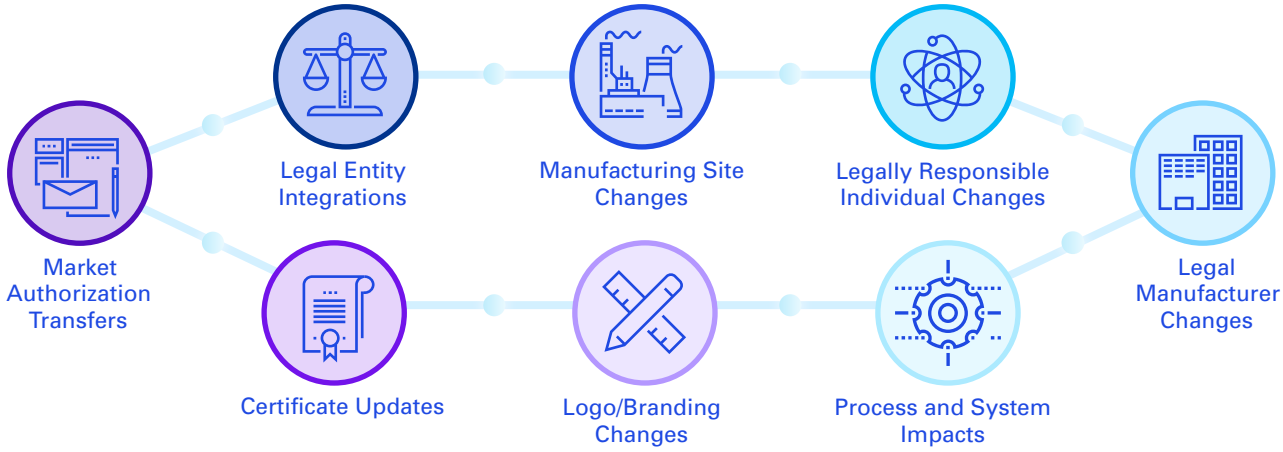
Driving regulatory success in Life Sciences M&A

Services for Life Sciences Companies

We help Life Sciences companies enable uninterrupted continued market access globally during mergers, acquisitions and divestures.

We also help develop and executive regulatory strategies to maintain appropriate product licenses with health authorities globally during and after the M&A transactions.

Regulatory is impacted by many cross-functional changes resulting from M&A



Due Diligence

- Assessment of submission documentation for compliance with global regulations
- Evaluation of global product submission status to marketed inventory

Regulatory Planning

- Developing and conducting regulatory assessments
- Analyzing regulatory assessments to create supply continuity strategy
- Gaining cross-functional alignment on supply continuity strategy

Submission Execution

- Coordinating the creation of submission dossiers
- Supporting the creation of submission documents
- Tracking & communicating submission and approval status

Manufacturing Cutover

- Reviewing and updating documentation for M&A related changes (e.g., invoices, CoA, etc.)
- Identifying any stock build requirements to support individual markets
- Coordinating artwork review, change requests, translations and mock-up creation

Regulatory M&A – example client engagements

Supported a large divestiture of a global medical device and pharmaceutical company

- Performed impact analysis to identify country level submission and label change requirements
- Prepared regulatory and labeling implementation strategy with cross-functional alignment
- Supported creation of regulatory submission documents by market

Facilitated a carve-out of a top medical device manufacturer

- Analyzed the carve-out related changes (i.e. legal entity, branding, manufacturing sites) to determine the product labeling changes and regulatory submissions required
- Prepared detailed roadmaps and execution planning documents for the entire carve-out process

Led the separation of a leading diagnostics company

- Developed the product registration, labeling change, and ISO certification strategy for the separation of a leading IVD organization
- Organized and supported 'Day 1' readiness assessment process

Helped the acquisition of a medical and surgical product manufacturer for a global life sciences company

- Conducted a regulatory impact analysis to identify potential health authority submission requirements
- Developed regulatory strategies for 50+ markets to complete product registration transfers and updates
- Tracked overall progress and milestones related to regulatory submission preparation and approvals

Why KPMG?

We have extensive experience

Our teams have worked with clients across the life sciences industry, which means we bring deep experience and the 'so what' to each project

Tested approach and toolkits

Based on our experience we have developed toolkits and playbooks that accelerate our onboarding and enable us to drive impact immediately

Ability to scale

Our network of global professionals have the ability to quickly onboard to support fast moving acquisitions and divestitures

Contact us:

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