



Regulatory Affairs Target Operating Model

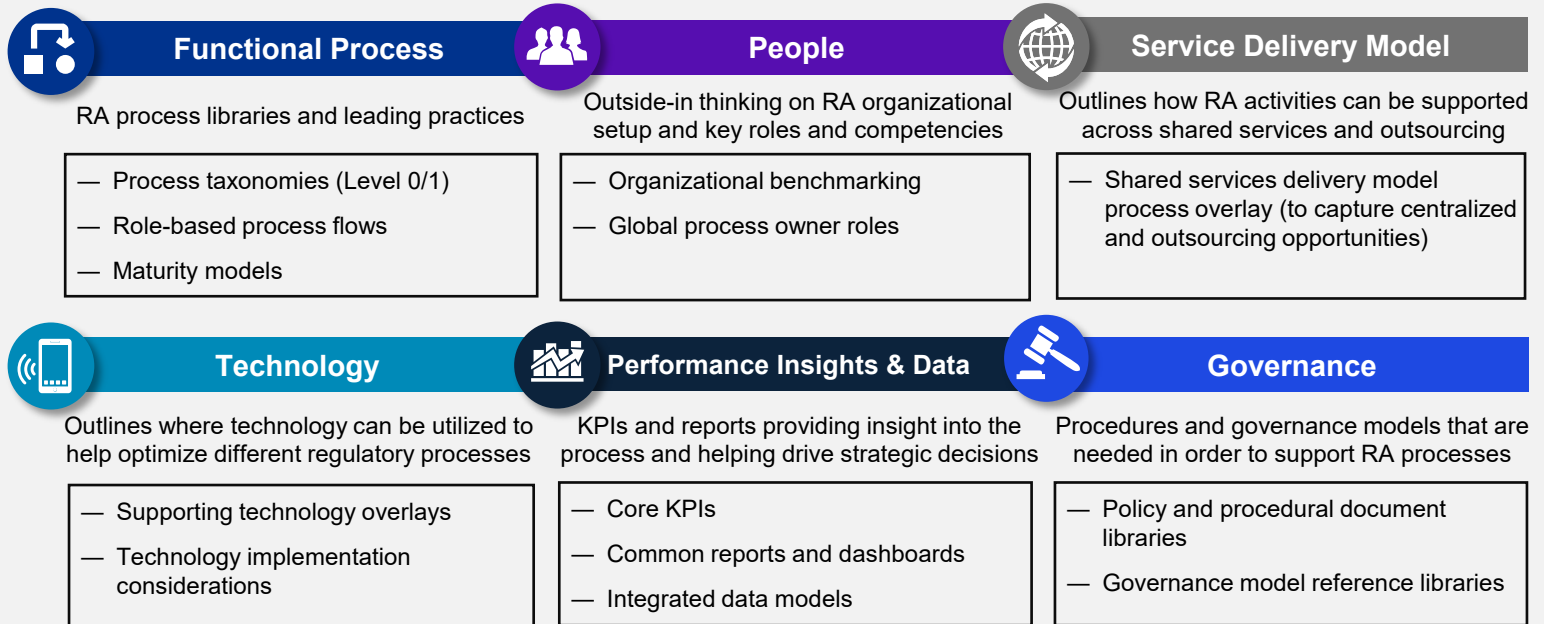
Driving value in your Global Regulatory Affairs organization – through a structured approach across six design layers

Challenges Designing an Effective Operating Model

In the Life Sciences industry, it is becoming increasingly important that Regulatory Affairs operating models are flexible and efficient in order to meet demand and reduce overall cost, while also enabling the function to provide strategic inputs across the R&D value chain. Often companies design functional transformation programs in an attempt to help optimize their regulatory operating model, but many face challenges in realizing the intended business outcomes.

A Blueprint for Rapid and Sustainable Transformation

The Regulatory Affairs Target Operating Model toolkit offers a structured approach to generate a succinct understanding of each organizational component and a methodology to achieve leading practices. The toolkit helps shape your business transformation and maps out practical ways to achieve lasting value from your strategic investments. The toolkit has the following modules:



Potential Benefits of KPMG Target Operating Model

- ✓ Identify and address problem areas quickly and efficiently
- ✓ Prioritize and sequence implementation opportunities with defined frameworks
- ✓ Align the impact of business change through different design layers

Example client engagements – Regulatory Affairs operating model transformation

1

Designed an optimized Regulatory Affairs resourcing model

- Assessed the global regulatory affairs resourcing model to evaluate opportunities for change
- Designed a business case, impact assessment, and implementation plan for each prioritized opportunity area
- Further built out future state impacts across people, process, and technology

2

Developed a target state Regulatory Affairs operating model

- Delivered analysis defining the current state operating model with summary of key takeaways and improvement opportunities identified
- Developed a target state operating model that centralized and standardized processes across the RA organization, removing inconsistent service models and siloed activities

3

Completed Global Regulatory Affairs function and process assessment

- Evaluated organizational and financial baseline of current models and IT system maturity
- Designed detailed organization structure including organizational charts, initial sizing/cost models and RACIs that incorporated feedback from client
- Developed roadmap for implementation of preferred changes

4

Led operating model assessment and design for the Regulatory Affairs function

- Developed high level process mapping (Level 0 and Level 1) for E2E global regulatory processes
- Completed process diagnostics for prioritized processes to capture the current state and identify opportunities to leverage automation and advanced technologies
- Synthesized and prioritized opportunities for improvement in a high level roadmap

Why KPMG

Extensive experience on complex projects

We have an established approach for adding value and can provide client references upon request

Highly trained team members

Our team has a mix of industry and consulting experience that we bring to our client engagements

Regulatory Affairs comparators and accelerators

We have a tailored target operating model and methodology specific to Life Sciences Regulatory Affairs

We bring a combination of business and technical expertise

We can help you solve a wide variety of challenges, and can support large, global companies

Contact Us



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