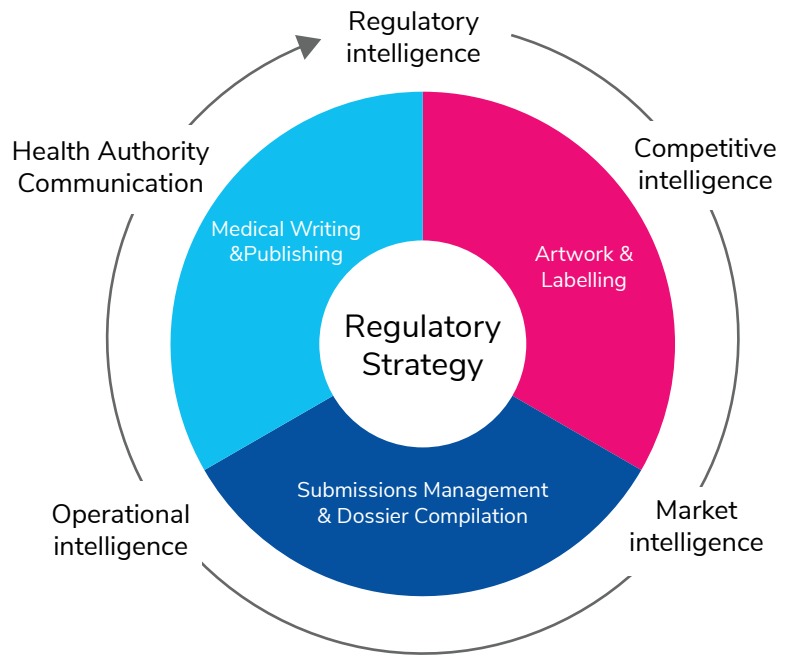# Effective Strategy and Efficient Operations in Regulatory Affairs

![indegene logo]

Achieve Predictability and Speed in Regulatory Approvals

We offer technology-led regulatory innovation and right domain expertise across the product development lifecycle, right from regulatory intelligence and planning, to content authoring, submissions, and HA feedback management, ensuring compliance in the laborious and dynamic regulatory landscape

Regulatory intelligence

Competitive intelligence

Market intelligence

Operational intelligence

Health Authority Communication

Regulatory Strategy

Medical Writing &Publishing

Artwork & Labelling

Submissions Management & Dossier Compilation

Healthcare organizations face unique challenges

- Long time to submission and delayed regulatory approvals

- Non-comprehensive intelligence across multiple markets

- Low compliance on health authority query responses

That's why Indegene Regulatory Affairs delivers

- **Effective Regulatory Strategy**
  Designed with real-time insights

- **Efficient Regulatory Submissions**
  Accelerated planning and submission pathway for first-time-right outcomes

Here's how we can help you

Bold Vision
build capabilities, culture

Accelerate
and scale up outcomes

Personalize
experience

Future Ready Healthcare

Healthcare expertise, content and conversations

NEXT

Fit-for-purpose technology

indegene

Agile operations and culture

Here's how Indegene RA Solutions work

Regulatory Strategy	e-CTD/CTD Submission Support	Artwork & Labelling
Regulatory Submissions Management	Quality & Compliance	Medical Writing

Dynamic Regulatory Intelligence / Precedence and HA Query Insights Solution

NEXT™
Regulatory intelligence

Integrated Submission Planning and Tracking Platform

NEXT™
Regulatory Submission Planning

Enterprise-level management, reusable modules, machine-assisted authoring, reviewing, publishing

NEXT™
Label Lifecycle Automation

Analytics solution to predict potential queries from health authorities and recommend possible best responses.

NEXT™
HA Query Management

Using next-generation AI platforms, we generate real-time insights from health authority interactions, market intelligence, and competitive intelligence. Our team of experienced regulatory professionals continuously evaluates those insights and embed it into designing a regulatory strategy that enhances submission/approval success for you. We integrate intelligence into the authoring of submission content as well. We help you to accelerate the planning and submission pathway for first-time-right outcomes.

Here's how its different

- **Success with Speed**
  Increase probability and speed of regulatory approvals

- **Improved Compliance**
  Reduce compliance risks with information accuracy and quality

- **Cost Efficient**
  Reduce regulatory costs significantly

Here are just a few outcomes we delivered

>80%	100%	99.7%	100%	100%	>98.6%
First time approval	Compliance	Timelines met	Client audits cleared	On-time submissions	Quality

We celebrate entrepreneurship to customize solutions

50,000+
Reg & Safety documents authored

30,000+
Submissions supported

25,000+
Labels created/updated

Through local teams, we support healthcare organizations wherever they are

About Indegene

We are a technology-led healthcare solutions provider. We combine deep industry expertise with fit-for-purpose technology in an agile and scalable operating model. Many of the leading global healthcare organizations rely on us to deliver effective and efficient clinical, medical, and commercial outcomes every day. From strategy to execution, we enable healthcare organizations be future ready.

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