



GMP Production of Antibodies & Proteins for Critical Assays and Diagnostic Applications

From development to GMP production in 100 days

GMP Manufacturing of Critical Diagnostic & Assay Reagents

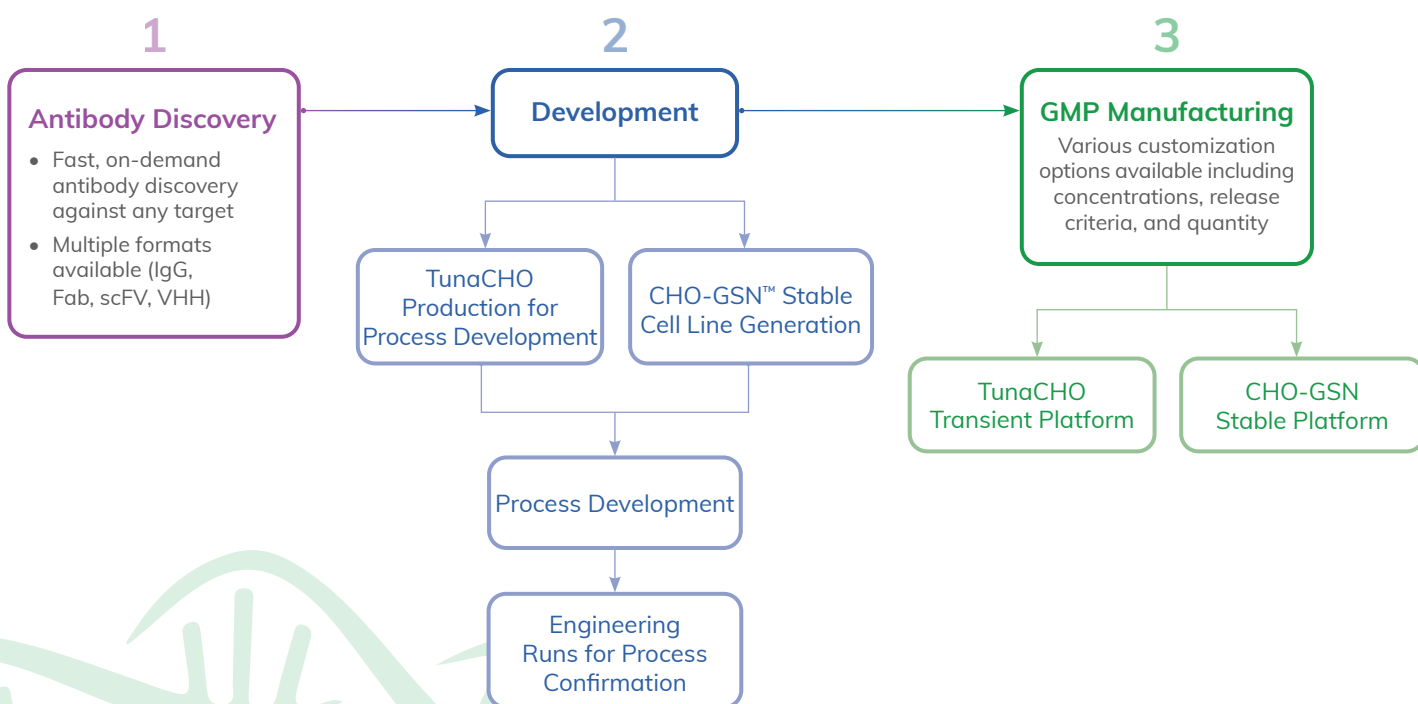
Antibodies and proteins are critical reagents with wide application in *in vitro* diagnostic developments, companion diagnostic and biomarker assays. Depending on final application, different quality standards may apply, from research use to full GMP production.

LakePharma Integrated Solutions for Reagent Manufacturing

- Complete workflow from discovery to full GMP manufacturing
- Flexible quality standards: from Bioprocessing grade to full GMP grade
- Fast timeline: 100 days from development to GMP manufacturing, in TunaCHO™ transient production
- Seamless transition from transient CHO to stable CHO production
- Cloud-based secure client portal for easy data management and communication
- **ISO:9001** certified GMP facility

Key Applications of Assay Critical Reagents

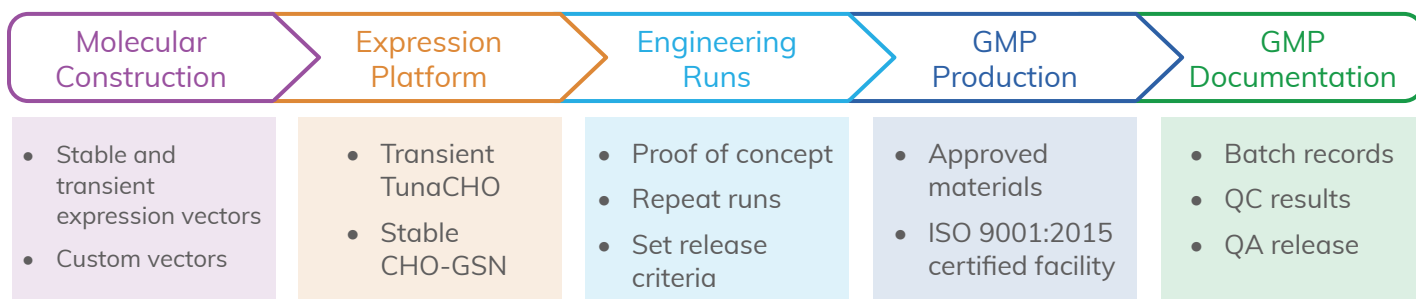
- QC assays in biologics manufacturing
- Companion diagnostic and biomarker assays
- Clinical diagnostic assay development



Bioprocessing Grade & GMP Grade Production

The Bioprocessing Grade (BPG) production meets requirements for a higher grade of quality while not requiring fully GMP production standards. BPG services support highly aggressive timelines, while offering flexible quality modules and documentation to support various needs. GMP grade includes early engineering runs to ensure final GMP productions under ISO:9001 meet full regulatory requirements for highest quality standard.

Bioreagent Manufacturing Workflow



LakePharma Offers a Full Range of Quality Standards from Research to GMP

Features	Research Grade	BPG	GMP
Single-use material	Optional	✓	✓
Animal source free	✓	✓	✓
Raw material documentation	✗	CoA with limited QC testing	<ul style="list-style-type: none"> Material specifications CoA with QC testing QA disposition
Operating space	No restrictions	No restrictions	Dedicated space
QC release testing	✗	Optional – CoA	✓
Batch record/documentation	✗	✓	✓
QA oversight/approval	✗	Optional	✓
Quality systems (deviations, OOS, etc)	✗	Optional	✓
Equipment calibration & maintenance	✗	✓	✓
Equipment IQ/OQ	✗	✓	✓
Applications	General	<ul style="list-style-type: none"> Early-stage validation of diagnostic kits/assays Preliminary regulatory filing Critical reagents for QC release assays 	<ul style="list-style-type: none"> Late-stage validation of diagnostic kits/assays Large-scale manufacturing Regulatory filing Critical reagents for QC release assays

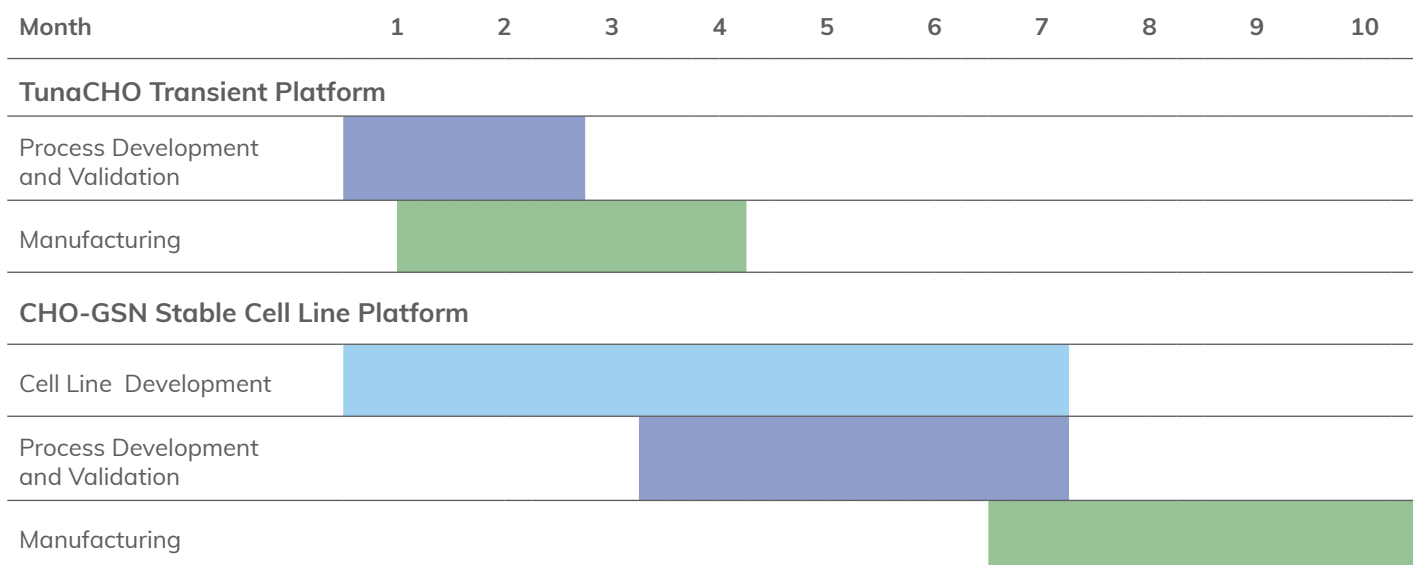
CHO Expression Platforms for Manufacturing

LakePharma offers two royalty-free platforms for production of recombinant proteins and antibodies. Both platforms offer a seamless transition from R&D productions to manufacturing. The table below provides a comparison between the two platforms.

	Transient TunaCHO Platform	Stable Cell Line CHO-GSN Platform
Parent Cell Line	CHO-K1	CHO-K1
Production Method	Transient	Stable
Animal-Product-Free	Yes	Yes
Timeline from Concept to Manufacturing	100 days	<ul style="list-style-type: none"> • 6 months for stable pool generation • 9 months with clone generation
Productivity	~ 1 g/L	~ 3 g/L
Benefits	Fastest path to commercialization	Consistent quantity and quality
Cost	<ul style="list-style-type: none"> • Lower entry cost • Higher long-term manufacturing cost 	<ul style="list-style-type: none"> • Higher upfront investment • Cost efficient for long term manufacturing
Production Scale	1 – 20 L	1 – 100 L

Timeline Comparison

Various service packages are available and can be tailored to clients' timeline and needs. The Gantt chart below outlines the standard timeline comparison of transient and stable cell line platforms.



LakePharma's Integrated Solutions for Antibody Discovery through Development and Manufacturing

Antibody Discovery & Engineering

- Hybridoma platform for *in vivo* discovery
- Phage and yeast display for *in vitro* discovery
- Affinity maturation, humanization, and more



Antibody Sequencing

Cloning and sequencing services are available for:

- Hybridoma IgG regions from multiple species including mice, rats, rabbits, and hamsters
- Primate B cell IgG and IgM
- De novo sequencing of antibodies



Molecular Construction

Synthesis of antibody variable region, plasmid design and construction services:

- Multiple species and isotypes are available, with the option of synthesizing a custom constant region



Transient Production

CHO Transient Antibody Production

CHO cells are preferred since antibodies will maintain similar PTM profile to stable CHO cells.

Stable Production

Streamlined service includes stable cell line development using LakePharma's proprietary CHO-GSN platform for research/master cell bank generation.



Process Development/Engineering Runs

- Proof of concept
- Repeat runs
- Set release criteria



GMP Production

- Seamless tech transfer
- Reliable scale-up processes
- GMP runs for diagnostic proteins
- Release testing of GMP batches
- Stability studies for GMP batches
- Biorepository for GMP materials



Diagnostic Development & Manufacturing at LakePharma, Hayward, California

- ISO:9001 certified
- Full range of services in process development and manufacturing
- Flexible quality standard: BPG vs. GMP
- Effective project management with regular updates
- Secured online client portal -data and process management system – allows 24/7 access to project information (timeline, data, file sharing, team communication, etc.)



"LakePharma is nothing short of a true partner with Apollos Diagnostics. We will continue to work with LakePharma as a partner for all of our future antibody development campaigns!"

—John Alderete, Ph.D., MBA; Founder and President of Folium Biomed, LLC

LakePharma Provides Integrated Solutions for Biologics Development



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