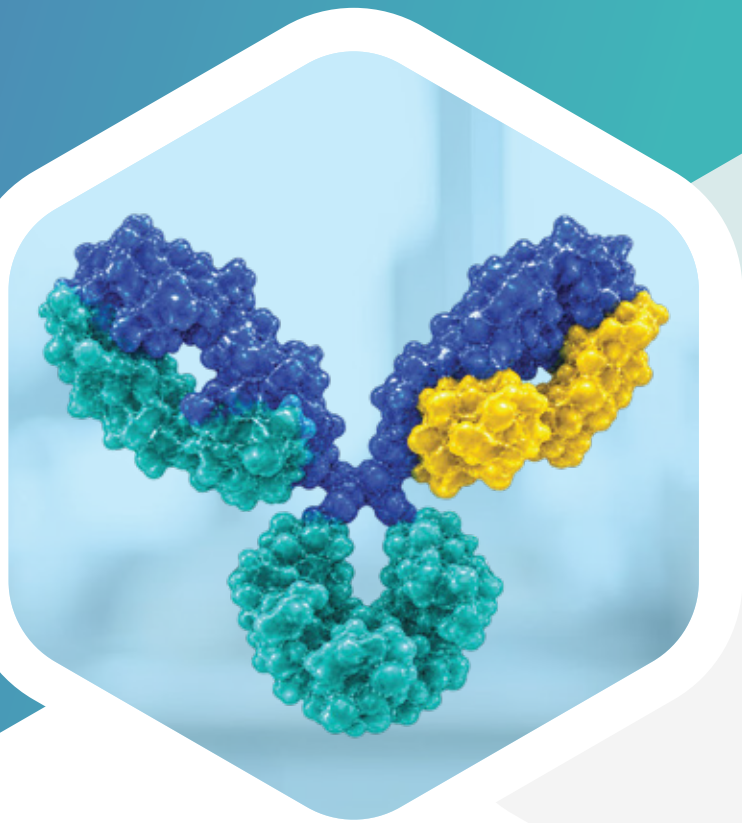
AURIGENE
PHARMACEUTICAL SERVICES

Gene to IND
Enabling in 9 Months



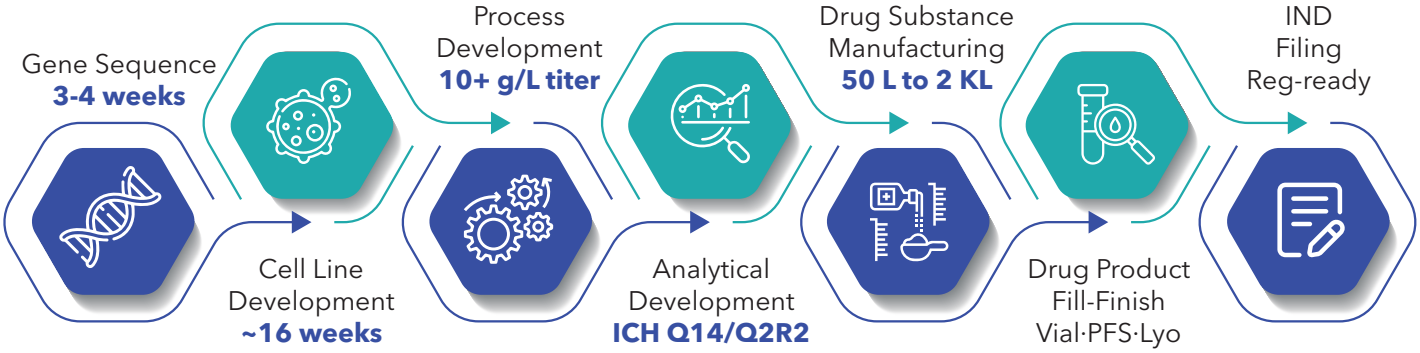
25
Years in Biologics

6
Bi-Specifics in journey to clinic

6
Biologics commercialized

Seamless Delivery - Relentless Precision

One integrated platform advances your asset from gene sequence to IND-ready GMP supply – cell line, process, analytical, drug substance and drug product under a single quality system, with zero hand-off risk.



U.S. FOOD & DRUG ADMINISTRATION · EUROPEAN UNION GMP · ANVISA · Health Canada · Pmda · KOREA MFDS

By the Numbers

10+
g/L
Peak titer via process intensification

200
mg/mL+
high-concentration, low-viscosity DP

12–14
weeks
Downstream process development cycle

100%
PPQ success across the last 4 years

Proven in Practice

Case Study | Complex Bispecific

One molecule, solved end to end - process, analytical and drug product.

Process Development

2x improvement in titre, with **>99%** product purity at DS stage

50% reduction in resin cost, through 2x binding efficiency

Analytical Development

Impurity definitively assigned by LC-MS – homodimer ruled out, heavy-chain clipping localised

Dual-arm engagement confirmed – orthogonal TAA and CD3 cell-based bioassays

Drug Product / Formulation Development

Buffer and pH locked in **14** days via rapid screening

<1% aggregation (HMWS) held across stability, lyo and liquid

AURIGENE
PHARMACEUTICAL SERVICES

For more information

Please write to contactapsl@aurigeneservices.com

Visit www.aurigeneservices.com

Website

Linkedin