The benefits we bring to our partners:

- ✓ Exceptional industry knowledge and experience at competitive pricing.
- ✓ Superior leadership team abreast of all current industry trends, and continuously directing company initiatives toward solutions to market challenges
- ✓ A large, deeply talented project management team to ensure expedited project results without sacrificing quality
- ✓ Constant focus on communication enabling stronger client project participation and control
- ✓ Strength of diversity – our team is made up of over 15 different nationalities
- ✓ Peace of mind from knowing you have found the right partner

Our Prestigious Partners:

Pfizer, VIATRIS, Cosette PHARMACEUTICALS, Strides Shasun, zydus Dedicated To Life, torrent PHARMA, HETERO, Otsuka, Biocon, Emcure SUCCESS THROUGH INNOVATION, Baxter, MICRO LABS LIMITED, Mankind, LAURUS Labs Knowledge . Innovation . Excellence, AUROBINDO

FIND THE BROCHURE IN YOUR LANGUAGE:

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Choice of Experts...

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Ashram Road, Ahmedabad-15
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neocubes pharma LLP
Choice of Experts...

Subsidiary of
neoplus translation
Empowering Word Solutions

Neocubes Pharma is sister concern company of **Neoplus Translation** established since 2012.

Our people have extensive knowledge and experience in all aspects of Pharmaceutical Translation, Regulatory Affairs, Pharmacovigilance, GxP & Sourcing. As we have integrated services covering from start of the product development until authority's approval and lifecycle management, Neocubes Pharma can be your one stop solution.

Through our Translation, Voice over, Medico Marketing expertise, you can reach to all markets like Europe, CIS, Francophone countries, Asian and GCC region.

We are experts in **Europe, US, Canada, Australia, CIS, EAEU, GCC** and **RoW** counties.

www.neocubespharma.com

PHARMACEUTICAL TRANSLATION, LOCALIZATION AND DTP

- ✓ Drug Dossier, DMF / ASMF translation for CIS, China, Mexico, Latam and Francophone countries
- ✓ Product Information (SmPC, Leaflet and labelling)
- ✓ Translation of Medico marketing material
- ✓ Localization (Content, Website, Videos)
- ✓ Multilingual Voiceover & Dubbing
- ✓ Subtitling & Transcription
- ✓ Multilingual Desktop Publishing (DTP)
- ✓ Interpretation (Simultaneous or Consecutive)

PHARMACOVIGILANCE (EUROPE, UK, US, ROW)

- ✓ Complete PV setup
- ✓ Case search, processing and reporting
- ✓ EU QPPV and Local QPPV
- ✓ PSMF preparation & Maintenance
- ✓ Signal Detection
- ✓ PSUR, PBRER, PADER, DSURs
- ✓ Comprehensive PV Service for the RoW Region
- ✓ Medical information Call Centre
- ✓ Manage safety variation

REGULATORY AFFAIRS

- ✓ Dossier & DMF gap analysis
- ✓ Dossier & DMF drafting
- ✓ Scientific advice in EU and USFDA (US Agent)
- ✓ Deficiency response (Dossier/DMF)
- ✓ Dossier submission management:
  - ➤ EU: DCP, National, MRP, Duplicate, CEP, ASMF
  - ➤ USFDA: ANDA and DMF (Type I, II, III, IV and V)
  - ➤ Canada: ANDS, DINA and DMF
  - ➤ TGA, EAEU and GCC

MEDICAL & SCIENTIFIC WRITING

- ✓ Module 2.4 and Module 2.6 (Non-Clinical)
- ✓ Module 2.5 and Module 2.7 (Clinical)
- ✓ PSURs, PBRER, PDERS & Risk management plan
- ✓ SmPC, Leaflet, Labelling
- ✓ Scientific justification/Bio waiver
- ✓ Slide Decks, Visual Aids, Manuscript, Abstract
- ✓ Lay person summary
- ✓ Clinical study protocols & reports (Phases I to IV)
- ✓ Informed Consent Forms & Safety Narratives

ADMINISTRATIVE & LIFE CYCLE MAINTENANCE

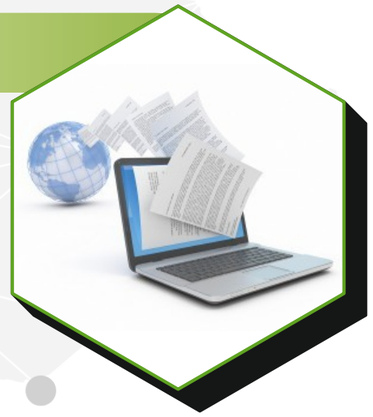
- ✓ MA holding in Europe
- ✓ Readability Testing & Bridging report
- ✓ Risk assessment: Environmental, Elemental, Nitrosamine
- ✓ Drafting of SmPC, Leaflet, Labelling
- ✓ Artwork Creation for Leaflet, Carton and Blister
- ✓ Life cycle maintenance activity:
  - ➤ Europe (Dossier/DMF): Variations like Type IA/IAin,
  - ➤ Type IB, Type II, Renewal
  - ➤ USFDA: Annual report, CBE0, CBE30, PAS

GxP & AUDITING

- ✓ Plant Mock Inspection (API and Finished product)
- ✓ GMP Trigger (EU/USFDA/PICS)
- ✓ Third Party Vendor Audit
  - ➤ API manufacture
  - ➤ Finished product Manufacture
  - ➤ KSM, Excipient, Packaging vendors
- ✓ Clinical Site monitoring
- ✓ Computer System Validation
- ✓ PDE/OEL reports

eCTD PUBLISHING (EUROPE, US, AUSTRALIA, CANADA)

- ✓ Baseline eCTD creation
- ✓ MAA application EU, Canada, TGA
- ✓ ANDA/NDA dossier publishing for USFDA
- ✓ Dossier publishing for EAEU region
- ✓ CEP DMF publishing
- ✓ ASMF publishing
- ✓ DMF (Type I, II, III, IV and V) for USFDA
- ✓ eCTD life cycle management
- ✓ NeeS to eCTD conversion



SOURCING

- ✓ Dossier (EUCTD or USCTD format)
- ✓ CDMO sourcing (solid oral, liquid and injectable)
- ✓ CMO sourcing for reduction in operational cost
- ✓ Tech transfer support
- ✓ Project management at CDMO
- ✓ Vendor management
- ✓ Annual sourcing contract
- ✓ Excipient and API sourcing
- ✓ Tech transfer support