

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

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 lifecycle, 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.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- Product scope includes human and veterinary medicinal products comprising all types of APIs (chemicals, biologicals, biosimilars, herbals & homeopathics)
- Strategic consultancy during pharmaceutical development and lifecycle 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



25+ years of experience
in global regulatory
maintenance, CMC



100+ CMC experts
worldwide



500+ quality overall
summary expert reports
prepared



Proven track record
with 6,000 successfully
completed projects

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

APPROVAL /
AUTHORIZATION

PRODUCT
MAINTENANCE

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PHARMALEX

CONFIDENCE BEYOND COMPLIANCE

PHARMALEX IS THE LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

Stay **one step ahead** of essential requirements needed by health agencies. Our knowledge accelerates your business success.

Knowledge. Accelerated.

