

Supporting a Global Indication Launch for a Biotech

The client is an international biotech company that focuses on the discovery, development, and commercialization of RNA interference therapeutics for genetically defined diseases. The company was planning for health authority approvals globally for one of their existing drugs for a new indication for a disease that is estimated to be a multi-billion-dollar market.

Since this was an international rollout with immense financial implications and leadership pressure, the client needed dedicated, centralized program leadership to ensure the launches were on time and successful. To do this, the biotech client engaged Clarkston Consulting to manage all packaging and labeling activities for the new indication launches across all planned markets.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY



Biotech

PRODUCTS AND SERVICES



RNA interference therapeutics for genetically defined diseases

PRIMARY OBJECTIVES

- Identify and align on the shortest possible packaging and labeling timelines, both internally and with contract manufacturers, to accelerate time to market while still maintaining a high level of confidence for success
- Ensure alignment across all cross-functional team members (*i.e., quality, packaging engineering, external manufacturing, artwork, regulatory, planning, etc.*)
- Successfully launch packs on time with new indication to 14 markets and distribute to 3PLs

RESOLUTION

- Conducted multiple workshops to align on the shortest possible project timeline
- Facilitated contingency planning sessions based on various risks, such as delayed health authority approvals, contract manufacturer mishaps, etc., and created backup plans
- Created and maintained 14 detailed project plans and three dashboard views for team and leadership that tracked all upcoming and overdue activities
- Developed and maintained a RAID log to record open items and important decisions and risks
- Facilitated weekly project meetings of 20+ stakeholders across five departments to ensure all project activities stayed on track
- Due to the critical nature of the project, initially provided bi-weekly executive updates to VPs, monthly updates to the Steering Committee, and periodic slide deck updates to Operations and Quality leadership to keep everyone informed and escalate blockers and risks where needed

KEY BENEFITS

- Successfully launched the new indication into 14 markets on time
- Improved pack and label's cross-functional ways of working, as stakeholders were more aware of how their activities fit into the bigger picture, allowed for more open lines of communication, and improved relationships with their contract manufacturers due to the increased structure
- Packaging plans, templates, meeting style, and governance structure can be leveraged for future lifecycle management changes and project management activities



KPIs

- Successfully launched new indication on time with an accelerated timeline in all planned markets for 2025
- Developed 14 project plans, 1 RAID log, and 3 dashboards to ensure project readiness
- Collaborated with contract manufacturer via 10 joint working sessions, weekly meetings with cross-functional working team, bi-weekly with supply chain and manufacturing VPs (for first 6 months), and monthly with Steering Committee

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