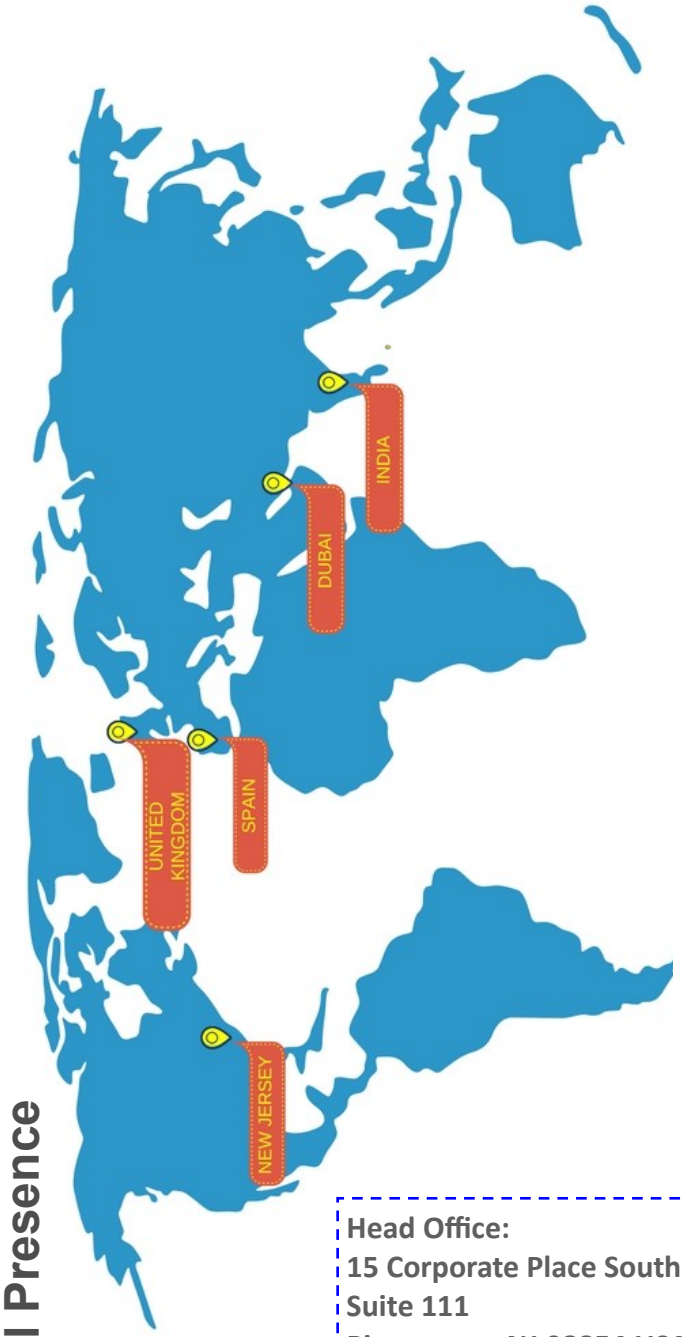
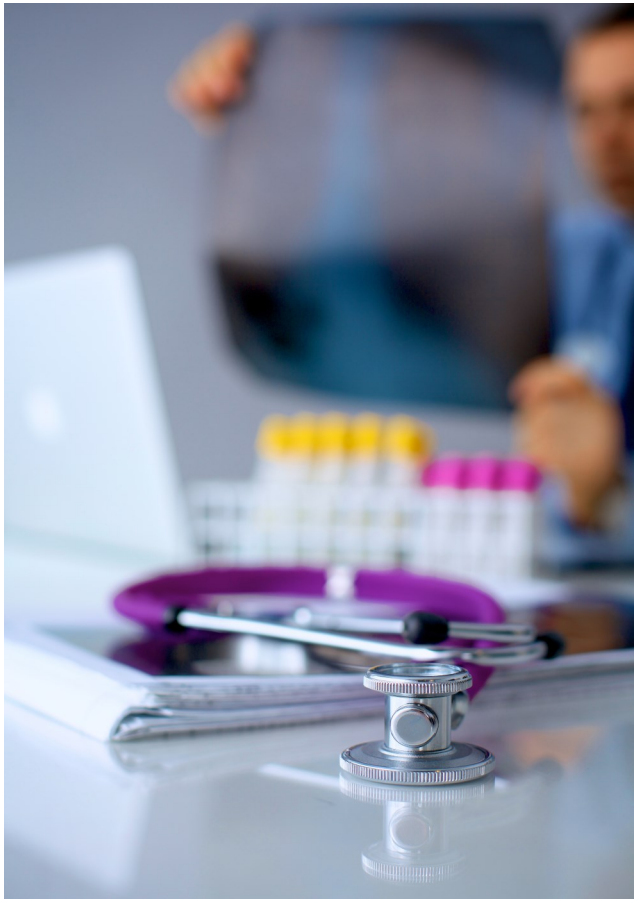
Why 4C Pharma Solutions

- Reduce the burden of In-house Operations to focus on R&D
- Owned and Managed by Pharmacovigilance & Regulatory Affairs experts
- Cost-efficient, turnkey solutions
- Pre-validated **ARGUS** safety database for case processing
- Comply with electronic submissions
- Leverage **ISO certified** processes to improve quality, and secure data
- Support across all time zones for enhanced patient care
- Trained team for rapid start-up and ramp-up of operations
- Enhance quality, consistency, and speed of case processing
- Increase operational efficiency while reducing costs
- Improve compliance and adherence to global regulations
- Flexibility to adapt rapidly to fluctuating case volumes
- Handle regulatory inspections effortlessly with confidence

Global Presence



Head Office:
15 Corporate Place South
Suite 111
Piscataway, NJ 08854 USA
Tel: +1 (732) 529-6989
@: info@4cpharma.com



4C

Your Responsibility
Our Passion

WHAT WE OFFER

WHO WE ARE

Comprehensive Pharmacovigilance, Regulatory Affairs, Medical Writing Training and Argus Hosting Solutions

We are equipped with

- ISO 9001:2008 Certification
- ISO 27001:2013 Certification
- OSP Certification
- Validated Ready to Use Argus Safety System

We pledge by

Complete - Complete Services
Correct - Correct Actions
Consistent - Consistent Results
Compliant - Compliant Regulations

Drugs, Devices, Biologicals, Nutraceuticals, Biosimilars

Pharmacovigilance

- Literature Search
- Case Processing
- Electronic Submissions
- Periodic Reports
- Signal Detection
- Risk Management
- Medical Monitoring
- PV Department Setup
- Training
- SOP Preparation

Medical Information Call Center

- 24X7 Support
- Global & Multilingual Support
- Qualified HCPs for MICC
- Inbound MI / AE / PQCs
- Follow-up Calls with Targeted Questionnaires
- Field Alert Reports Filing
- FAQs, MSLs and DHPC
- Product Replacement & Refund Support
- User-friendly dashboard with metrics

Regulatory Affairs & Medical Writing

- Regulatory strategy
- Global / Country Specific Submission
- CTD / NeeS / eCTD Compilation and Publishing
- Class Labeling & Artwork
- CCDS / CCSI / SmPC / PIL Authoring, Review and Updates
- Regulatory Information Management
- Lifecycle Management Support
- Manuscripts
- Clinical & Nonclinical Overviews
- Medico Marketing Writing
- Regulatory / Technical Writing
- Scientific Posters

Argus Hosting & Support

- Argus Implementation - Cloud / On-Premise
- Computer System Validation
- Database Configuration / Customization
- Workflow & Dictionary Management
- Business & Reporting Rules
- Integration with Other Tools & Modules
- Data Migration
- Patches / Upgrades
- Technical & Functional Support
- Argus Training
- Regulatory compliance (HIPAA / 21CFR / EU Annex 11)
- Custom Reports and Metrics
- Business Continuity & Disaster Recovery

QA / QC (Language / Medical Review), Good Clinical Practices, FDA, EMA, InfoSec Compliance