

**\*symbiosis**

Pharmaceutical Services

Aseptic Manufacturing Specialists

**Getting your life-changing medicine to patients faster**



**Symbiosis values time as much as you do. With rapid access to manufacturing slots, and extensive expertise and experience across a range of modalities, we can get your product to patients faster.**

Since our establishment in 2011, Symbiosis has maintained a focus on what is important to you; time. From getting your first molecule into clinic to looking for regular small-scale commercial supply, finding partners who can meet your timelines can be challenging.

Our purpose-built MHRA-licenced manufacturing facility has delivered over 1000 projects for clinical and small-scale commercial products. Our seasoned experts can help guide you through your next manufacturing project. The fundamental aim at Symbiosis is to meet your most demanding timelines by offering access to manufacturing slots within weeks, not months, and ensuring that your critical project is delivered on time, to the highest quality standard.

- ＊ GMP fill finish of sterile drug products
- ＊ Aseptic liquid filling and lyophilisation
- ＊ Clinical and small-scale commercial manufacturing
- ＊ FDA inspected and MHRA licensed facility
- ＊ ATMP capability to commercial scale including BSL2 capabilities





## Symbiosis – the ideal partner for:



**Biotech:** virtual, emerging and established biotechnology companies.  
We treat your fill-finish project as a priority



**Speciality, and medium to large Pharma**  
Providing capacity and rapid batch turnaround to supplement your in-house capability



**Commercial fill-finish projects**  
Ideally suited to ATMP and viral vector manufacturing providing the right capabilities and expertise



**GMP process intermediates**  
Including plasmids and other critical materials used in your process





## Modalities

Symbiosis has a proven track record of delivering aseptic manufacturing projects across a range of modalities:

- ＊ **Advanced Therapy Medicinal Product (ATMP) and Viral Vector Therapies**

Clinical and small-scale commercial manufacturing of advanced therapeutics such as viral vectors for cell and gene therapies and raw materials such as plasmids

- ＊ **mAbs and Recombinant Proteins**

Extensive experience in delivering hundreds of biological drug projects allowing us to support your clinical trials

- ＊ **RNA and Peptide Therapies**

Often have challenging manufacturing and handling requirements that need specialist knowledge and experience

- ＊ **Antibody-Drug Conjugates**

Overcome your development and manufacturing challenges with a partner that has the experience and capabilities to handle your highly potent ADC

- ＊ **Small Molecules**

Symbiosis has provided GMP manufacturing across a wide range of small molecule applications, including highly potent materials requiring specialist handling

- ＊ **Vaccines**

Supporting clinical batches across traditional attenuated or inactivated products to recombinant, viral vector and nucleic acid-based vaccine technologies







## ATMPs and Viral Vector Therapies

### Leading the way in viral vectors

ATMPs are complex, often requiring multiple considerations across the manufacturing supply chain. Critical raw materials, such as plasmids, must be thoroughly tested, and products such as viral vectors require highly-specialised handling procedures.

Many target markets for ATMPs are for orphan indications, meaning that their small batch sizes can be challenging for larger-scale manufacturers to handle.

At Symbiosis, we specialise in the provision of aseptic fill and finish services for ATMPs, especially viral vector applications. From our Biosafety Level 2 (BSL-2) facility, we have developed our experience in the GMP manufacture of viral gene therapies since 2014.

Guided by our experts and specialist capabilities, we also help you manufacture the critical raw materials essential to your processes, from plasmids to viruses to other buffers and dilutants.

With a focus on the accelerated delivery of clinical and small-scale commercial batches, Symbiosis is the partner of choice for many ATMP developers.





## mAbs and Recombinant Proteins

### **A proven track record of supporting GMP fill-finish**

Over the past 40 years, recombinant proteins have risen to become a core part of the therapeutic landscape. From relatively small hormones to large and complex monoclonal antibodies (mAbs), the manufacturing process is now well-characterised and well-understood. However, consideration must still be given to how the therapy will be delivered to the patient and therefore what the final product format will be.

Symbiosis has extensive experience in delivering many hundreds of clinical projects related to mAbs and recombinant proteins. We can support your clinical trials.



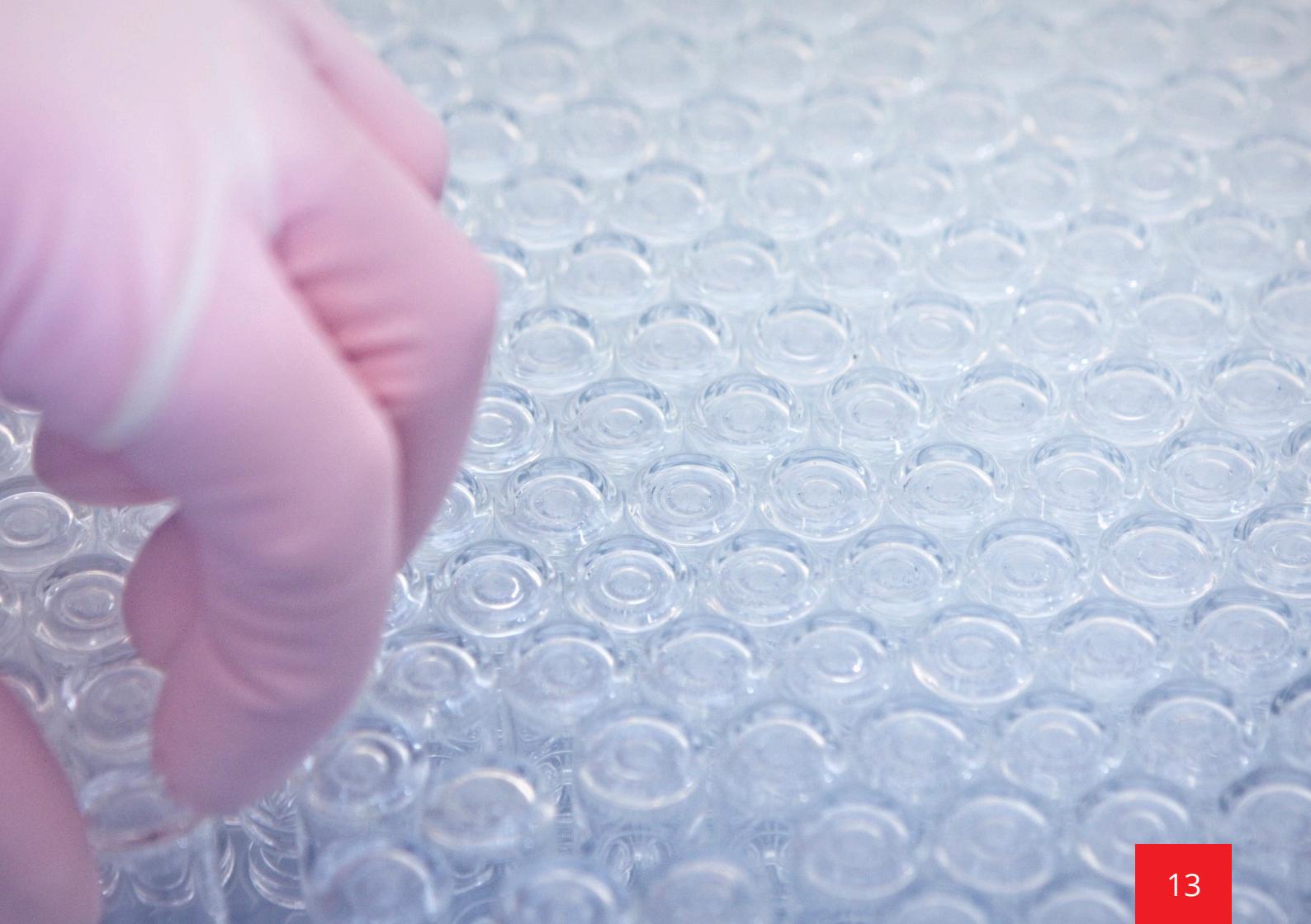


## RNA and Peptide Therapies

### Confidently meeting your specific needs and tight timelines

There are many exciting and dynamic biotechnology companies developing the next generation of RNA and peptide therapies. However, these amazing therapies often have challenging manufacturing and handling requirements that require specialist help.

Overcome these challenges with a trusted and established partner by your side. At Symbiosis, we are backed by years of experience and expertise in handling both RNA and peptide-based projects. Our flexible GMP aseptic manufacturing facility has specialist capabilities and state-of-the-art equipment that helps you get your therapy to patients quickly.





## Antibody-Drug Conjugates

### A trusted and established specialist in manufacturing services for ADCs

Overcome your development and manufacturing challenges with a partner that has the experience.

The ADC market is principally focused on delivering novel anti-cancer therapeutics, and leverages the targeted and highly specific delivery capability that conjugated antibodies confer by linking them to potent or cytotoxic small molecule drugs, for example. The drug can be targeted to kill cancer cells preferentially.

Symbiosis has a decade of experience in handling small molecule, biologic, and ADS drugs and does in its dedicated, purpose-built, and GMP-compliant sterile manufacturing facilities. Our industry experts and dedicated containment suite for GMP aseptic filling are equipped to handle a range of Safebridge® category ADCs up to category 3 in clinical and small-scale commercial batches.

With experience in aseptically manufacturing multiple ADCs, for biotechnology and pharma companies to use in clinical trials, Symbiosis is perfectly positioned to facilitate accelerated development through the drug development pathway.





## Small Molecules

### Providing GMP manufacturing services across a wide range of modalities

Many small-molecule pharmaceuticals cannot be terminally sterilized using heat or irradiation, requiring aseptic manufacturing processes. Highly-potent molecules may also call for special handling requirements within a containment environment.

Throughout our history, we have provided GMP aseptic manufacturing services for small molecule projects, and our dedicated containment suites are equipped to handle highly-potent drugs across the entire filling process.

Gain rapid access to our manufacturing suites to accelerate your small molecule projects and ensure your timelines aren't missed.





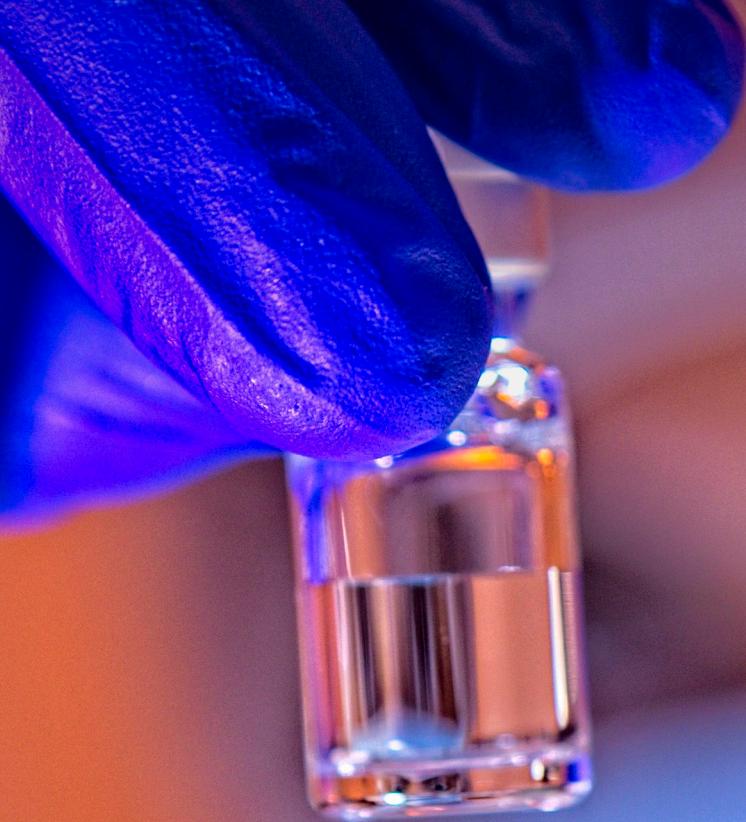
## Vaccines

### Your agile partner to clinical trials

As viral vectors and nucleic acid-based vaccines increasingly gain regulatory acceptance, traditional manufacturing models must evolve to keep up. Agile biotechnology companies and research institutions need to find experienced and scalable partners to bring their vaccines to the clinic.

From traditional attenuated and inactivated vaccines to recombinant, viral vector and nucleic acid-based vaccine technologies; Symbiosis works with you to deliver clinical and small-scale commercial vaccine batches.

From our BSL-1 and BSL-2 GMP aseptic fill and finish facilities, we have successfully delivered many vaccine projects, including the clinical supply of Oxford-AstraZeneca SARS-CoV-2 vaccine based on a chimp adenovirus viral vector platform.





## Sterile Fill-Finish

- \* GMP compliant and FDA inspected viral vector fill-finish
- \* Filling for small-volume parenteral materials into 2ml-100ml glass vials
- \* Bulk liquid volume handling up to 70 litres
- \* Bulk lyophilization in Lyoguard® trays  
Batch sizes ranging from 100-3,500 vials
- \* Controlled temperature filling
- \* Vial washing and depyrogenation
- \* Small-scale GMP drug product manufacture:
  - Small molecules and biologics
  - Antibodies, proteins, peptides, nucleic acids and ADCs
- \* Viral vectors:
  - Cytotoxics, cytostatics and highly potent APIs
  - Placebo, diluent and comparator



## Drug Product Testing

- \* Analytical method development and validation
- \* Analytical method transfer
- \* ICH stability testing (incl. photostability, freeze-thaw, in-use)
- \* Filter compatibility testing
- \* Container closure compatibility testing
- \* Microbiological finished product validation and testing:
  - Sterility
  - Endotoxin
  - Particulates
- \* Analytical release testing, including:
  - HPLC
  - Karl Fischer
  - SDS PAGE
  - ELISA, etc.





## Qualified Person Release

- \* QP GMP certification of drug product
- \* QP release to clinic
- \* Regulatory support for IMPD preparation



## Clinical Labelling & Packaging

- \* Open label and blinded studies
- \* Non-clinical studies
- \* In-house label printing
- \* Full-colour external label, box design and printing
- \* QA review and certification of final product



## Controlled Temperature Storage

- \* Stability storage at full range of ICH conditions
- \* Protocol preparation and final study reporting
- \* 24-hour continuous monitoring and recording
- \* Alarmed chambers with 24/7 call-out
- \* Potent drug handling / storage
- \* Viral vector storage
- \* Certificates of Conformance for storage



## Notes

**symbiosis:**

*noun*

(symbioses) biology.

a close association between two organisms of different species, usually to the benefit of both partners, and often essential for mutual survival.

By definition, symbiotic relationships go beyond the individual agenda. That philosophy led us to call the company 'Symbiosis'. Our goal is to ensure the success of your project is to exceed your expectation, first time, every time.

**Symbiosis Pharmaceutical Services**

Stirling Innovation Park

Stirling

FK9 4NF

United Kingdom

625 Massachusetts Ave, 2nd Floor,  
Cambridge,  
MA 02139,  
USA

+44 (0) 1786 220 000 | [contact@symbiosis-pharma.com](mailto:contact@symbiosis-pharma.com) | [www.symbiosis-pharma.com](http://www.symbiosis-pharma.com)