Infill Life Sciences
Creating the difference

Infill where you will find the **Solutions** & **Plans** to meet all your needs.

INFILL LIFE SCIENCES LLP

Pharmaceutical Consultancy Services

Let's Start the Conversation

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WHO WE ARE ?

Infill is the go-to consulting partner for companies small and large seeking to bring innovative, safe and effective drug products to global markets.

Infill provides pharmaceutical consultancy services in Drug Development, Analytical, Quality, Regulatory and other areas for global markets.

"CUSTOMIZE SERVICES SPECIFIC TO CLIENTS' NEEDS"

Company's Core Values

VISION & MISSION

Vision

Infill's vision is to better serve the Health Care industry by engaging the Scientists and Subject Matter Experts to ensure the delivery of Quality Medicines to the community.

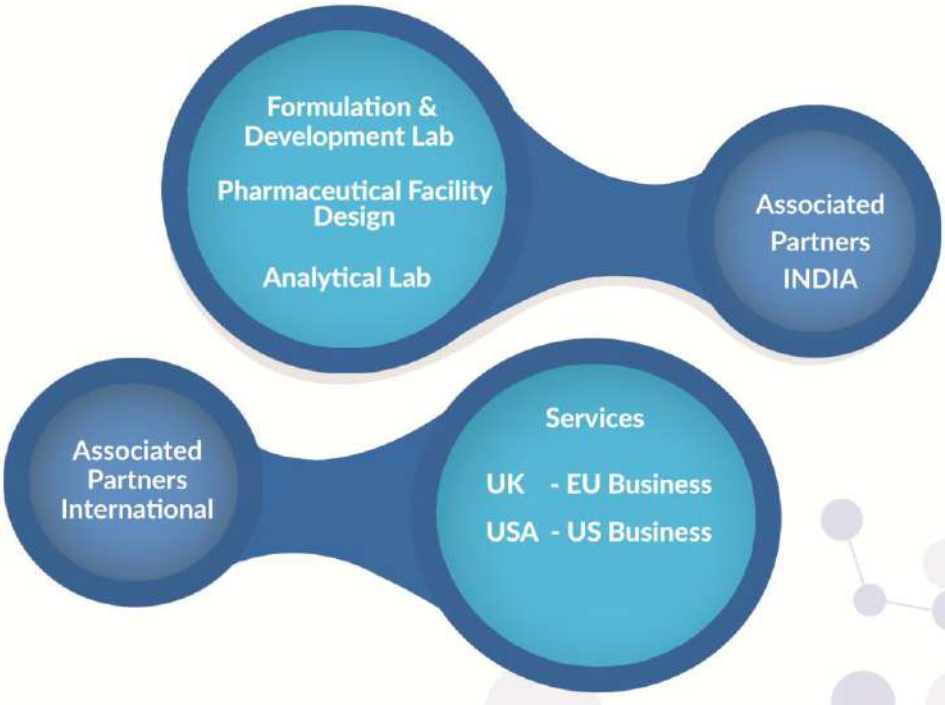
Mission

Infill is a multi-disciplinary firm whose mission is to establish research based go-to consulting firm in the field of Health Care to provide clients' with objective solutions.

Strategic Alliance Management

When considering a strategic collaborator in your drug development process, you need a trusted partner who can serve as an extension of your team. That's why we offer our strategic alliance expert partners to facilitate your unique requirements and deliver the best possible client experience.

Alliances:



OUR SERVICES FOR GLOBAL MARKET

FORMULATION & DEVELOPMENT (F&D) SERVICES

Our formulation development teams supports in the design and optimization of formulations

- Sterile Dosage Form
  - Ophthalmic
  - Injectable
- Oral Dosage Form
- Topical Products
- Complex Products
  - Drug + Device Combination
  - Oncology Products
  - LMWH Products
  - Controlled Release Injectable
  - Peptide Products
- Facilitate in scale-up, technology transfer, and process performance qualification.
- Development Strategies & Pathway
- Scientific & Technical assistance
- Preparation of product development report as per QbD.
- Setting of quality specifications for drug substance and drug product as per requirements.
- CMC documentation: Batch Manufacturing Records, Batch Packaging Records, Specifications, Protocols etc.
- Formulation development of New Chemical Entities (NCEs).
- Support in the pre-formulation, excipient-API compatibility assessment and optimization, physicochemical testing, formulation screening, lab scale formulation and accelerated stability studies to achieve the desired characteristics.

QUALITY SERVICES

(ASSURING QUALITY & SAFETY)

Quality Team has the skills and experience to assist pharmaceutical companies in setting & maintaining the Quality Management System.

- Quality System Procedures
- Support in Quality related Investigations
- Vendor Management
- Remediation Plan
- Change Control Management
- Support in Regulatory Audits
  - Pre-inspection Preparation
  - Writing Audit Responses
- Experienced in setting Quality System for Greenfield Projects
- Training
  - GMP training for manufacturing and laboratory persons.
  - Data Integrity
  - Good Documentation Practices
- Quality Risk Management
- Compliance Monitoring
- Complaint Management
- Integrity of Records & Data
- Our global network of experienced auditors are available to conduct audits,
  - GAP Analysis Audit
  - API Facility
  - Finished Drug Product Facility
  - Supplier and Subcontractor Audit

REGULATORY AFFAIRS (US, EU, ROW) & ANALYTICAL SERVICES

Pharmaceutical Regulatory Affairs Services includes,

- Strategies & Pathways for submission
- Dossier: Preparation, Review, Submission (CTD, eCTD) & Approval (IND, DMF, CEP, ANDA, MAA, etc.)
- e-CTD Submissions
- Provide expert regulatory CMC compliance advice throughout development
- Assessment as per the current Pharmacopeia updates
- Query / Deficiency Responses
- Regulatory Due Diligence
- US Representative for US submissions and EU Agent in Europe
- Support in the preparation of meeting request and briefing package/scientific advice. Facilitate in regulatory communications
- Pre-submission audit of the dossiers
- Labeling
  - Designing / review of labeling
  - NDC listing / Labeling updates
- Technical writing: Protocols, reports, specifications, policies, and procedures.
- Life Cycle Management
- Training

Analytical Services

- Development of Analytical Method
  - Assay
  - Related Substances
  - Residual Solvents
  - Preservatives & Antioxidents
  - Dissolution
- Facilitate in the preparation of protocols for analytical activities (e.g. Validation, Stability etc.)
- Expert review of analytical method validation and method transfer data as per regulatory requirements

OTHER SERVICES / TEAM

Our Other Services includes,

- Facility Design (through associates)
- Support in Extractable & Leachable Studies.
- Elemental Impurities Assessment
- Training: Customized as per clients' need
- Outsourced Project Management (Contract Research & Manufacturing)
  - Sourcing of API (Active Pharmaceutical Ingredient)
  - GMP audit (API and FDF)
  - Finished Dosage Form (FDF Development and Manufacturing)

Team Experience

Infill Life Sciences has experience in Pharmaceutical Research & Development. Team have an extensive experience in the development of formulation for New Chemical Entities (NCEs) and Generic Products for global markets (USA, EU, ROW).

Quality team members have expertise in Active Pharmaceutical Ingredients (API) and Finished Dosage Form. Team is well experienced in facing facility inspections conducted by regulatory authorities (US FDA, MHRA, EDQM, ANVISA and ROW).

Team members are experienced in submitting dossier to regulatory authorities. Can design regulatory strategies for complex generics (LMWH, drug + device combination products, controlled release injectable) and NCEs.

"We have a winning combination of core people that excel in their respective fields of expertise."

Expert Panel-Global Presence

We have experts (available globally) of different areas (Formulation, Analytical, Quality, Clinical, Regulatory) on our expert panel to advice as a flexible and responsive consultancy.

Customize services specific to clients' need

Why Infill Life Sciences?

"Infill is based on the pillars of Honesty, Reliance, Trustworthy, Endurance"

- Top-tier Professionals
- Clients' Satisfaction
- Operational & Cost Efficiencies
- Global Presence
- Driven by Service

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