

From Lab to Launch - Faster

Access Accelerated Process Performance Qualification (PPQ) at FUJIFILM Biotechnologies

FUJIFILM Biotechnologies supports partners to create control strategies that last the life-cycle of their molecules. Our teams work with partners to find optimal solutions to accelerate time to market.



Problem:

A biopharma partner with an orphan therapy faced a need to perform PPQ on compressed timelines of a potent molecule expressed in *E. coli*. This encompassed accelerated tech transfer, validation of analytical methods and extensive process characterization coupled with a need to reconfigure the manufacturing suite and install bespoke processing equipment.

Solution:

FUJIFILM Biotechnologies orchestrated a streamlined PPQ-to-submission roadmap that included:

Network Expertise

A team composed of process development, manufacturing, quality, regulatory, CMC and engineering experts spanning our global network was deployed.

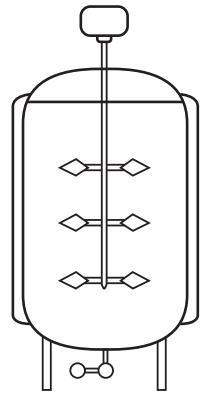
Supply Chain Considerations

Procured atypical, process specific and single source critical materials suitable for cGMP, by leveraging FUJIFILM Biotechnologies' global presence to expedite critical materials orders at competitive prices.

Flexibility to Partner's Needs

E. coli manufacturing operations were configured to include single-use assemblies for down-stream processing.

FUJIFILM Biotechnologies procured custom-made long lead chromatography equipment to derisk delivery of partner's therapy demands.



Impact:

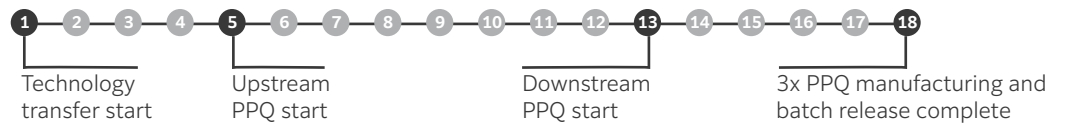
Rapid transfer into FUJIFILM Biotechnologies and success in accelerated PPQ



18 months from technology transfer start date to 3 x PPQ complete



Ability to operate at speed was a function of high compliance manufacturing (an average 2 deviations per batch were raised during the entire PPQ campaign)



Partners for *Life*

"Partners for Life" represents a transformative approach to development and manufacturing, emphasizing relationships founded on trust and transparency — founded in people-centric values, transformative science and innovation, and unprecedented delivery.

FUJIFILM Biotechnologies
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