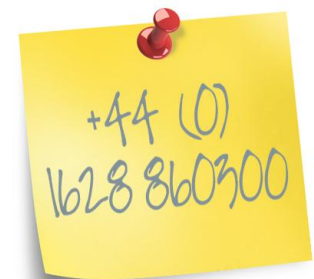


# Who we are

Founded in UK in 1998, Pharmalink Consulting has grown to be the world's leading Independent Regulatory Affairs Consultancy.

We provide top quality [interim Regulatory Affairs resource](#) in addition to our [consultancy services](#).

We offer the following Regulatory Affairs support services to healthcare clients on a global basis:



# RA Solutions that fit your business

## **Regulatory Services**

### **CMC & Manufacturing Compliance**

Gap analysis & remediation  
Preparation of  
CTD Module 2 & 3  
DMF preparation  
Validation  
TPM site identification  
Contract QP  
Import documentation and  
licensing  
GLP/GMP audit  
Pre-approval inspections

## **Regulatory Strategy**

Regulatory agency  
meetings  
Filing strategy  
Response to agency  
queries  
Advisory Committee  
preparation  
Scientific Advice  
Lifecycle management  
Input from Subject Matter  
Experts

### **Filing Expertise**

IND/IMPD  
Original NDA/MAA  
ANDA  
BLA  
510K/PMA

## **Clinical**

Preparation of  
CTD Module 2 & 5  
Review of protocols &  
CSRs  
CTA preparation  
Review of IBs  
IRB/EC documentation  
Orphan indication  
Pediatric development  
plans  
Amendments  
Medical writing  
GCP audit

### **Post-marketing Maintenance**

sNDA/variations  
Annual Reporting  
Post-marketing Commitments  
Safety reporting eg PSUR

## **Advertising & Promotion/Labeling**

USPI/PLR/SPC/CDS  
User testing  
Packaging

### **Regulatory Operations**

CTD/eCTD/dossier  
preparation  
Submission advice  
Translation service

### **Non-clinical**

Preparation of  
CTD Module 2 & 4  
Review of toxicology &  
pharmacology studies



# Pharmalink Affiliate Network

In response to our Clients' needs, we have created the PAN – a global network of Regulatory Consultants who can provide local assistance or advice, saving you time and money.



Visit our website to see our [global coverage](#)

# Global Pharmalink Offices

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