



**Integrated solutions
for ASR manufacturing
at Curia**

What are analyte-specific reagents (ASR)?

“ASRs are defined as antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding and chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.”

Source: 21 CFR 864.4020 (a)

Integrated solutions for analyte-specific reagent (ASR) discovery and manufacturing

Identification and quantification of substances in biological specimens can be achieved with analyte-specific reagents (ASR)

- Examples include monoclonal antibodies against idiotypes, proteins, or haptens
- Can be used in PK assays to measure free or total drug levels in preclinical and clinical studies, and as positive controls in ADA assays

Discovery, engineering, development, and GMP manufacturing of ASRs performed in San Francisco Bay Area

CURIA INTEGRATED SOLUTIONS



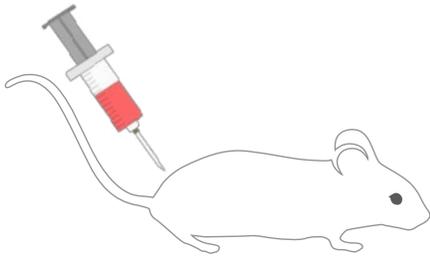
Antibody discovery

ASR antibody discovery

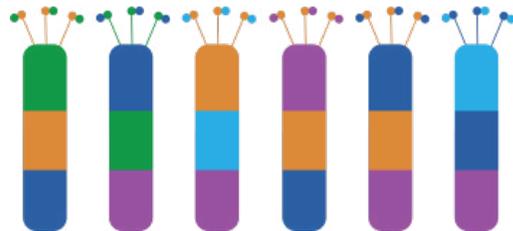
- Fast on-demand antibody discovery against any target
- Multiple formats available (IgG, Fab, scFv, VHH)

MULTIPLE APPROACHES AVAILABLE

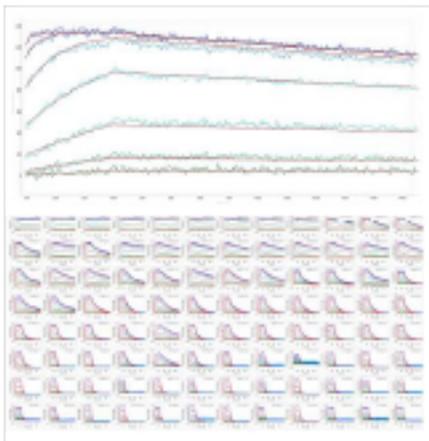
Immunization-based hybridoma and/or immune phage/yeast display



Naïve/synthetic phage display libraries



POWERFUL KINETIC-BASED SCREENING



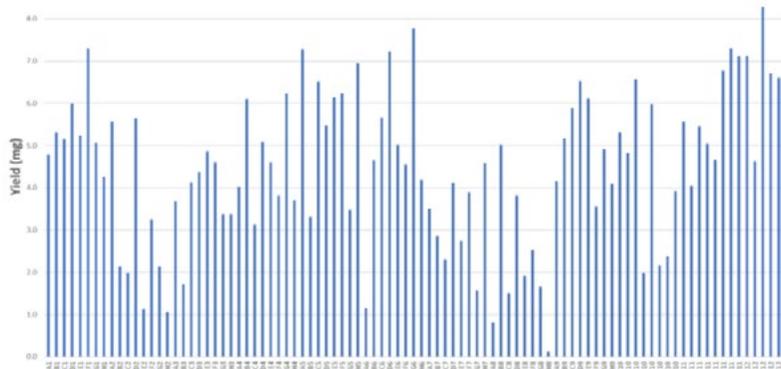
Carterra® LSA® high-throughput SPR

Development

Transient protein production with TunaCHOSM platform

- Productivity can reach 2 g/L
- Consistent titer from 10 mL shake tubes to 20 L in WAVES
- Flexible scale and faster timeline

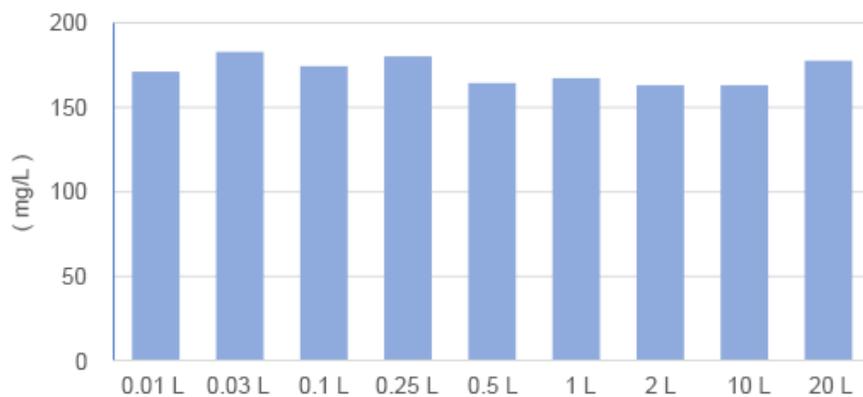
TunaCHO HIGH THROUGHPUT PRODUCTION



Average yield:
4.53 mg from 10 mL production

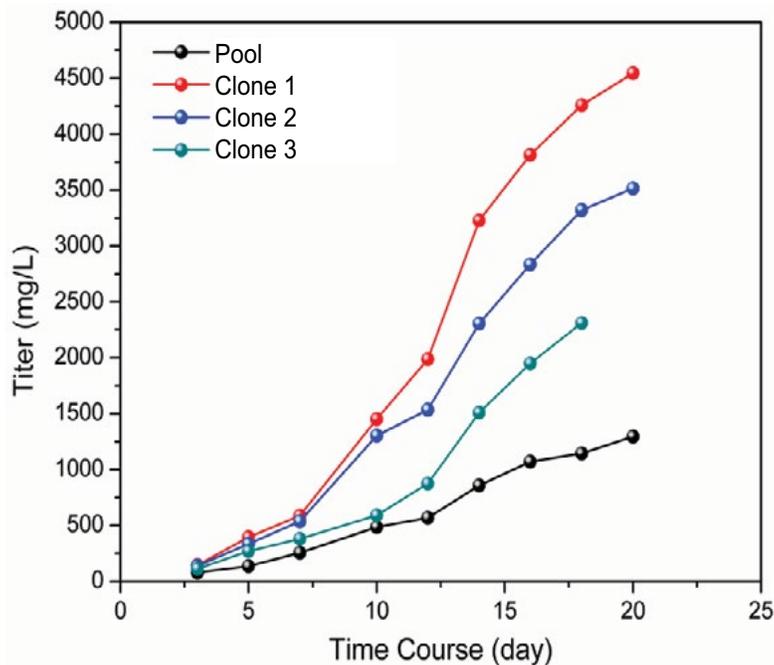
Best yield:
>10 mg from 10 mL

CONSISTENT PRODUCTIVITY AT DIFFERENT SCALES



CHO-GSNSM platform to make cell lines for manufacturing

- GS selection in CHO-K1 with GS knockout
 - » High selection pressure
 - » Enrichment of high yield clones
 - » Good stability
- 3-7 grams per liter
- Multiple programs in clinic
- Have produced challenging molecules
- Royalty-free commercial license
- Curia provides RCB, MCB, upstream, downstream, analytical and formulation packages



GMP manufacturing

GMP manufacturing for ASR support

Curia can manufacture components of *in vitro* diagnostic kits for ASR or companion diagnostic applications under GMP conditions.

KEY HIGHLIGHTS



ISO 9001:2015 certified



Various customization options available:

- Concentrations
- Release criteria
- Quantity



Two royalty-free CHO platforms are available to accommodate different timelines and needs:

TunaCHOSM TRANSIENT PLATFORM

- Quick turnaround since RCB step is not needed
- 1-100 L production tailored for specific needs

CHO-GSNSM STABLE PLATFORM

- Robust, high performance
- Flexible production scale from small to large quantities



PROCESS DESIGN & DEVELOPMENT

- Proof of concept
- Small-scale models
- Seamless tech transfer
- Analytical method development

GMP MANUFACTURING

- Validated equipment and utilities
- Upstream and downstream processes
- Single-use materials



WORKING WITH CURIA

Various service packages are available tailored to your budget, timeline, and needs.

- Comprehensive technology platform
- Technical consultation with experts in antibody discovery, protein production, and GMP manufacturing
- Online data system for 24-hour access to project information (timelines, data, team communications)
- Strong project management with regular project updates (email and teleconferences)

ABOUT CURIA

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients. Our biologics and small molecule offering spans discovery through commercialization, with integrated regulatory and analytical capabilities. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics. ***Learn more at curiaglobal.com***

Solutions developed by Curia

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