

Biosimilar Development at Aragen

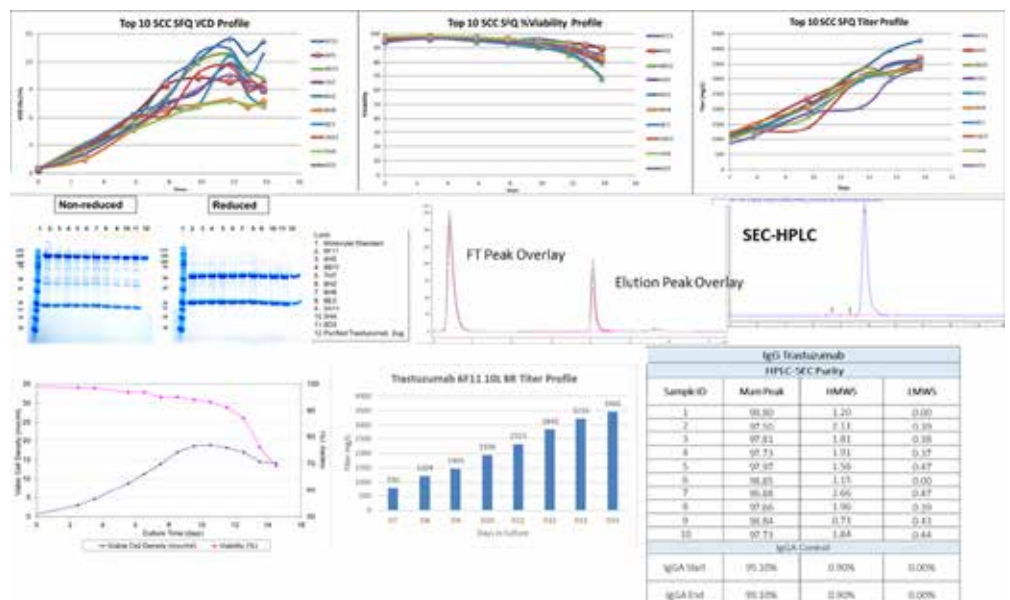
Over the past decade, the Aragen team has successfully expressed biologics including antibodies, antibody fragments, bispecific antibodies, fusion proteins, hormones, and growth factors. Aragen offers high-expressing cell lines for biosimilar development.

Cell Line Development for Biosimilars

- RapTr2022 with high titer and reduced timeline- Royalty-free CHO DG44 and CHO GS platforms
- Our in-house developed CHO DG44 platform can deliver titer >4g/L in 5 months
- Aragen also offers a CHO GS platform that can deliver titer >6g/L in 5 months
- Our CLD platform uses a chemically defined serum free medium and proof of clonality to support IND filing
- Robust upstream and downstream process development (250 ml high-throughput multi-parallel robotic bioreactor systems, e.g., Ambr250) to match originator molecule

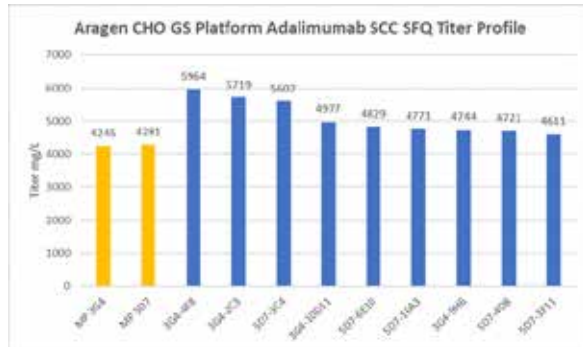
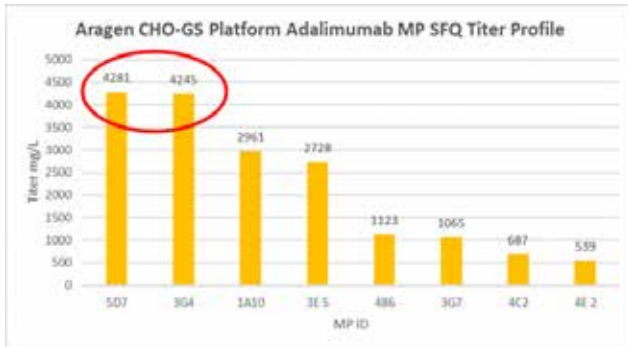
Comprehensive analytical and bioassay packages to support clone selection of biosimilar cell line development: Trastuzumab

- Generation of clonal cell lines.
- Evaluation in fed-batch shake flask.
- Validation of shake flask data in AMBR250 and Bioreactor.
- Analytics to meet the characteristics of innovator lot



Adalimumab using Aragen's proprietary Vector.

- Stable bulk pool (BP) evaluation reached ~700mg/L.
- Mini pool (MP) generated, and MP reached up to 4.2g/L.
- SCC generated from the top two mini-pools and fed-batch shake flask reached up to 6 g/L.
- Single cell clones show stability over 60 days in respect to cell growth, maintaining high viability and specific productivity.
- Using Aragen's optimized process from transfection to single cell clone evaluation completed in 18wks.

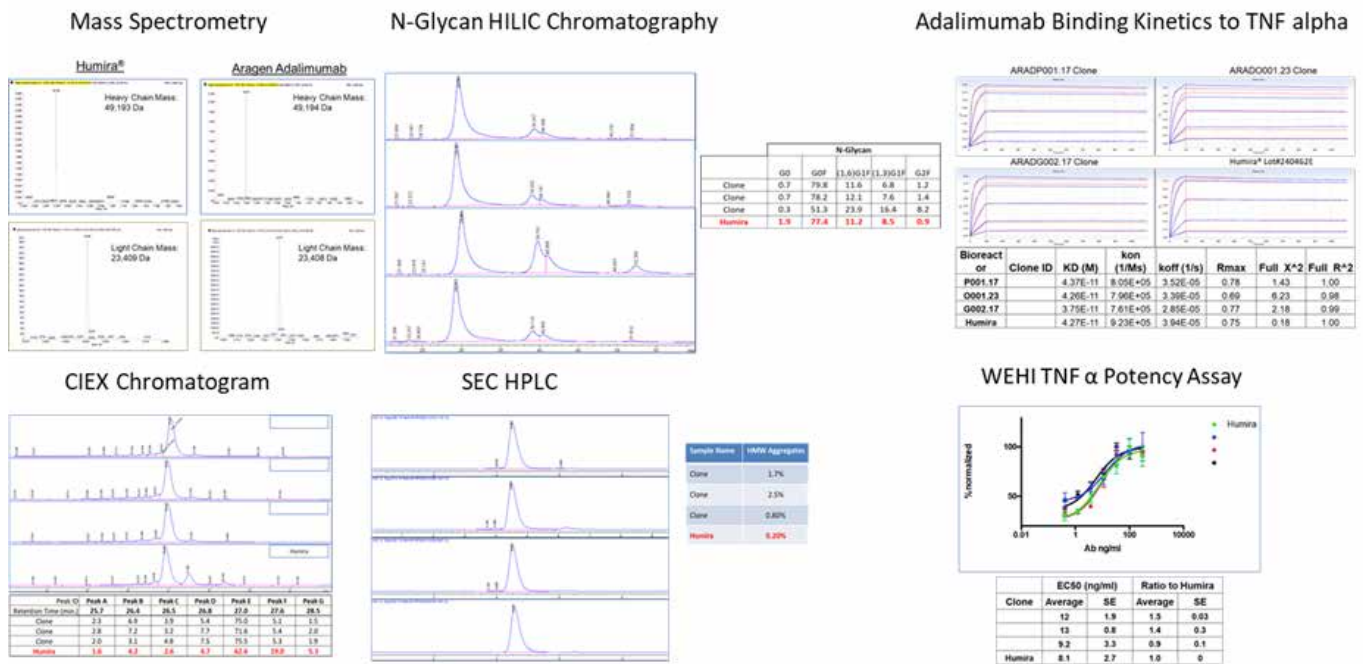


Process development

- Media adaptation
- Shake flask fed batch evaluation with different media and feed.
- Scalable and consistent data from shake flask to 1L and 5L bioreactor in terms of VCD and titer profile

Analytical characterization

- Rigorous and comprehensive analytics to support biologics discovery and development
- Aragen analytics capabilities include CE-SDS, cIEF, SEC-HPLC/MALS, LC/MS, DLS/SLS, LAL, HIC, HILIC, and SPR/BLI.



Let's begin the Conversation

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