Pharmazone

402, Shafalya Elegance Nr. Shakti Arcade, .
Science City Rd, Sola, Ahmedabad, Gujarat – 380060 .

Pharmazone

Company Overview

Year Established

2009
(HQ: Ahmedabad, Gujarat, India)

Global Access

4
Global Offices

Employees

145+ FTEs
100+ 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**

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SERVICE PORTFOLIO

GXP Services

- GMP Audits
- GCP Audits & Monitoring
- GDP Audits
- GLP Audits
- GVP Audits

Quality

- QMS
- Audits and Inspection Readiness
- Qualification and Validation
- Digitalization Support
- Remediation
- M&A Due Diligence

Regulatory Affairs

- Submission & Publishing
- Artwork & Labeling
- RIMS (Regulatory Information Management System)
- Dossiers, e-CTD, DMF & CEP
- Intelligence & Market Access
- Medical Devices & Biologics

Pharmacovigilance

- ICSR/Case Processing
- Literature Search
- Aggregate Reporting
- Signal Management
- Risk Management
- QPPV Services
- Medical Information

Pharmaceutical Engineering

- Greenfield & Brownfield
- FAT Audits

Programmes & Consulting

- Product Development & CMO
- Clinical Programs Management
- MA Licensing (Market Authorization) & Supply
- Tech Transfer Support
- GTM (Go To Market) Services

www.pharmazones.com

bd@pharmazones.com

Pharmazone

Why Pharmazone?

- Integrated Solution range spread across entire Drug Development Chain & Product Life Cycle.
- Strong brand legacy and experience of executing 6000+ Regulatory, Quality, GxP & PV Projects
- Most organized midsize Regulatory & Pharmacovigilance firm in APEC Region
- Team of 240+ GxP & Regulatory Consultants/Experts located globally
- Flexible Working Model : 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 70+ countries
- Pioneer in the field of GxP Audits & Consulting
- Customized consulting solutions & complete support for “Go to Market” Strategies including EU – GMP Support

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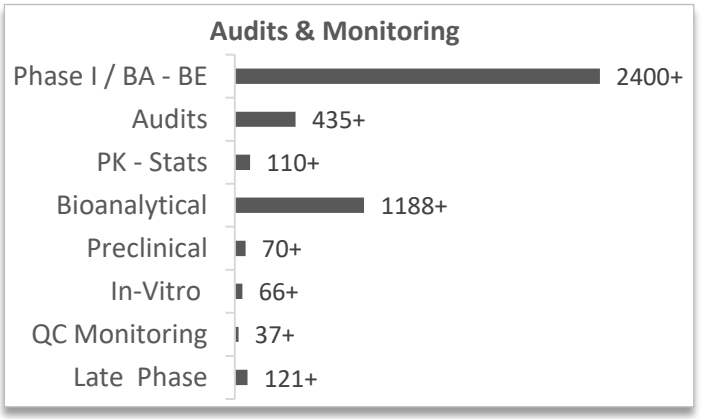
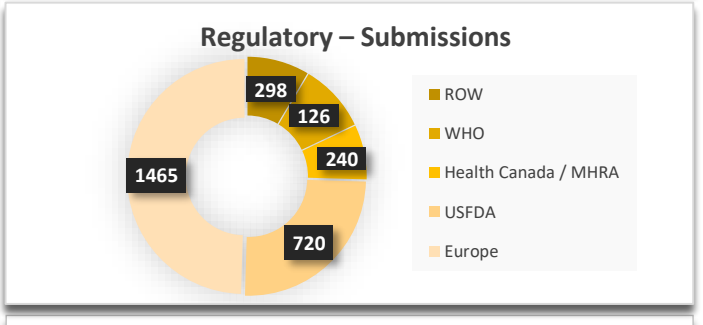




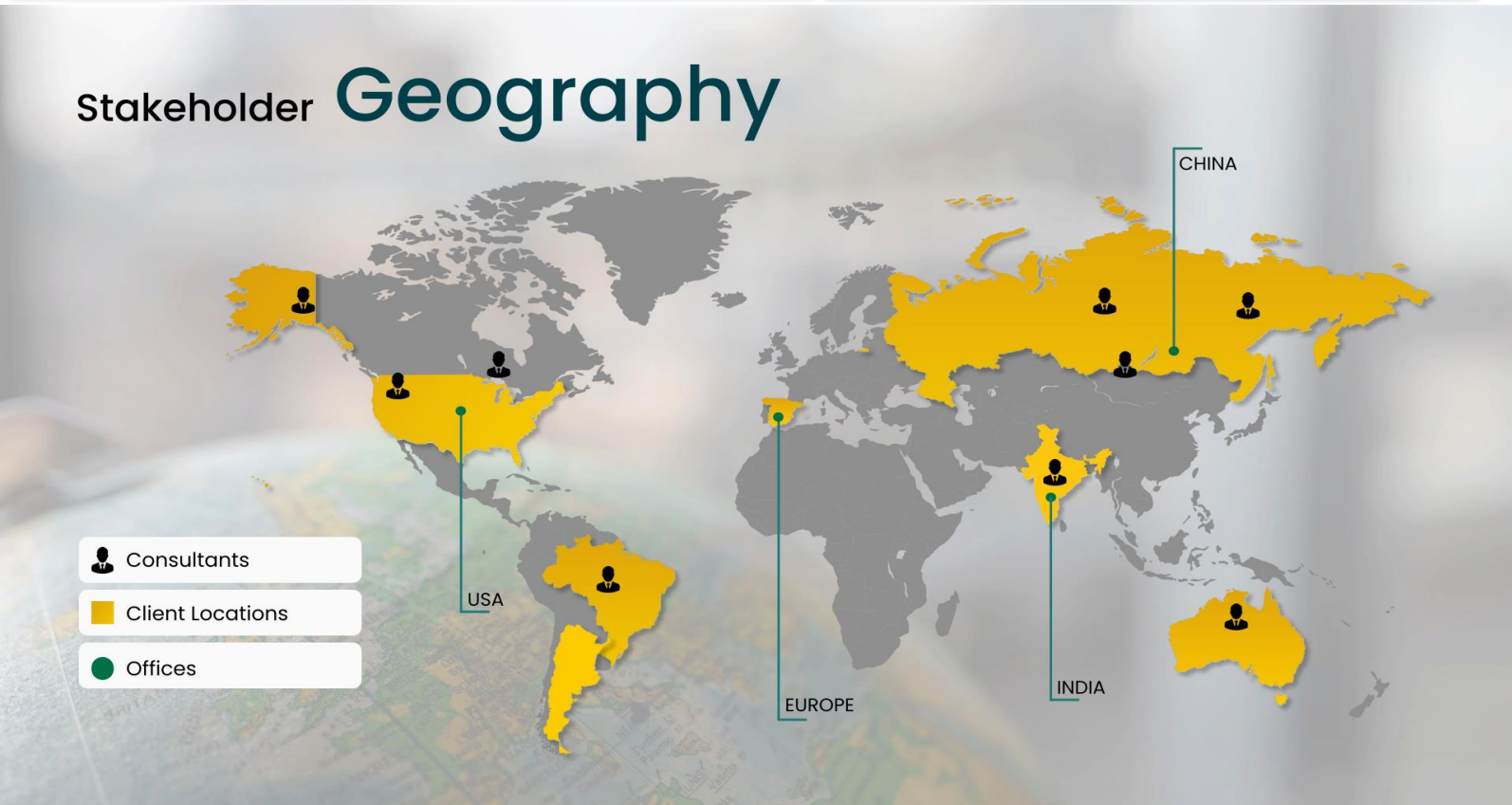
CROs Monitored
- **115+** BE CROs
- **160+** Hospital Sites

Total Project Monitored
3100+

Client Served
300+

CRO Setup and Upgradation
41+

Stakeholder Geography



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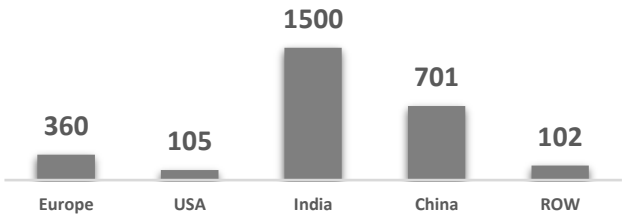
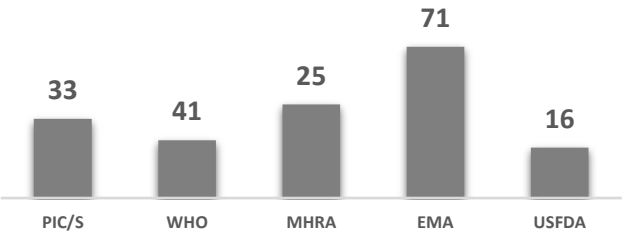
Total Projects
3000+

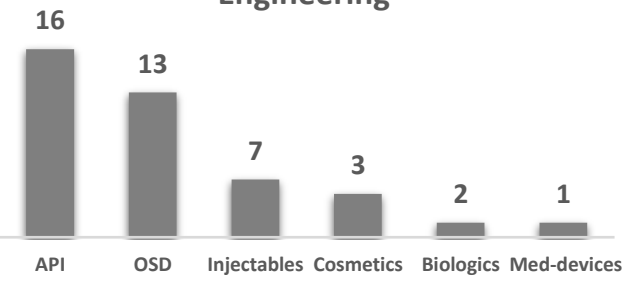
Supplier Qualification Audits
(API, Intermediates, KSM, PM, CDO – Lab & FDF's sites)



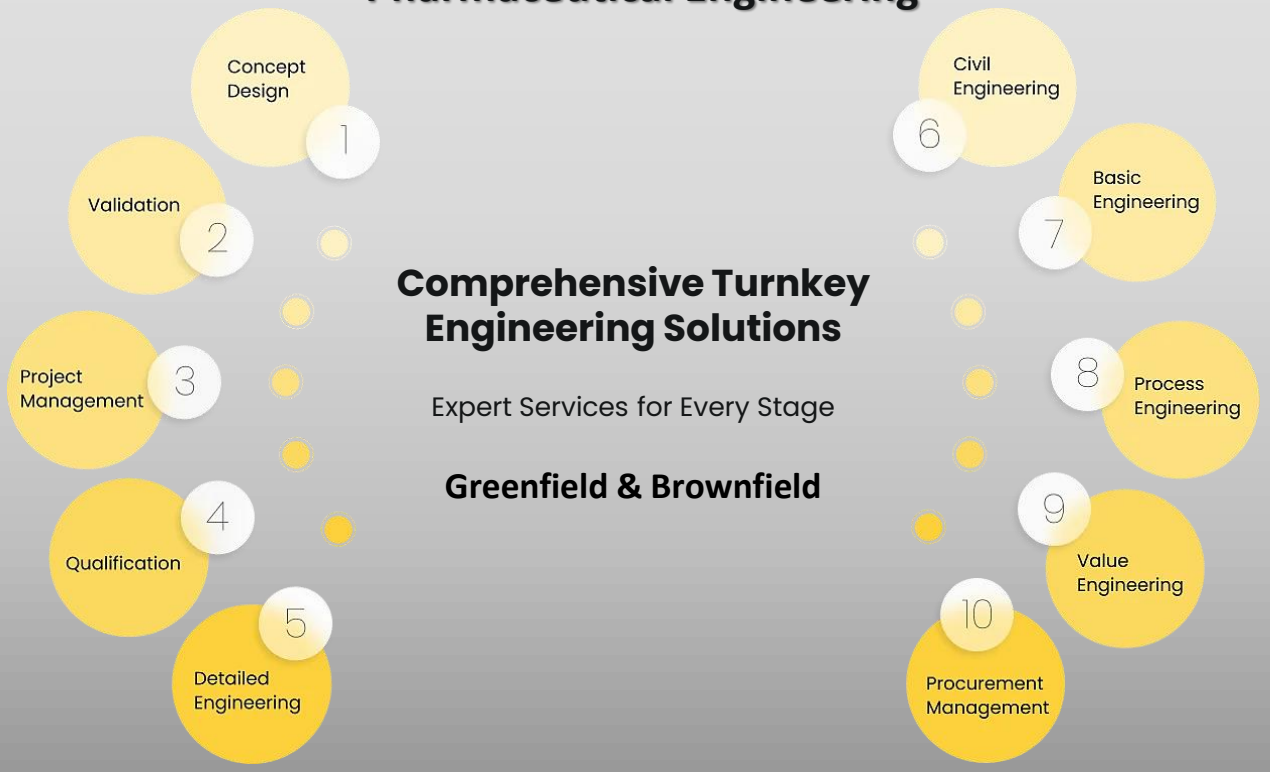
Certification & QMS Upgradation



Engineering



Pharmaceutical Engineering



Comprehensive Turnkey Engineering Solutions

Expert Services for Every Stage

Greenfield & Brownfield

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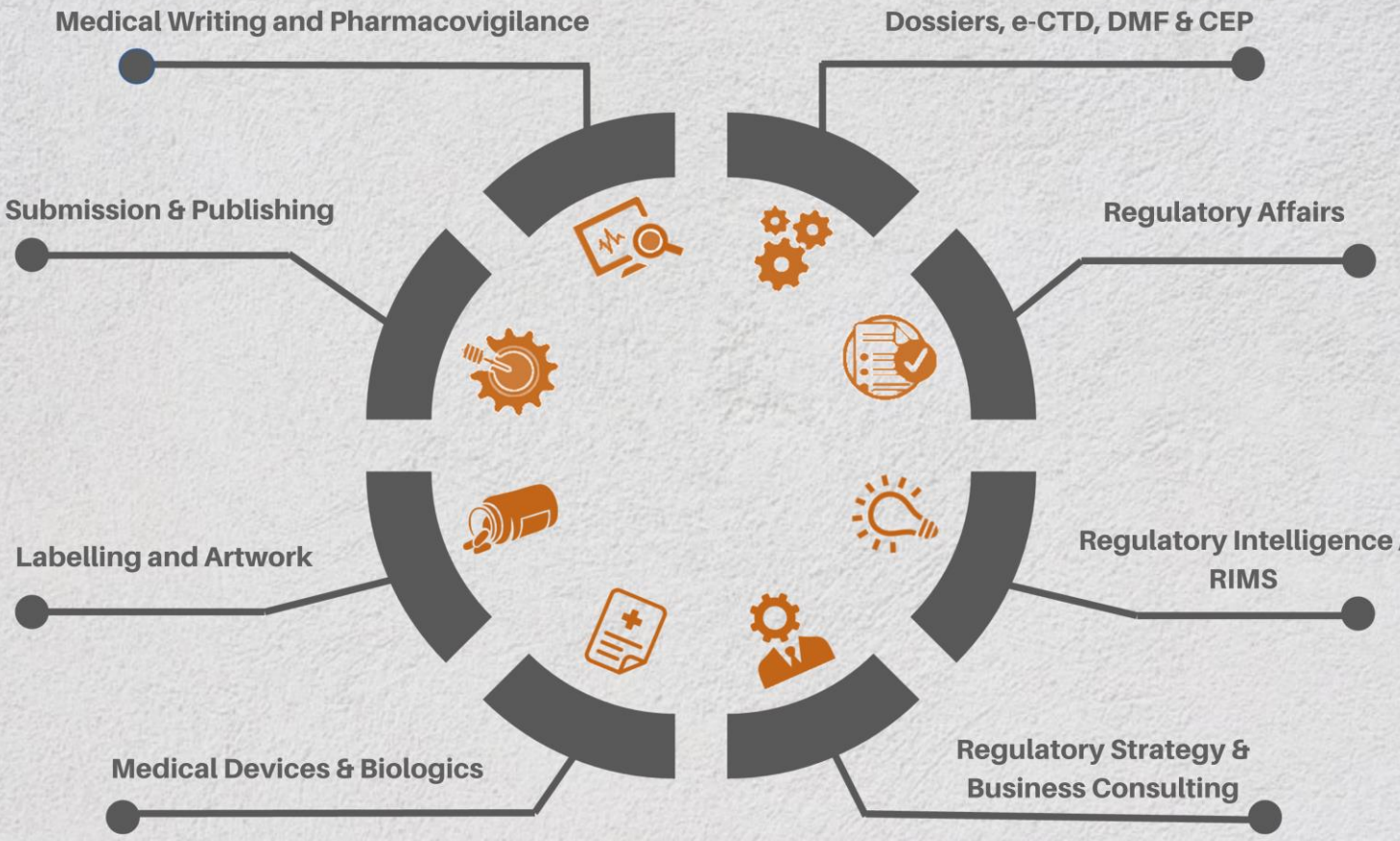
REGULATORY CONSULTING SERVICES

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 |

400+ projects | 1200+ Products Supported in 30+ Countries Globally |

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

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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

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

Risk Management Plan

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

Signal Detection

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

Medical Information Call Centre

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

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 |

210k+ ICSR cases processed | 4M+ Literature | 900+ Aggregate Reports | 920+ Products Supported |

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

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Pharmazone

CHINA

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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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COMPLIANCE MATTERS

Get in touch with us by scanning the QR Code