

BIOTECHNICA PHARMA Global SERVICES

- Dossier / ANDA Preparation
- QP Declarations
- BE Study Design and CRO Selection
- Regulatory Submissions & Follow Up
- Pharmacovigilance
- MA Holding
- Creating EU Set ups
- EU products importation
- EU Batch Control / Batch Release
- Manufacturing Expediting & pre-shipment inspections
- Distribution