*symbiosis
Pharmaceutical Services

# The Assurance Of Regulatory Compliant, GMP Aseptic Manufacturing

With over 15 years of GMP aseptic fill-finish experience and proven regulatory excellence, Symbiosis is the ideal manufacturing partner for your next injectable drug product, whether for clinical trial or commercial sale.

Our FDA inspected and MHRA licensed facilities, robust quality management systems and industry-leading expert team all combine to help get your life-saving therapy to patients who need it most.



## GMP Compliance

- Annex 1 compliant cleanrooms and adherence to all relevant GMP guidelines
- QP confirmation and / or certification
- Routine management of client and regulatory audits / inspections

## Regulatory systems and oversight

- Electronic GMP quality management using validated software
- Dedicated Quality Assurance, Quality Systems and Qualified Persons teams supporting our GMP learning culture
- Validated processes, equipment and systems aligned with MHRA and FDA expectations

## Global compliance support

- Expertise in writing IMPD and IND documentation and regulatory pathways
- GMP compliant to global standards including FDA and MHRA
- Ongoing alignment with emerging UK, EU and US regulatory guidance

## Collaborative assurance

- A dedicated single point of contact for streamlined project communication
- Efficient documentation flow from manufacturing to product release
- Close collaboration with our QA and QP teams ensures visibility and guidance throughout

**For more information about our regulatory capabilities or to discuss your next drug product, get in touch:**

THE KING'S AWARDS FOR ENTERPRISE 2025 INTERNATIONAL TRADE

+44 (0) 1786 220 000 | contact@symbiosis-pharma.com | www.symbiosis-pharma.com