



## Cell Line Development: Reducing Timeline to IND Submission

Cell line development (CLD) is a critical component of any biologic development. CLD will lead to a successful journey across numerous stringent regulatory approval processes and first-to-market of your innovative biologic molecule. The CLD process involves expert scientific personnel, various robust host cell lines, and advanced process development infrastructure to mitigate clinical trial failures and delivery of biotherapeutics to the critical patient population. In this article, we describe how collaborating with Aragen, your company will develop a cost effective CLD project and expedite the BLA and IND filings on your innovative biotherapeutic.

Scientists and technical staff at Aragen, supported by well-equipped laboratories serve you in customizing cell line selection for developing research cell banks (RCBs). Our CLD expertise spans over 28 years in the industry, and our researchers are specialized in managing a wide range of host cell lines (CHO, SP2/0, and NS0) and expression vectors (DHFR, Glutamine Synthetase (GS), and antibiotics). We are also expert in developing new biologics that are difficult to express for a variety of reasons, including specific physicochemical features or complex formats. We have assisted our clients from molecule design to tech transfer to manufacturing. Continuous optimization of the CLD process parameters based on the individual needs of the clients allowed us to improve with each new project.

As of today, Aragen has completed more than 200 CLD projects, with over one hundred of those cell lines in the clinic. Presently, more than four of Aragen's cell lines have produced marketed products. We offer several CLD platforms customized to the specific requirements of the customers. Currently, we offer three CHO CLD platforms namely CHO DG44, Sigma CHOZN GS, and Asimov CHO GS. Our internal CHO DG44 platform is a free-to-own (royalty-free) and high productivity option that can deliver >4g/L product in 5 months for a range of biologics:

## Aragen Capabilities

- Reduced Timeline for Cell Line Development.
- Accelerating speed to IND submission.
- The DG44 platform has an extensive record with Health Authorities and uses commercially available media and feeds.
- Sigma's CHOZN platform is based on deletion of the CHO glutamine synthetase (GS) gene with Talon gene editing technology. The resulting GS-/- CHO host and expression vector with GS selection is a great combination for companies as an established GS selection system. Regulators are familiar with its efficacy and operation, and its expression vector produces titers equivalent to that of the DG44 platform.
- Asimov is a more recent platform that also employs the GS knockout in the CHO host. Asimov uses artificial intelligence (AI) to optimize the expression cassette, which is especially useful for new formats or difficult to express proteins.
- Deciding which CLD platform would work best for your product is challenging. Therefore, Aragen provides cost effective approaches to test different platforms simultaneously without losing time on the way to IND.
- A poorly expressed product is a suitable candidate for testing on multiple platforms. Simultaneous testing provides a mitigation strategy to the risk of having to repeat CLD due to low titers or poor product quality that results in high material costs (COGS). We have optimized breaks in the CLD process so that parallel work can be stopped as soon as data is available to determine which platform is the most effective.
- Timelines associated with CLD processes-5 months.
- Once the research cell bank is ready, bioreactor evaluation and stability studies are conducted in our facilities to enable clone selection and tech transfer.
- Infrastructure at Aragen for CLD- Our cell line development facilities are in Morgan Hill, California, USA to provide expert scientific and regulatory assistance. We have been serving clients from all around the globe for more than 28 years.
- Aragen is trusted by clients in a variety of industries, including biotech, agrochemicals, and veterinary medicine.

Let's begin the conversation

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