

MML PHARMA SERVICES CAN NOW PROVIDE EU IMPORTATION, QP RELEASE AND DISTRIBUTION SERVICES FOR BOTH INVESTIGATIONAL MEDICINAL PRODUCTS AND LICENCED PRODUCTS.



MML Pharma Services provides pharmaceutical product lifecycle support from conception through to marketed product. Each phase of the product lifecycle is supported with an understanding of the current regulatory, technical and quality requirements. Strategic insight and hands on application provides the correct level of support for our clients. Our focus is on the chemistry, manufacturing and control elements of the product.

This support encompasses product and process based services, further complemented by operational services with the provision of importation, release and distribution activities in accordance with Manufacturer's / Importer's Authorisations (MIA and MIA (IMP) 32694).

Enhancing all of this is a project management philosophy which identifies and overcomes critical issues in a timely manner and facilitates the achievement of targets.

SERVICES PRODUCT

Our product based services take a product from development through clinical trial and support it as a marketed product.

The strategic development to identify and implement the correct regulatory pathway is of paramount importance and must be done at the earliest stage of product development possible. Proven competence in the provision of Investigational Medicinal Product Dossiers, Marketing Authorisation Applications and Licence Variations makes MML Pharma Services the ideal partner.

OPERATIONS

The operational services allow MML Pharma to import, QC, QP release and distribute both investigational medicinal products and licenced finished products. These services are offered on a bespoke basis to ensure that each customer's needs are handled effectively, including the provision of order handling and management reporting as best suited to the customer in question.

PROCESS

Process based services provide the knowledge to ensure compliance to GMP and GDP. Our knowledge base, notably from active EU QPs, includes the development of Quality Management Systems, GMP improvement programmes, technical transfer and GMP/GDP quality audits. We have extensive experience of API manufacture and finished form production and assembly, including all aspects of quality control.



PHARMACEUTICAL PRODUCT LIFECYCLE

| | Formulation Development | Clinical Trials | Marketing Authorisations | Licensed Products |
|-------------------------------|-------------------------|--|--|--|
| Product based services | Product development | Preparation of Investigational Medicinal Product Dossiers (IMPD) | Preparation of Marketing Authorisation Applications (MAA) Product technology transfer | Assessment and preparation of licence variations and line extensions Product technology transfer Preparation of licence renewals |
| Operational services | | Importation of clinical trial supplies (MIA (IMP)) | | Importation of Licenced Products (MIA) and Clinical Trial Comparators (MIA (IMP)) |
| Process based services | | Worldwide Quality Audits to GMP / GDP | | |
| | | GMP Assessment and Improvement Programmes | | |
| | | Provision of EU Qualified Person | | |
| | | Preparation and Review of Quality Management Systems | | |
| | | Programme and Project Management | | |