



## Cell Line Development at Aragen; Accelerating speed to IND

Cell line development is a critical stage in the development of a biologic. Efficient cell line development is crucial for successfully traversing clinical trials and numerous stringent regulatory approval processes. To minimise clinical trial failures and to deliver optimal products, cell line developers should possess expert scientific personnel, various robust host cell lines, and advanced process development infrastructure. This article describes how Aragen can be a suitable partner for your cost-effective cell line development project and can align the roadmap for early BLA and IND filing.

### **Aragen's capabilities for Cell Line Development**

Aragen's laboratories and expert scientific assistance enable unrivalled cell line creation, resulting in research cell banks (RCBs) amendable to IND and BLA filings. Our CLD expertise spans over 28 years in the industry, and our researchers are specialized in handling a wide range of host cell lines (CHO, SP2/0, and NS0) and expression vectors (DHFR, Glutamine

Synthetase (GS), and antibiotics). We excel at developing new compounds that are difficult to produce due to physicochemical features or complex formats. Aragen assist clients at every step of the development process, from molecule design to tech transfer to manufacturing. Continuous optimization of the CLD process parameters based on the individual needs of the clients allows us to improve with each new project.

Aragen has completed more than 200 cell line development projects, with over 100 of those cell lines in the clinic following an investigational new drug (IND) application. More than four of Aragen's cell lines are producing marketed products.

### **Different platforms for specific requirements of the customers**

Currently, we offer three CHO CLD platforms including CHO DG44, Sigma CHOZN GS, and Asimov CHO GS. Our internal CHO DG44 platform is an essentially free-to-own (royalty-free) and high productivity option that can deliver >4g/L in 5 months for a range of

biologics. The DG44 platform has an extensive track 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<sup>-/-</sup> CHO host and expression vector with GS selection is a great combination for companies after an established GS selection system. Regulators are familiar with its efficacy and operation, and its expression vector produces titers equivalent to 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 proteins that are anticipated to be difficult to express.

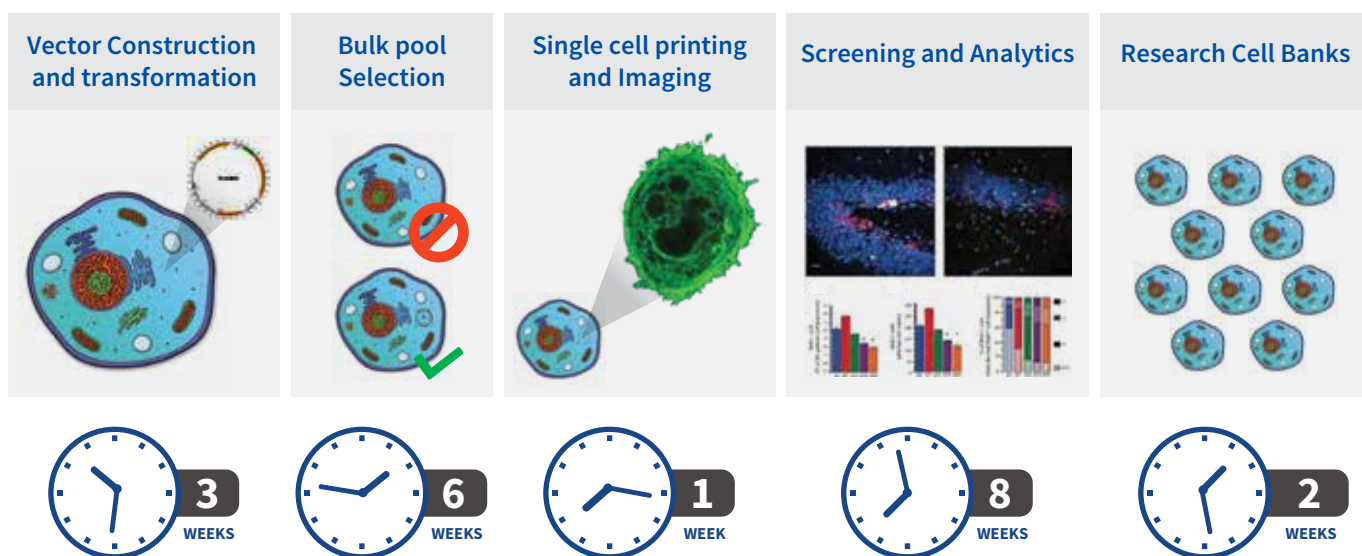
Deciding which CLD platform would work best a priori is challenging. Therefore, Aragen provides cost-effective approaches to test different platforms simultaneously without losing time on the way to IND.

A poor expressing 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). If two platforms have comparable titers, then the superior product quality or reduced milestone costs can drive the platform decision. 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 Cell line development processes

A normal cell line creation process at Aragen takes no more than 5 months. Once the research cell bank is ready, the bioreactor evaluation and stability studies are conducted in our facilities to enable clone selection and tech transfer. Figure 1 demonstrates the process of cell line development at Aragen with timelines.

**Figure 1. Process of cell Line Development at Aragen**



### Infrastructure at Aragen for Cell Line Development

Our cell line development facilities are in Morgan Hill, California in the United States with expert scientific and regulatory assistance. We have been serving clients from all around the globe for more than 28 years.

Depending on the unique requirements, we provide global resources and excellent capabilities at every level of the cell line generation process. We believe that each of our client's ideas has the potential to change people's lives. Our goal is to deliver clients' products to clinics while minimizing risk and maximizing efficiency. Aragen is trusted by clients in a variety of industries, including biotech, agrochemicals, and veterinary medicine. If you would like to learn more about our CLD capabilities, please contact our customer support team, and we'll be pleased to help you realize your vision.

Let's begin the Conversation

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