AGC Biologics

CHEF1™

Proprietary Expression Technology

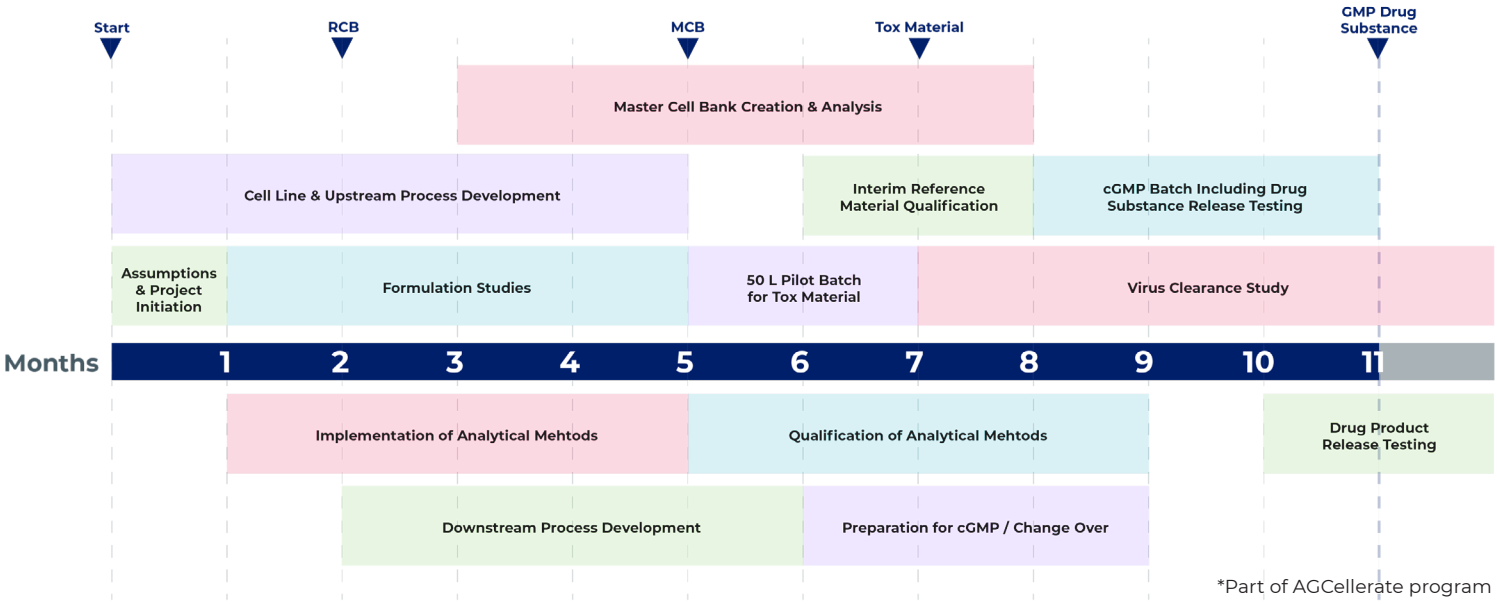
The CHEF1 expression system is used extensively to create **clinical production cell lines** and support **commercial manufacturing**. The platform accelerates development of cell lines for cGMP production by using robust procedures and reliable raw materials, including chemically defined media, adapted Chinese hamster ovary (CHO) cells, and proprietary expression plasmids, to rapidly produce high levels of recombinant protein.

CHEF1 allows **rapid isolation of CHO cell lines** expressing high levels of recombinant proteins. CHEF1 vectors are available with different selectable markers that permit multiple transfections of a gene of interest or genes encoding multi-subunit proteins.

The vectors can also be used to co-express proteins that perform post-translational modifications, which do not require gene amplification to achieve high-level expression. This enables the CHEF1 system to potentially decrease development timelines, depending on the project. This can also **reduce regulatory concerns** by eliminating the use of methotrexate, and potentially speed-up the initiation of early clinical trials.

mAb Timeline

Transfection to IND in 11 months*



*Part of AGCellerate program

CHEF1 Platform Technology

The CHEF1 platform technology incorporates CHO DG44 cells that have been adapted to suspension growth in our chemically defined media (CD-CIM1). With the CHEF1 vectors, CD-CIM1 media, and adapted CHO cells, stable expression pools can be generated in as little as five weeks, providing greater than 10 grams of protein in bench-scale production models for pre-clinical studies, purification, and analytical development. Since gene amplification is not needed, transfection pools can proceed directly into cell line cloning. A relatively large fraction of clones derived from a CHEF1 transfection express the protein of interest at high levels,[2] thereby reducing the number of clones that need to be screened to identify high-expressors.

Cell line cloning is completely serum-free and yields clones that easily progress from growth in tissue-culture plates to shake flasks in as little as three weeks. Early-stage productivity screens are highly predictive of future expression potential, enabling rapid cell line development timelines (see figure above). CHEF1 cell lines are stable throughout the in-vitro expansion phase required for large-scale production ensuring reliable manufacturing productivity.

All cell line development activities are well characterized and documented for process transfer to cGMP production. This timeline allows for rapid development and transfer of a cell culture production process, and therefore quicker entry into clinical trials.

CHEF1 Licensing Terms

A range of packages is available for pre-IND, clinical development, and commercial licensing terms.

References

1. Allison, Dan United States Patent, Number 5,888,809. March 1999.
2. Running Deer, J. and Allison, D. Biotechnology Progress, 20, pp. 880-889, 2004.

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***Claims valid as of January 2024.**

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