

Your Challenges Require Smart Solutions.



Regulatory Affairs

A service for manufacturers of

- Bio- and Pharmaceutical Products
- Medical Devices
- Packaging Materials for Pharmaceutical Products

Our Services:

**for Human Medicinal Products, Generics,
Herbal Medicinal Products, Medical Devices,
Veterinary Medicinal Products, Homeopathics**

- Consulting
- Conception of regulatory strategies
- Scientific advices
- All MAAs (CP, DCP, MRP, NP)
- All types of documents (CTD, eCTD, ASMF, NTA, STED, CEP, IMPD etc.)
- All CTD modules (1 to 5)

- All variations types (IAIN, IA, IB, IB unforeseen, II, line extensions)
- Grouping and work-sharing options
- Life cycle management
- Package leaflets (conception, mock-up, readability user test)
- Pharmacovigilance incl. QP service
- Cultivar screening of herbal drugs
- Due diligence of MA documents in case of purchase options

Further information about our service portfolio can be found at www.gba-pharma.com

