Vision:"To empower the global pharmaceutical industry en bloc and the dependent business entities leverage their core strengths of drug discovery, development and commercialization through our combined outsourcing expertise in CMC."

Profile: **Pharmaffiliates Analytics & Synthetics** (P) Ltd, is an integrated **CMC** (Chemistry, Manufacturing and Control) services Provider offering its expertise in Custom Synthesis, Analytical, Quality Assurance and Regulatory services with a right blend of competent people, **state-of-the-art infrastructure** facilities, cutting-edge technology and **certified processes** to pump your development pipeline with time & cost advantages and thus combat in the highly competitive markets and also acquiring the niche segments. We serve to be your strategic partner for outsourcing and help you right from strategic planning of CMC blue-print to accelerating the filing & representation for **NDAs and ANDAs** submitted in any regulated and semi-regulated markets, which save your time and efforts by focusing them in your core areas of operations.

Since its inception in 2001, Pharmaffiliates has been servicing customers across the globe and have capabilities to serve veteran pharmaceutical companies, API manufacturers, bulk drug suppliers, clinical CROs and other allied industries of **hydro-carbon value chain**. Our robustness in successful service delivery has its origin from a foundation of classical and modern chemical/research methodologies and process driven **ethical business practices**, which enables us to face the challenges of progressive and dynamic Life sciences industry. We are dedicated to cultivate and house a strong scientific base of the highest quality and striving to meet the needs of our clients, which made us the **first Indian company** to provide third party audits in India and neighboring countries on behalf of the European manufacturers in accordance with the EMEA requirements and so far audited more than 14 companies and another group of 8 awaits our audit.

Team:A war can't be won without a good leader and the very essence of leadership is that you have to have vision and we are headed by our founder and visionary **Dr.A.K.Sabharwal** who has over 30 years of Industrial experience in Pharmaceutical Research, Quality Assurance and Regulatory affairs with major global pharma giants. He has successfully handled breakthrough research projects and also number of inspections conducted by regulatory authorities like **US-FDA, MCC, TGA Australia, MHRA, HPB Canada & Hungarian Health Authorities** etc. and has been instrumental for Approval of numerous APIs and Drug products from Regulated Authorities.

Pharmaffiliate's young and dynamic team includes visionary leaders, **highly-skilled scientists**, management professionals and other competent technical staff, drawing on a range of experience from the academic and private entities. With an access to state-of-the-art infrastructure and equipment, and we have perfect techniques for the synthesis and analysis of new chemical entities (NCE), impurities, metabolites and starting materials for your pre-clinical and clinical research. We have extensive experience in custom synthesis, developing **analytical techniques** for ensuring the quality of your APIs, Intermediates, formulations, specialty fine chemicals and allowing us to act as your strategic partner for all CMC services with reliability, cost effectiveness and high success rate. Our commitment to our clients is to provide excellence and integrity in science, complemented by our uncompromising drug quality, absolute confidentiality, **dependable project management**, timely delivery and responsive customer service.

Quality: As a company founded by researchers, we recognize the inextricable connection between the quality of tools and practices and the success of research. Our commitment to quality is exemplified by our **ISO 9001:2008 & ISO 17025:2005 certification**. All our services are delivered according to strict **ICH-GMP/GLP** guidelines and are accompanied with certificates of analysis. All studies are performed after the protocols are approved by our customers. Customers have option to either follow protocols available with Pharmaffiliates or provide us the protocols of their own. Complementing to our full commitment to quality, we allocate uncompromised resources to innovate best practices and tools that fosters the drug discovery and development.

A brief overview of service portfolio was detailed below. We shall send you **further details** of our independent service(s) upon request. In case of confirmed date of visit and list of visitors.

Reach us at info@pharmaffiliates.com

Visit us at www.pharmaffiliates.com

Services Overview

We are a **Contract Research Organization** (CRO) providing synthesis & analytical services for drug substance development in the milligram to gram scale quantities to the pharmaceutical industry in most aspects of the drug development process. Our state-of-the-art facilities, equipment and procedures have been designed for the production and certification of compounds that may be used in pre-clinical and post clinical studies which will be submitted to regulatory agencies worldwide, for approval of INDs and NDAs. Our service portfolio is broadly categorized as follows:

CUSTOM SYNTHESIS & ANALYTICAL SERVICES

- Synthesis of NCEs and intermediates required for Pre-Clinical studies.
- Design and scale-up Synthesis of pharmaceutical related substances from **mg to kg**.
- Development, Validation and Transfer of Analytical Methodologies as per ICH guidelines.

IMPURITYSYNTHESIS &PROFILING

- Isolation, Identification, Characterization and Structure Elucidation of:
  - Reference Standards
  - Impurities
  - Metabolites
  - Degradation Products
  - Deuterated Compounds
- Synthesis of Impurities, degradation products andmetabolites
- Use state-of-the-art instrumentation

STABILITY STUDIES

- Stability programs which are geared towards high throughput production
- Stability Storage in full ICH compliant conditions.
- Stability testing of APIs, finished products, clinical testing material
- Stability ovens, walk-in chambers, Analytical instruments are 21CFR part 11 compliant.

REGULATORY CONSULTING & TRAINING

- Dossiers and ANDA in CTD-Q format for CMC
- Regulatory support for US-FDA, MHRA-UK, HPB-Canada, TGA-Australia, EMEA and Hungarian authorities.
- Third Party Audits
- GMP Training

Reach us at info@pharmaffiliates.com

Visit us at www.pharmaffiliates.com

Why Pharmaffiliates?

There are many companies that can provide Synthesis & Analytical services across the globe. We understand that. So why should you choose Pharmaffiliates over other players? Here are the Top 5 reasons to choose us as your strategic outsourcing partner:

1. **Locational Advantage:** As we are located in India, most English speaking population after USA with abundant trained and experienced scientists, availability of raw materials, low-cost infrastructure coupled with regulations which are aligned with International Regulatory agencies. **Pharmaffiliates** can directly offer 50-60% of cost advantage in pharma research and development still adhering to IPR norms.

2. **Global Quality Standards:** We strive to deliver matchless accuracy in results with unmatched quality consciousness, stringent audits, which monitor every step of the research process in compliance with International Study Protocol.All this supported by well trained and well-coordinated research personnel, integrity, innovation and confidentiality. We observe world standards to achieve best quality results i.e. ICH, USFDA and Good Laboratory Practice (GLP),since we are a **certified ISO 9001:2008 & ISO 17025:2005**CMC company.

3. **Leading Edge Facilities:** Our 25,000sft of instrumentation and lab facilities are located about 250 Km north of New Delhi and 10 Km from the Chandigarh airport at the foot hills of Himalayas at Panchkula. We shall provide you the list of equipment available in our independent service brochures upon request along with onsite photography

4. **Proven Expertise:** With more than 6 years of experience and expertise in Custom Synthesis,Impurity,Synthesis,Method Development-Validation-Transfer, Impurity Profiling, Stability Storage and testing, preparation of regulatory dossiers (CTD-Q) for CMC approval of NDAs and ANDAs and thus delivering end-to-end CMC services. We can also take up even the unsolved mysteries of custom synthesis of impurities, reagents, intermediates, metabolites from grams to kilograms capacity.

5. **Size Matters:** As we are small in size and are completely self-controlled, we don't have heavy overheads to pass on the same to our customers. Our cost control measures will be translated to enormous cost advantages for our clients.

6. Each Working standard is with its Certificate of Analysis, Chromatographic purity, Infra-red spectra, NMR spectra etc with interpretation. Typical Certificate of Analysis is enclosed

7. **Pharmaffiliates Team** strives to add more products to the existing list of keeping in mind the Regulatory requirements.

You Can reach us Below:-

Pharmaffiliates Analytics & Synthetics (P) Ltd.
Plot Number 225,Industrial Area, Phase II
Panchkula,Haryana-134109
India.
Telephone: +91-172-5066494
+91-172-5066495
Mobile: +91-9216119588

Email: info@pharmaffiliates.com