

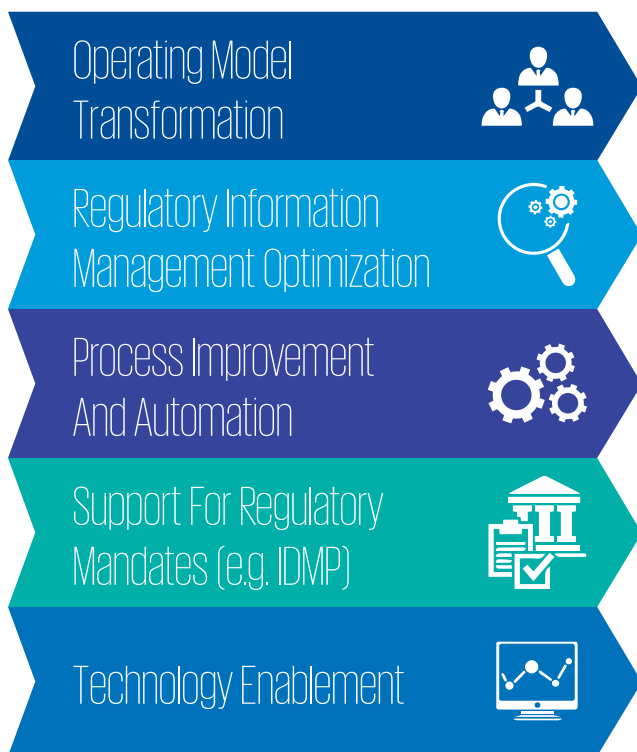


# Regulatory Operations Transformation

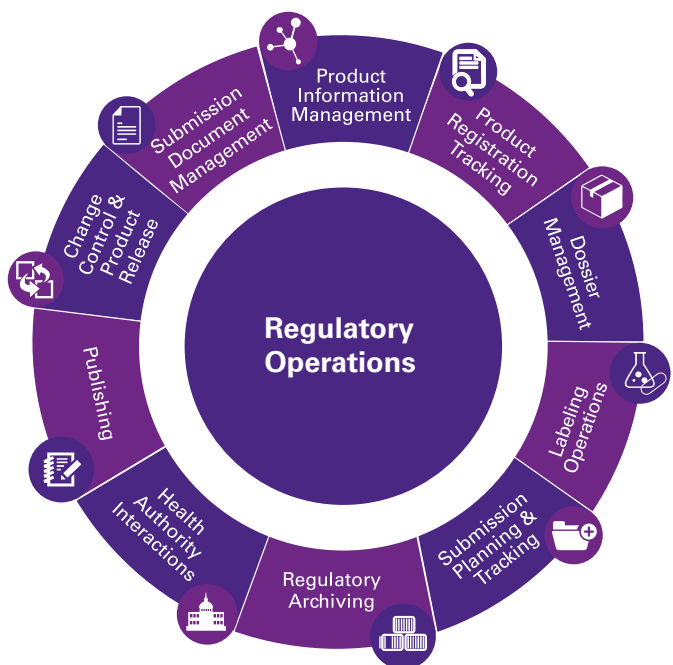
Our goal is to help our clients improve efficiency within their Regulatory Operations function by implementing process and technology changes. These transformational changes help Life Sciences companies bring products to market more quickly, while reducing compliance risk and enabling a sustainable approach to regulatory maintenance activities.

We provide a wide range of services including current state assessment, future state design, technology implementation support, data collection & harmonization, program management and change management.

## What we do



## Transformation focus areas



## What you get from KPMG



**Collaborative working style** from concept to realization of your future state vision



**A focus on total value delivered** across end-to-end operations



**Sustainability of benefits** through structural improvements and continuous knowledge transfer



**Deep industry insights** and focus on innovation

## Example client engagements

1

Supported a Top 10 Pharma with an end-to-end business transformation of its Regulatory Affairs organization

- Helped design and implement target operating models for both proprietary and established products
- Completed detailed cost and headcount modeling
- Provided ongoing support for rollout of new organization
- Led effort to define RA system transformation roadmap

2

Supported a Fortune 500 Life Sciences company with implementation of a global Registration Management solution

- Facilitated RFP and vendor selection process
- Designed target operating model
- Led configuration workshops
- Gathered, cleansed and uploaded data from each region to support global rollout of registration module (both Pharma and Med Device products)
- In parallel, completed a diagnostic of existing data sources for IDMP and created IDMP roadmap

3

Helped lead a global technology-focused RIM transformation program for a Top 10 Pharma company

- Provided Program and Project Management across several workstreams
- Provided Change Management and Communications
- Helped facilitate key process and technology decisions
- Provided independent oversight over program

## Contact us



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