



CONTENT AND REVIEW OF CHEMISTRY, MANUFACTURING AND CONTROL (CMC)

 **A PHARMALEX SOLUTION THAT
EXCEEDS YOUR EVOLVING NEEDS**

Our **chemistry, manufacturing and controls (CMC) group** provides regulatory guidance in setting specifications, method development and validation of documentation. We can help you build a **positive relationship with EMA, FDA** or your local health agencies.

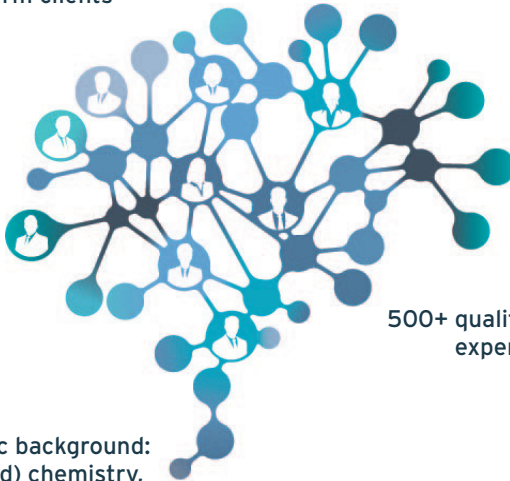
Whether it is a case of first-time submission, change control or maintenance throughout the life-cycle, our multi-disciplinary teams take care of GxP, technical writing, regulatory strategy, change control and submissions on a **global basis**. We have a great record of success in supporting your CMC needs - both chemicals and biologicals.

EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

9 out of the top 10 pharmaceutical companies are valued long-term clients



20+ years of experience in global regulatory maintenance support and CMC



500+ quality overall summary expert reports prepared



Broad scientific background: pharmacy, (food) chemistry, biology, biochemistry, biotechnology

Proven track record with 6,000 successfully completed projects



MARKET &
LAUNCH

PRODUCT
MAINTENANCE



"We can assume complete responsibility for safeguarding regulatory compliance throughout the respective product life cycle."

- Dr. Jörg Strähle, Senior Director, CMC Services, Head of Regulatory CMC

PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- ▶ Product scope includes human and veterinary medicinal products comprising all types of APIs (chemicals, biologicals, biosimilars, herbals & homeopathics)
- ▶ Strategic consultancy during pharmaceutical development and life-cycle management
- ▶ Compilation of quality dossiers (ICH and non-ICH)
 - CTD modules 3 and 2.3
 - IMPD, IND
 - ASMF/DMF, CEP
 - Normative document
- ▶ CMC and technical writing
- ▶ CMC maintenance support: change control and quality variations
- ▶ Gap analysis / due diligence (e.g. in-licensing activities)
- ▶ CMC and GMP compliance
- ▶ Optimization of the supply chain
- ▶ GxP services (GMP, GACP, GDP) including audits

contact@pharmalex.com
www.pharmalex.com



Dr. Jörg Strähle
 Senior Director, CMC Services, Head
 of Regulatory CMC
joerg.straehle@pharmalex.com



Dr. Thomas Eberwein
 Senior Director,
 Head of Regulatory CMC
thomas.eberwein@pharmalex.com

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology, and Risk Management worldwide. Our global teams of experts can take you through early strategic planning activities and nonclinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.



Since our founding in 1994, every single one of our clients is our top priority! We lead where others follow. We help clients to go beyond compliance, to capitalize on greater efficiencies, streamline complexity and to deliver true business value.

Ask us how we can make your job easier - over 600 customers are glad they did."

Dr. Thomas Dombeyer, CEO

PHARMALEX IN NUMBERS

