

# Offshoring of Lifecycle Management Operations

*This case study illustrates the offshoring of a portfolio of globally registered, well-established and highly active biological products from the headquarters to a service center in another country.*

## Scenario

Pharmaceutical companies face escalating operational costs annually, especially those focused on innovation. This financial pressure is compounded by the need to boost R&D budgets while managing reduced revenues due to patent expirations. To maintain competitiveness, companies must optimize their operational expenses. Offshoring has emerged as an effective strategy to achieve this.

In response, a multinational pharmaceutical company decided to restructure its Regulatory Affairs department by offshoring lifecycle management (LCM) operations. This move aimed to free up essential resources within the company. LCM was identified as the first operation to offshore due to its well-defined and established processes.

SEQOVA provided comprehensive support to ensure the success of the offshoring initiative, collaborating with the teams from strategizing to execution.

## The strategies deployed for the project:



## Planning & Execution

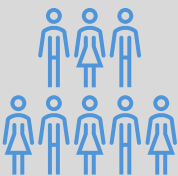
*Following the defined strategies, SEQOVA collaborated closely with the team. An organizational analysis was conducted to establish the governing processes and risk mitigation plan, incorporating appropriate Key Performance Indicators (KPIs) and service level expectations. This ensured a structured and measurable approach to the offshoring initiative.*

### COUNTRY / SERVICE HUB IDENTIFICATION



- Low labor cost
- Availability of ample resources with required skill set and experience
- Easy access to the talent pool
- Known location as service hub

### TEAM ESTABLISHMENT



- Number of resources analyzed
- Skill set and experience defined
- Effective team structure analyzed
- Onboarding process structured
- Recruitment initiated

### PRODUCTS / PROCESS TRANSFER



- Robust training plan and training materials prepared
- Training conducted and completed in 45 days
- Face to face and virtual meetings were conducted with the key stakeholders to introduce the new teams
- Roles and responsibilities and task flow document were prepared and circulated
- Effective communication channel was defined for the smooth communication with the internal and external teams
- Transition date was decided and announced to the organization

### OPERATIONS FROM NEW COUNTRY / SERVICE HUB



- Extensive support was provided for the first 3 months by the existing EU team
- After 3 months support was reduced to only in the event of critical scenarios
- After a year the team became completely independent handling the LCM operations successfully
- Process flows were developed to handle the tasks & health authority requests effectively
- Effective communication channel was defined for the smooth communication with the internal and external teams

### CLOSE OBSERVATION



- Close monitoring by the manager to support and guide the team
- Different trackers were developed for task allocation and to track the status
- Established a feedback mechanism to share the feedback received from stakeholders and to support the team to perform better
- Maintained an issue log sheet to list the issues and to address them with proper CAPA

### TRACKING OF DELIVERABLES



- Conducted weekly review of project tracker to ensure on-time delivery of the allocated task
- Conducted biweekly meetings with stakeholders to identify the issues at the early stages to address it timely
- Conducted monthly business review meetings to ensure the smooth running of LCM operations from the new hub
- Special focus on key submissions to ensure LCM compliance

## Risk Mitigation Plan

A well-crafted risk mitigation plan is essential to ensure a smooth transition and successfully managing the LCM operations from the new hub. By setting the right expectations for all stakeholders, this plan addresses potential challenges and provides strategies to manage them effectively. SEQOVA's team, with its extensive expertise and experience, played a crucial role in developing and implementing this plan, thereby facilitating a seamless offshoring process.

---

## Challenges

- Having the new team to adapt to the transferred process and products
- Developing the working relationship with the stakeholders to gain the trust and confidence, especially with the key and difficult stakeholders
- Understanding the different processes, units & stakeholders
- Maintaining an effective communication channel
- Ensuring team collaboration
- Maintaining the motivation levels of the team
- Retaining the talents

## Mitigation

- Supporting mechanism established to support both the existing and new team to adapt to the transition process
- Established regular meetings and workshops with stakeholders to discuss and align on the project progress and identify risks in advance
- Scheduled trainings, knowledge / trend sharing sessions, and touch points
- Maintain issue log to record both the manual and system related issues. Schedule recap learning sessions to learn from mistakes
- Establish robust reward and recognition program to appreciate the team and keep the motivation levels

---

## Outcome

Thanks to the collaborative efforts of various stakeholders, a successful outcome was achieved. While some resistance was encountered as expected, it was effectively managed. The structured approach and thorough planning ensured the offshoring initiative met its objectives.



### Objectives Met

Major milestones objectives were achieved that allows for solidification of confidence. As for missed milestones objectives, review and revise sessions were set in place to ensure the appropriate measures are taken.



### Large & Right Talent Pool Accessed

The new service hub proved to have an abundance of the right talent pool needed. With an average of 2 - 4 months from recruitment to joining date, depending on the seniority level.





### **Resource & Operations Cost Optimized**

During the initial and transition phase, resource and operation cost increased as anticipated. After Year 1, the budgeted optimization was met.



### **Business Operations Continuity Established**

With the new team in place, it has met one of the Business Continuity Plan observations.



### **Business Footprint Expanded to Another Country**

With the footprint established, other processes are being evaluated for offshoring.



**SEQOVA**  
WHERE INNOVATION BEGINS

[team@seqova.com](mailto:team@seqova.com)

Czechia. France. USA. India. China