

Know what's inside.



Regulatory Affairs

A service for manufacturers of

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

provided by Phytos, LAT, and LPU

Experts for Analytical Solutions



Phytos



LPU

GBA Regulatory Affairs Services

for Human Medicinal Products, Generics, Herbal Medicines, 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 (IA_N, IA, IB, IB unforeseen, II, line extensions)
- Grouping and work-sharing options
- Life cycle management
- Package leaflet (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



Benefits from Our Support

- **Laboratory and regulatory services out of one hand**
- **Great experience in medicinal product regulatory affairs for over 30 years**
- **Guidance from conception to life cycle**
- **Management and realization of your projects on due time**
- **Constantly up-to-date with continuing training**

If you are interested in our services, please contact:

Dr. Andreas Hofmann +49 731 97439-13 info@phytos.de

Elisabeth Obermeier +49 89 858967-112 kontakt@lat-gmbh.de

Stefan Woidich +49 731 97439-59 bd@lpu-labor.com

Further information about our service portfolio can be found at www.gba-group.de

Phytos

Labor für Analytik von Arzneimitteln GmbH & Co. KG
Leibnizstrasse 9, 89231 Neu-Ulm, Germany

LAT GmbH

Institut für Pharma-Analytik
Am Haag 4, 82166 Gräfelfing, Germany

LPU

Labor für Pharma- und Umweltanalytik GmbH
Fraunhoferstrasse 11a, 82152 Martinsried, Germany