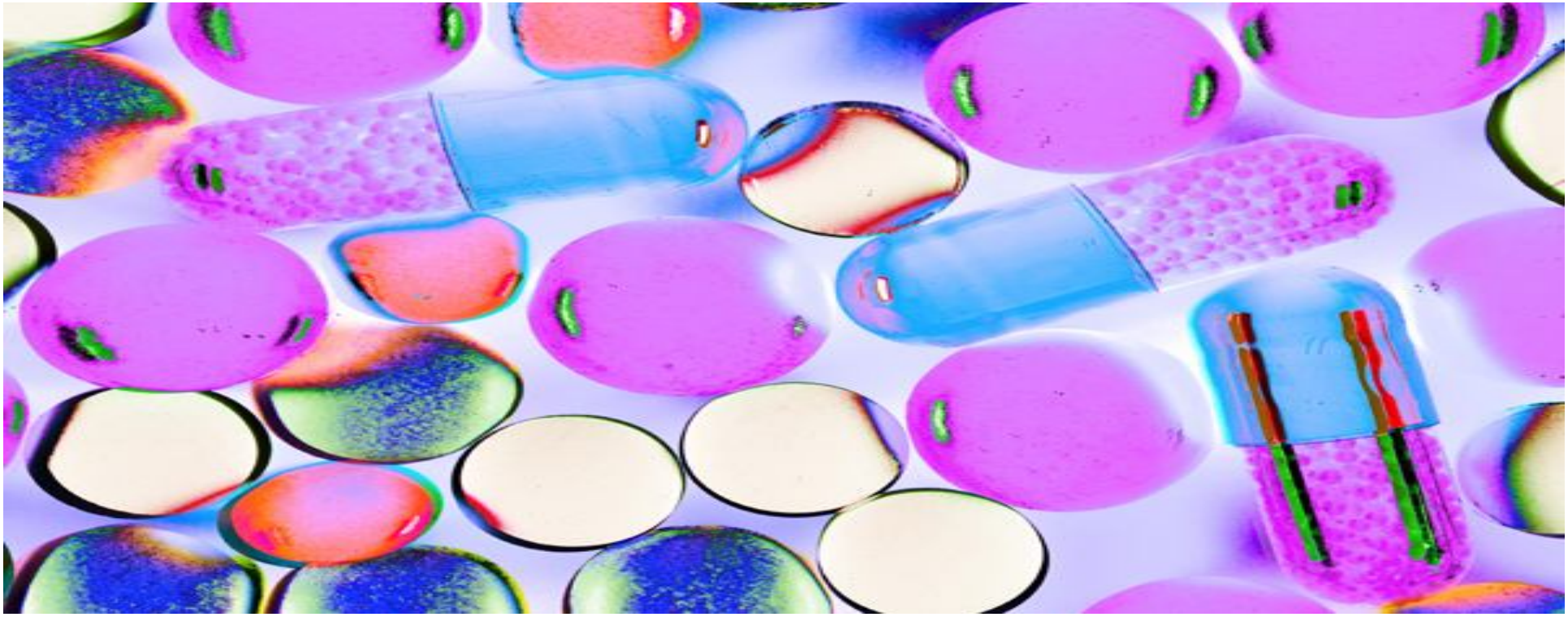

PharmaZone
Your Prefered Research Partner

" DIFFERENT SKILLS WORK TOWARDS SAME VISION
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Agenda

1. **Introduction**
2. **History**
3. **Services**

Introduction

- A company established in 2008 with an aim of becoming the total solutions provider organization in the field of Pharmaceutical research.
- Now a team of total 16 people with highly diverse and scientific background
- Our experts from different domains like Regulatory, Medical affairs, clinical trials, PK studies, API, Formulations, Manufacturing, Marketing enriching our service offering with their vast national/international experience.

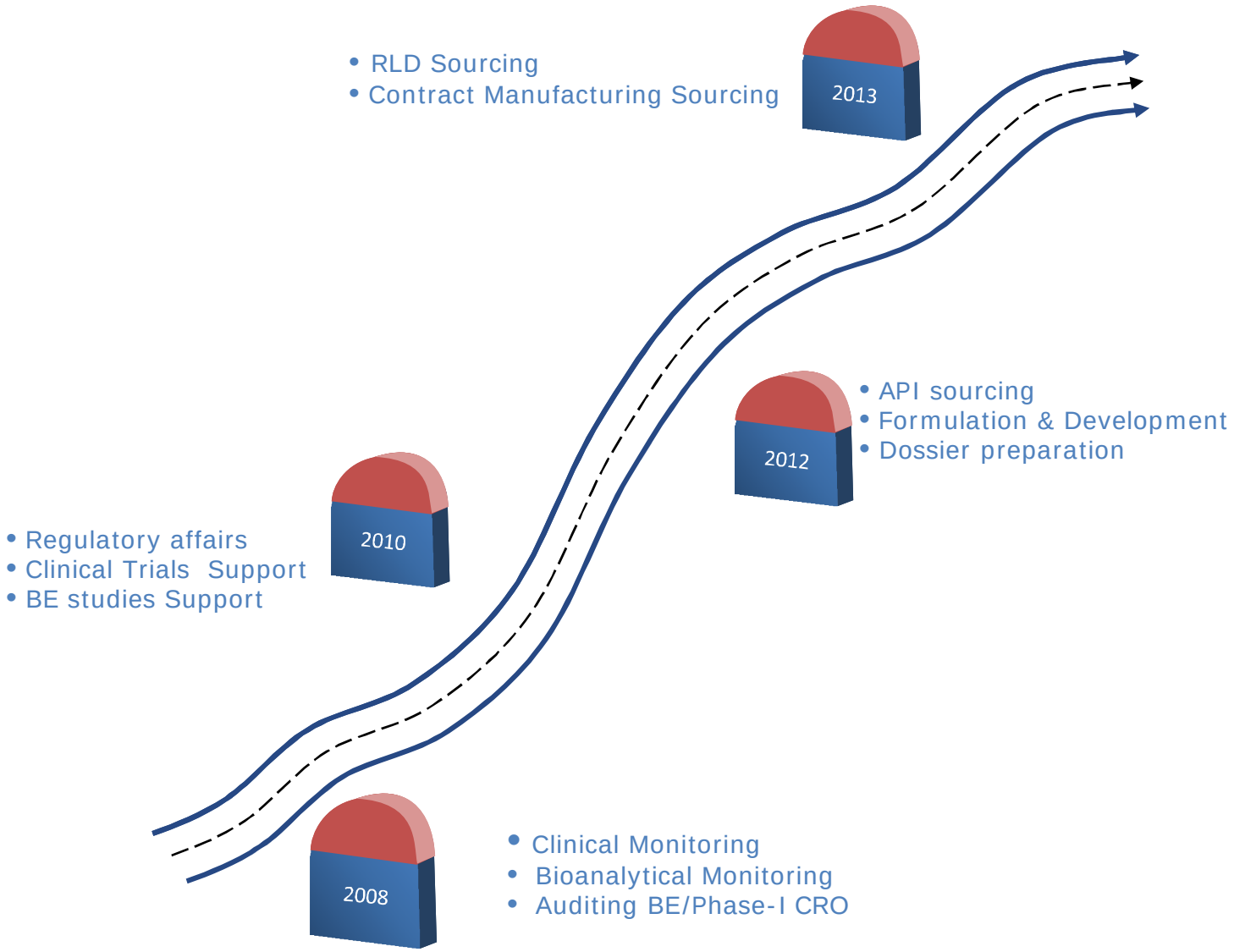
Mission:

To be best quality and most trusted Pharmaceuticals Support Service company globally.

Vision:

To crate a plateform where all possible solutions are available for Pharmaceutical Research and Development

History


• RLD Sourcing
• Contract Manufacturing Sourcing
2013
• API sourcing
• Formulation & Development
• Dossier preparation
2012
• Regulatory affairs
• Clinical Trials Support
• BE studies Support
2010
• Clinical Monitoring
• Bioanalytical Monitoring
• Auditing BE/Phase-I CRO
2008

Services

1 Auditing/ Monitoring

- o Clinical Monitoring of Phase trial and Bioequivalence studies
- o Bioanalytical Monitoring of Phase trial and Bioequivalence studies
- o System audits of Bioequivalence/Phase I CRO
- o GMP Audits

2 Clinical Research Support

- o Phase II to phase IV trials management Support
- o PK and PD studies Support
- o Medical Writing
- o Regulatory affairs

3 Pharmaceutical Research Support

- o API sourcing
- o Formulation Development
- o Bulk drug manufacturing
- o Dossier preparation

Auditing/ Monitoring

1 Clinical Monitoring of Phase trial and Bioequivalence studies

Activity

Independent Monitoring and Auditing of Clinical phase is done through…

- Pre study or Feasibility Monitoring Visit
- Site Initiation Visit
- Interim Monitoring Visit
- Site Close Out Monitoring Visit

Area of expertise are as follows;

- Bioequivalence and bioavailability Studies
- First-in Human Clinical Studies
- Dose Escalation Clinical Studies
- Multiple Dose Clinical Studies
- Multiple Day Dose Clinical Studies
- Dose Proportionality Studies
- Dose Tolerability Studies
- Thorough QT/QTc Studies
- Phase II Clinical Studies
- Phase III Clinical Studies
- Phase IV Clinical Studies

- ***All Processes are driven by already approved Pharmazone SOPs which can be shared with client upon request.***

Experience

o Clinical Monitoring of 18 sites during 2 phase II trials

o Clinical monitoring of 7 Phase 1 trials

o Clinical monitoring of more than 450 Bioequivalence studies- different regulatory submisssions

o Clinical monitoring of more than 60 bioavailability studies

Auditing/ Monitoring

2 Bioanalytical Monitoring of Phase trial and Bioequivalence studies

Activity

- Audit of sponsor or contract bioanalytical laboratory systems to assess sample assay performance and adherence to established procedures, industry standards, In house SOPs and FDA guidance for method validations, sample assays, and data reporting.
- Audit of Computer System Validation (CSV). Assessment of Reporting, Laboratory Information Management Systems (LIMS), or other data collection systems
- Assessment of all documentation procedures, study documentation, MD and MV reports

Bioanalytical monitoring Service is offered through…..

- **In Process Monitoring**: When biological samples are loaded in machines and Analysis is going on. All the samples of some subjects are monitored In process. (Choice of subjects is on random bases)

- **Retrospective Monitoring:** When analysis of all study samples is over. It includes all the Raw data check, samples check, Instrumentation check, all study data including draft Bioanalytical Report check

- ***All Processes are driven by already approved Pharmazone SOPs which can be shared with client upon request.***

Experience

Successfully done

o Bioanalytical feasibility audit at 25 CROs in India.

o In process monitoring of more than 80 BA/BE studies

o Retrospective monitoring of 250 BA/BE studies

Auditing/ Monitoring

3 System Audits of Bioequivalence/Phase I CROs

Our experienced team of auditors have vast experience of working in different BE/Phase I CROs as well as to establish their systems. Our system audit service covers entire systems, SOPs, Infrastructure, Regulatory audit and approval history, Human Resources and all other aspects of CRO

System Audit covers the audit of following departments

- o Clinical
- o Bioanalytical
- o PK and Bio-Statstical
- o Project Management
- o Regulatory Affairs
- o Medical Writing
- o Quality Assurance
- o Quality Control
- o Training and Development
- o HR and Admin (Supportive dept.)
- o IT (supporting dept.)

All Processes are driven by already approved Pharmazone SOPs which can be shared with client upon request.

Experience

Successfully done

o System Audit of 20 BE CROs/Sites in India.

o System Audit of 03 BE CROs out of India, based in Jordan, Canada

Auditing/ Monitoring

4 GMP Audits

Activity

With help of our vastly experienced and expert auditors we offer following auditing services

- GMP audits of Drug Manufacturing facilities
- Audits of Formulation and Development facilities
- GLP audits

Experience

o Our GMP auditor has experience of working more than 20 years in Pharmaceutical industry

o Has successfully carried out plenty of GMP audits of different Manufacturing facilities.

o Experience of setting up facilities and systems for many pharmaceutical companies in India. (For more than 15 companies including small, medium and large scale companies)

Clinical Research Support

1 Phase II to phase IV trails management Support

Activity

Phase II-IV clinical trial management services to Pharmaceutical, biotech and medical device companies through our associate CROs.

We propose

- Clinical Study Development Plan
- Clinical Study Feasibility across the country
- Budget Development
- Investigator Selection
- Regulatory Submission
- Investigator Meeting Coordination and Conduct

➢Special expertise in conducting cardiology medical device trials like cardiac stents and pacemakers.

➢Access to 40 full time cardiologist expert in doing large scale medical device trial in cardiology, through our collaboration with VIBGYOR Scientific Research, Ahmedabad.

Sourcing Experience

- 2 First in Man device trial
- 4 Pivotal studies of Device trials
- 1 Post- marketing surveillance study in cardiac device
- 1 study on Implantable graft during Vascular Surgery

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2 Pharmacokinetics and Pharmacodynamic Studies Support

Activity

Due to our huge experience in Auditing and Marketing area, We know all Indian and Some of Non-Indian CROs in better ways through their systems and procedures. We make sure that you get the best partner of choice for your study conduct by ensuring following

o Compound specific method validation report
o Submission specific (USFDA, ANVISA, AFSSAPS, WHO, MHRA, DCGI) Regulatory Audit and Approval details for the sponsor
o Best prizing for the sponsor from various Biocenters in India
o Audit before study initiation this includes Feasibility Audits of CROs by assessment of Clinical, Bioanalytical, Biostastical capabilities including complete systems.
o Independent monitoring services on behalf of sponsor during the study conduct

Bioequivalence Studies :

- Fasting / fed effect
- Immediate / modified-release preparations
- In Vitro / In Vivo Correlation
- Dose escalating studies/ Multiple dose / Steady state studies
- Drug-drug interaction studies
- Healthy volunteers / special population studies/ Patient based studies

Clinical Research

3 Medical Writing

Activity

Experience

o Clinical trial protocol for 3 phase IV studies

o Clinical trial protocol for 3 PK/PD studies on patients

o Informed consent for and CRF preparation for 3 phase IV studies

o Review and editing of more than 50 bioequivalence studies report

o Review and editing of more than 20 bioavailability studies report

4 Regulatory affairs

Our regulatory experts based out of USA and Europe having wide experience of working with USFDA takes care of your regulatory requirements with their vast experience and associations.

Services	Regulatory Body
Protocol review from the regulatory experts	USFDA
IND, ANDA submission to FDA and its follow up	USFDA
API- USDMF submission to EU countries and its follow up	USFDA

Experience

- 3 Clinical trial application
- 22 DCGI NOC
- 26 Import license and 2 Export license
- 6 Protocol review from FDA
- 2 IND submission to FDA
- 5 ANDA submission to FDA

Pharmaceutical Research

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1 API Sourcing

Activity

Strategic collaboration with many Indian companies who have a vast experience of preparing EDMF ,US-DMF and DMF for semi regulated market

How we work

•Act as a complete facilitating partner between our client Pharmaceutical companies and our trustworthy supplier companies.

•Identify the specific requirements of our client Pharmaceutical companies for API, other Raw materials, intermediates, Excipients .

•Find out the right sources from domestic market who can provide them all above mentioned with proper quality and competitive cost with all applicable regulatory guidelines into consideration.

Sourcing Experience

Sourced more than 30 API for various clients in US, Europe, Taiwan and Turkey

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2 Formulation Development

Activity

In association with our partner formulation development CRO (CMO), We offer following formulation development services;

o Complete analytical development and validation as per ICH requirement.

o RLD evaluation

o Drug excipient interaction study

o Formulation development to match the dissolution property of RLD in OGD and multimedia dissolution.

o Accelerated stability in primary pack along with RLD

o Scale up-identifying the critical process parameters and process optimization.

o Technology transfer

o Bio-batch or exhibit batch manufacturing

Sourcing Experience

O Presently supporting formulation development for 02 ANDA

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3 Bulk drug manufacturing

Activity

Our associates possess expertise in the manufacture of high volume Finished Dosage Forms and effectively control their release profile. This expertise is in the field of sterile as well as non-sterile dosage forms.

Pharmaceutical bulk drug manufacturing plants of our business associates have been accredited by highly respected international regulatory bodies like the US FDA, ISO, UK MHRA , MOH Turkey, MCC (South Africa), WHO (Geneva) and TGA (Australia).

Sourcing Experience

Few business proposals are under discussion

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4 Dossier Management

Activity

With our experts associates we offer services for dossier management

o preparation of dossier for US-FDA, EU, TGA, MCC, WHO in eCTD format.

o Review and submission of the dossier to the specific countries with the help of our agent in the local countries

o Management of regulatory queries on the dossier within minimum possible time

With our network in Pharma industry across the world we also manage In licensing and Out licensing of the dossier for various countries.

Experience

o worked on one ANDA submission to FDA

o Out licensed two dossier for MOH Turkey

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India

A - 204, Satyamev II,
Nr. Gujarat High Court,
Opp. Kargil Petrol Pump,
S. G. Highway,
Ahmedabad, 380061,
Gujarat,
Telefax: +91 079 27660750
E: info@pharmazones.com

THANK YOU