Benefits of an accelerated network integration for the management of a high demand, multimodal molecule

Using our KojoX[™] operating philosophy our partners benefit from our modular manufacturing approach, maximizing operations and design through:

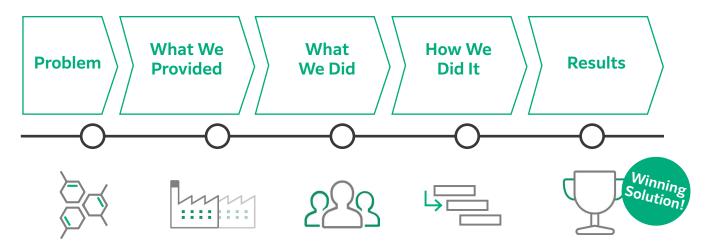
 Alignment across scales and technologies providing fast scalability and de-risking the supply chain

• Expedited regulatory approval fueled by broad experience supporting the entire product life cycle

• Supply chain agility, redundancy, and scalability with Tech Transfers across our integrated network

FUJ^I**FILM**

Diesynth



High-Volume Molecule

FUJIFILM Diosynth Biotechnologies' partner has a highvolume, complex, multi-modal molecule.

Partner wants to secure supply continuity with a well-defined BLA submission timeline.

Network Solution

FUJIFILM Diosynth Biotechnologies offered either a single-site or a multi-site network solution to fulfill the partner's needs for supply continuity and access to extensive regulatory pathway experience.

Program Diligence Team

FUJIFILM Diosynth Biotechnologies and the partner formed a team to conduct a due diligence sprint. The goal was to evaluate the feasibility of a single-site versus a multi-site network approach and to develop actionable project plans.

Together, the companies developed a fast-track plan to validate multiple processes. This plan includes method validation, process characterization, PPQ preparation, execution of PPQ campaigns (both manufacturing and release), validation report generation, and regulatory support for BLA submission.

Outputs

The program diligence team created the following:

- Detailed milestones and sub-tasks from current state through BLA submission
- Aligned validation strategy
- Mitigation plans to identify risks
- Single-site versus multi-site network approach comparison
- Analysis of additional process development/ optimization requirements
- Program governance model
- Executive summary highlighting benefits versus risks for decision-making purposes

multi-site network including the commercial supply solution.

The partner agreed

FUJIFILM Diosynth

to proceed with

Biotechnologies'

recommended

Outcome



Partners for Life