

BIOMANUFACTURING SERVICES



Experts in the development and manufacture
of biopharmaceuticals



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Through its acquisition of Avecia Biologics, MSD is able to offer biomanufacturing services supporting the biotechnology and pharmaceutical industries from pre-clinical process invention to post-launch, commercial scale manufacture.

Our industry-leading expertise enables customers to improve the cost-effectiveness and profitability of new therapies, whilst maintaining fast-track progress into, and through, their clinical development programme.

Process development & scale up

Our experience ensures process development is applied appropriately dependent upon the development needs of customer products at different clinical stages.

- Expression in *E.coli* and yeast, including *Pichia pastoris* and *Saccharomyces cerevisiae*
- Wide range of constructs and expression options including development of a customer's existing system or creating one de-novo from our family of microbial therapeutic protein production systems, including our pAVEway™ system
- Purpose built fermentation areas up to 100L scale
- 100L scale pre-cGMP pilot plant for process demonstration and supply of pre-clinical material
- Full range of analytical methods available for in-process and final product analysis
- Development of stable product formulations



cGMP manufacturing

Four cGMP streams for the manufacture of microbially-derived biologics provide capacity from 100L to 5000L.

- cGMP cell banking facility for production of cGMP Master and Working Cell Banks
- ABC1000: 100L and 1000L fermentation scale cGMP pilot plant for rapid manufacture of Phase I-III clinical product
- ABC5000: 2 x 5000L manufacturing streams for large scale and Phase III, process validation and commercial supply
- Flexible plant configurations including disposables technology and re-ferment volumes of 10000L
- Full range of stability testing capabilities for drug substance and drug product



Quality & regulatory support

Independent Quality Unit with representation on programme teams.

- FDA/MHRA inspected cGMP facilities
- Compliance with Orange Guide Annex 18 and USA cGMP regulations
- Regulatory support for IND/CTA Submission, DMF and CMC as required
- QC Analysis and release of raw materials, environmental and water, in-process/final, retained samples
- Ownership and use of Qualified or Validated Methods
- Quality Agreement/interactions with customer



Programme management

MSD Billingham brings a distinctive management approach to programmes:

- Each programme is supported by a dedicated, multi-disciplinary team led by a focused programme manager
- Close customer interaction is promoted through regular teleconferences and face-to-face meetings
- Programmes are milestone structured to ensure timely delivery



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