



## COMPLIANCE MATTERS



# Company Overview



Year Established

**2009**  
(HQ: Ahmedabad,  
Gujarat, India)



Global Access

**4**  
Global Offices



Employees

**105+ FTEs**  
**90+ Consultants**



Clients

**450+**  
Clients globally  
7 of Top 10 Generics  
3 of Top 10 Innovator



Certifications

**ISO 9001**  
**ISO 27001**  
**ISO 13485**



Industries

Pharmaceuticals  
(Generics/Innovations),  
Biotech,  
Medical Devices  
Consumer Health

## AWARDS & RECOGNITION

- Top 10 Clinical Research Service Provider Organizations award by **Silicon India-2018**
  - Best Healthcare Brand – Gujarat 2018 award by **CMO Asia and ABP News**

## SERVICE PORTFOLIO



### GCP Services

- Monitoring – BA/BE/Phase I
- Monitoring – Late Phase (Phase II & III) Clinical Trials
- Monitoring – Bioanalytical, PK- Stat
- CRO Set-up & Up-gradation
- Audits (Qualification-GCP/GLP Investigation, Project based)
- Clinical Programme Management



### GMP Services

- Supplier Qualification Audits
- GMP Audit Reports Library
- Regulatory Accreditation
- Plant Set-up & Engineering
- Technical Qualification Services
- GMP Compliance and QMS Upgradation



### Regulatory Affairs

- Regulatory Operations
- Regulatory Affairs
- Regulatory Intelligence, Information Management COTS
- Regulatory Strategy & Business Consulting
- Health Authority Mandates
- Regulatory Labeling and Artwork
- Regulatory Software
- Medical Writing and Pharmacovigilance



### Pharmacovigilance

- ICSR Management
- Aggregate Safety Reports
- Risk Management Plan
- Signal Detection
- Medical Information Call Centre
- Other Integrated Services



### Programs & Consulting

- Product Development (Dossiers)
- Regulatory & Clinical Strategy
- Clinical Program Management (CPM)
- Tech Transfer Programs
- In Out Licensing
- Onsite & Off-shore Support
- Go To Market (GTM) with commercial services
- Knowledge process outsourcing (KPO)

## Why Pharmazone?



Integrated Solution range spread across entire drug development chain & product life cycle.



Strong Brand Legacy and experience of Executing 5500+ Regulatory & GxP Projects



Most organized midsize Regulatory & Pharmacovigilance firm in APEC Region



Team of 200+ GxP & Regulatory Consultants/Experts located globally



Flexible Working Model for Regulatory & PV Services: Project Based, FTE Based & Hybrid



Robust Operations, Delivery Team & QMS System



Satisfied Clientele of 450+ customers from USA, EUROPE, CHINA, INDIA & ROW



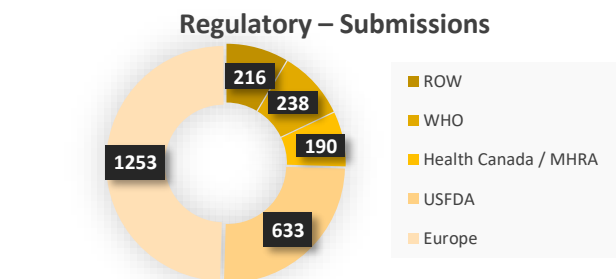
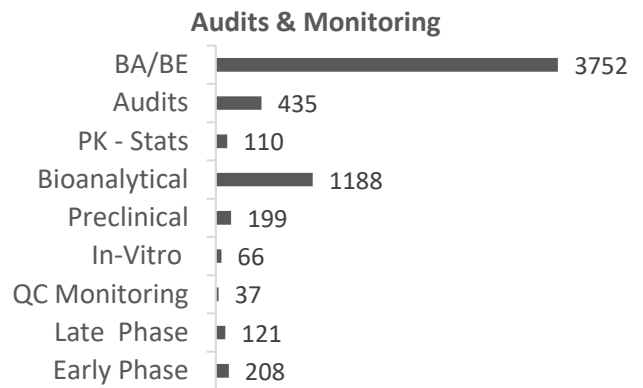
Project Footprints in 45+ countries



Pioneer in the field of GxP Audits & Consulting



Customized consulting solutions & complete support for “Go to Market” Strategies



#### CROs Monitored

- 115+ BE CROs
- 160+ Hospital Sites

#### Total Project Monitored

**4700+**

#### Client Served

**300+**

#### CRO Setup and Upgradation

**41+**

## GLOBAL FOOT PRINTS



Field Force - Monitoring



Offices



Client Locations

**Head Office** - 402, Shafalya Elegance, Science City Road, Sola, Ahmedabad, Gujarat, India



[www.pharmazones.com](http://www.pharmazones.com)



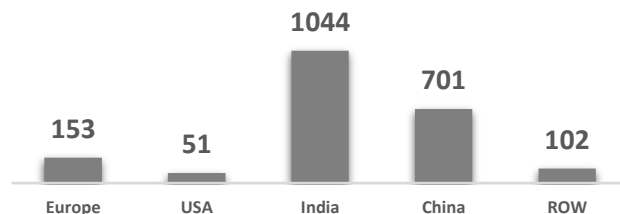
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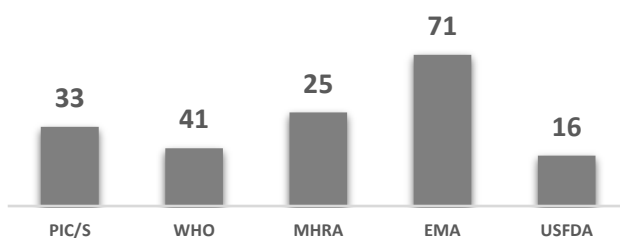


## Supplier Qualification Audits

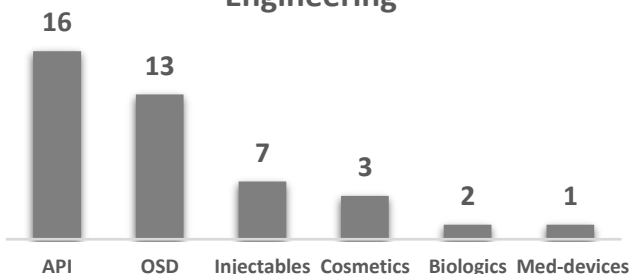
(API, Intermediates, KSM, PM, CDO – Lab & FDF's sites)



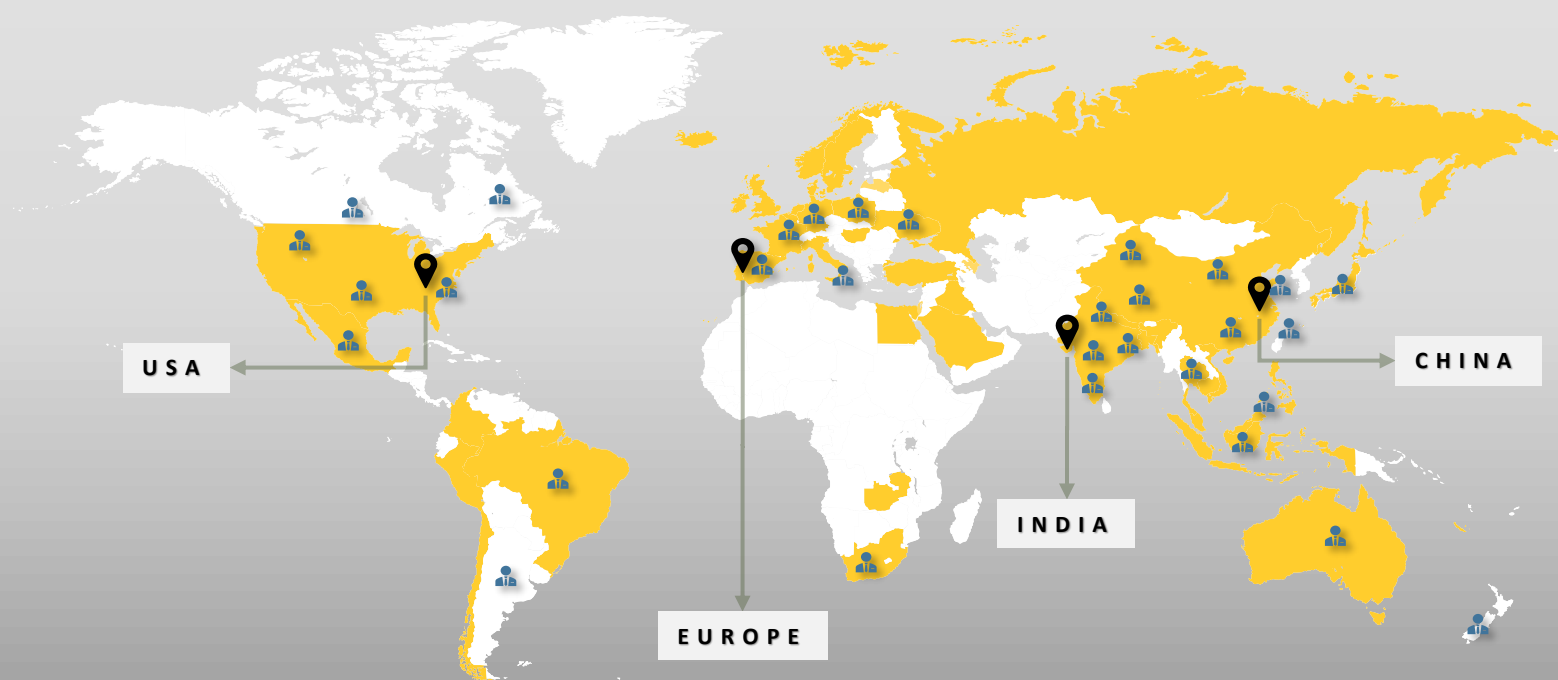
## Certification & QMS Upgradation




## Engineering



## GLOBAL FOOT PRINTS



 Auditors

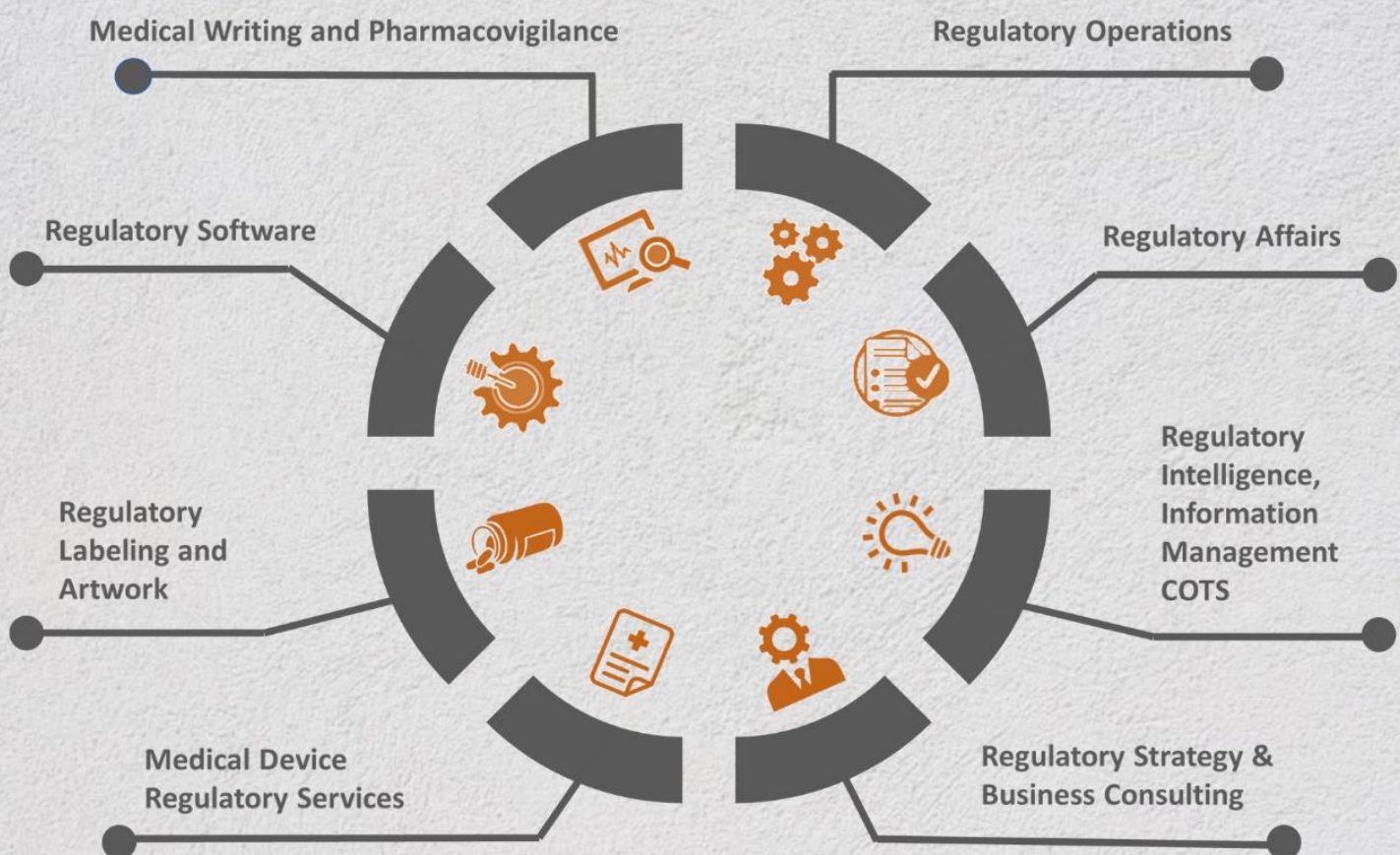
 Offices

 Client Locations

**Head Office** - 402, Shafalya Elegance, Science City Road, Sola, Ahmedabad, Gujarat, India

## REGULATORY CONSULTING SERVICES

Pharmazone's regulatory consulting team comprises senior pharmaceutical regulatory experts with extensive experience in product/devices development, preparation of global registration strategies and successful registration of products and medical devices with regulatory authorities worldwide. Our team develops and manages product-device-indication-specific global regulatory strategies that enable the most efficient registration pathway(s) and yield a high probability of getting successful approval.



### Pharmazone Experience Snapshot

**4 Global Offices | 15+ year's of Legacy | Experienced Team |**

**380+ projects | 1200+ Products Supported in 30+ Countries Globally |**

**Wide range of areas covered including Orphan Drugs, Oncology, Bio-tech, Medical Devices & Nutraceuticals.**



## INTEGRATED PHARMACOVIGILANCE SERVICES

Pharmazone offers comprehensive Pharmacovigilance and safety monitoring services from early development support through post-approval initiatives to established life sciences and medical device companies to meet their Pharmacovigilance obligations, maximise their drug/device development success and therefore their product value. We have experienced and skilled medical and science professionals with first-hand knowledge of Pharmacovigilance requirements. Pharmazone Pharmacovigilance Services Includes:

### ICSR Management

- Case intake and Triage
- Data entry
- MedDRA Coding
- Narrative preparation
- Quality control and medical review
- Reporting

### Risk Management Plan

- Risk Identification
- Risk management plan development
- Development of risk minimization
- Assessment of risk minimization
- Risk Communication & Implementation

### Medical Information Call Centre

- Inbound/Outbound Calls
- Collection of Reports
- Product complaints
- Medical information
- 24 X 7 Support

### Aggregate Safety Reports

- Periodic Safety Update Reports (PSUR)
- Benefit-risk evaluation report (PBRER)
- Periodic Adverse Drug Experience Report (PADER)
- Developmental Safety Update Report (DSUR)
- ACO reports – Addendum to clinical overviews

### Signal Detection

- Signal Detection, Prioritization, Assessment, Analysis, & Evaluation
- Statistical Analysis in Large AE Databases
- Active Surveillance
- Signal Assessment using PV database

### Other Integrated Services

- QPPV Services
- Literature search and medical information
- Complete Pharmacovigilance system set-up
- SOP development & Implementation
- Inspection and Audit support
- Archival Management
- Training & IT Systems Management Support

## Pharmazone Experience Snapshot

**4 Global Offices | 15+ year's of Legacy | Experienced Team |**

**135k+ ICSR cases processed | 920+ Products Supported in 35+ Countries Globally |**

**Wide range of areas covered including Orphan Drugs, Oncology, Bio-tech & Medical Devices.**



**CHINA**

Room 1903, 350 Jingang Rd, Pudong,  
Shanghai, China

**USA**

7950 Old River Road, NC 28425 USA

## Global Locations

**INDIA**

402, Shafalya Elegance, Nr. Shakti  
Arcade, Science City Road, Sola,  
Ahmedabad 380060, Gujarat, India.

**Europe**

Campo Grande, 28, 3rd C, - Lisbon,  
district of Lisbon, municipality of  
Lisbon, parish of Alvalade - Portugal



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