REGULATORY SUPPORT SERVICES

Our team of professionals has an extensive knowledge of the evolving regulatory landscape for cell and gene therapies. We are ready to support our customers every step along the way through advanced therapy development and regulatory approval.

EXTENSIVE: Our regulatory support begins at Investigational New Drug Application (IND) filing and continues through market authorization support and maintenance.

KNOWLEDGEABLE: From working on a variety of projects over many years, we have developed a comprehensive understanding of the changing landscape of regulatory approvals for advanced therapies, and can help our customers predict and respond quickly to change.

GLOBAL: We support customers who are applying for approval with multiple regulatory authorities, ensuring that the most stringent regulations are adhered to.

REGULATORY SUPPORT

Our regulatory affairs program can support customers with pre-IND, IND and Biologics License Application (BLA) document creation and submission. We create and maintain Drug Master Filings (DMF) for our cell lines, plasmids, facilities and analytical methods, providing an end-to-end solution.

The full regulatory affairs program at WuXi Advanced Therapies includes:

- Meeting Package Preparation
- Pre-IND Briefing Document Creation
- IND, IMPD and BLA Authoring & Submission
  - CMC, Facility & Material Controls
- Drug Master File Authoring, Submission & Revision (Type II and V)
  - US FDA, Health Canada
- Pre-Approval Inspection Readiness
- Marketing Authorization Support and Maintenance
- Annual Product Review

Our facilities are designed and qualified to meet US, EU, China and other major health authority standards, and we have quality systems and processes in place to maintain compliance.

Accrediting Body	Accreditations/Certification
A2LA	ISO/IEC 17025:2017
FDA	FEI: 1000122198
EMA	NL/H 20/2015837 and 32242
TGA	MI-2021-CE-02267-1

For more information on Regulatory Support Services, please contact: **atu.info@wuxiapptec.com**