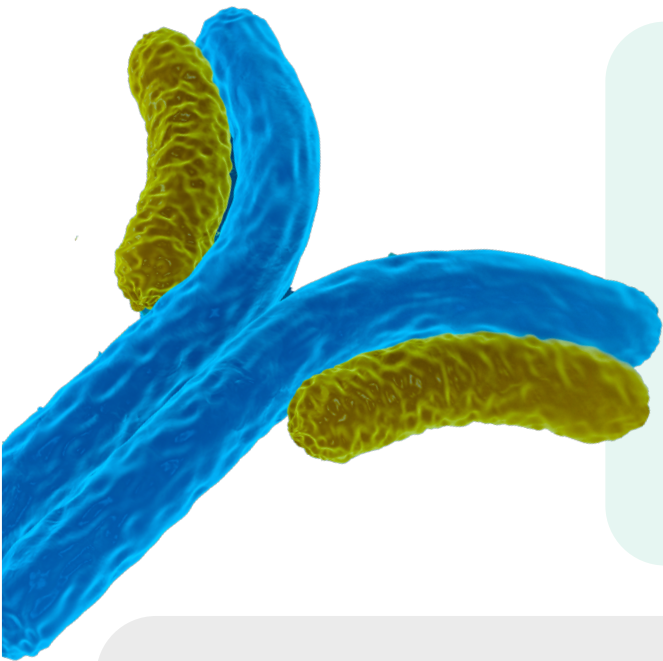


Providing Our Partner with **Solutions in Titer, Host Cell Protein, and Scalability**

FUJIFILM Biotechnologies works with partners to support late-stage clinical trials



Problem:

A biopharma partner faced a need to:

1. Generate a new clonal recombinant cell line to support late-stage clinical trials.
2. Tightly control post translation modifications during the cell culture process.
3. Maintain the same quality target product profile as in phase 1 process

Solution:

The FUJIFILM Biotechnologies team leveraged in house development tools and orchestrated a streamlined timeline focusing on engineering in quality, including:

Network Expertise

- Global teams developed a new repertoire of analytical methods for titer, quality, and activity

Close collaboration with partner

- Technology transfer into FUJIFILM Biotechnologies network in < 2 weeks

Customer Focus

- Transparent and real time data sharing expedited the selection of clonal cell lines based on optimal product quality attributes and titer

Impact:

Our early focus on building quality into the phase 3 ready process included improvements in:

- **Titer** – 30% increase compared to the original cell line
- **50% reduction in product related impurity profiles** that further increased yield
- **Improved process economics** through reduction of costly process additives – enabling commercial viability at scale
- **Overall maintenance of phase 1 QTPP** for streamlined progression to phase 3

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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