Intelliscend Pharma Research & Consultancy Pvt. Ltd.

Intelliscend brand derived from the combination of intelligent and ascend

INTELLISCEND AN INTELLIGENT PHARMA TECHNICAL CONSULTANCY OFFERING EXPERTISE IN PHARMACEUTICAL DEVELOPMENT FOR COST EFFECTIVE RESEARCH AND CONSULTANCY, QUALITY DELIVERABLES WITH SPEED

INTRODUCTION

Intelliscend is a pharmaceutical technical consultancy offering services in formulation and analytical development. We have expertise in technology transfer, bio equivalence support, Quality By Design (QBD), regulatory activities, and ANDA/OTC/Veterinary product development consulting for all regulated markets. We offer full service from concept to commercialization, working with our customers' R&D and delivering the results fast and cost-efficiently.

We provide end-to-end solutions for all markets, from small and mid-size companies venturing for regulated markets to established companies seeking formulation development and tech transfer. Our consultants have expertise in more than 100 molecules and display strong and effective project management.

Intelliscend is capable of handling various technologies using QBD and DOE concepts as well as developing generic products using para IV. We cater to Indian companies as well as various international clients including firms in the US, Japan, Brazil, UAE and the EU countries.

Intellectual Capital and Experience

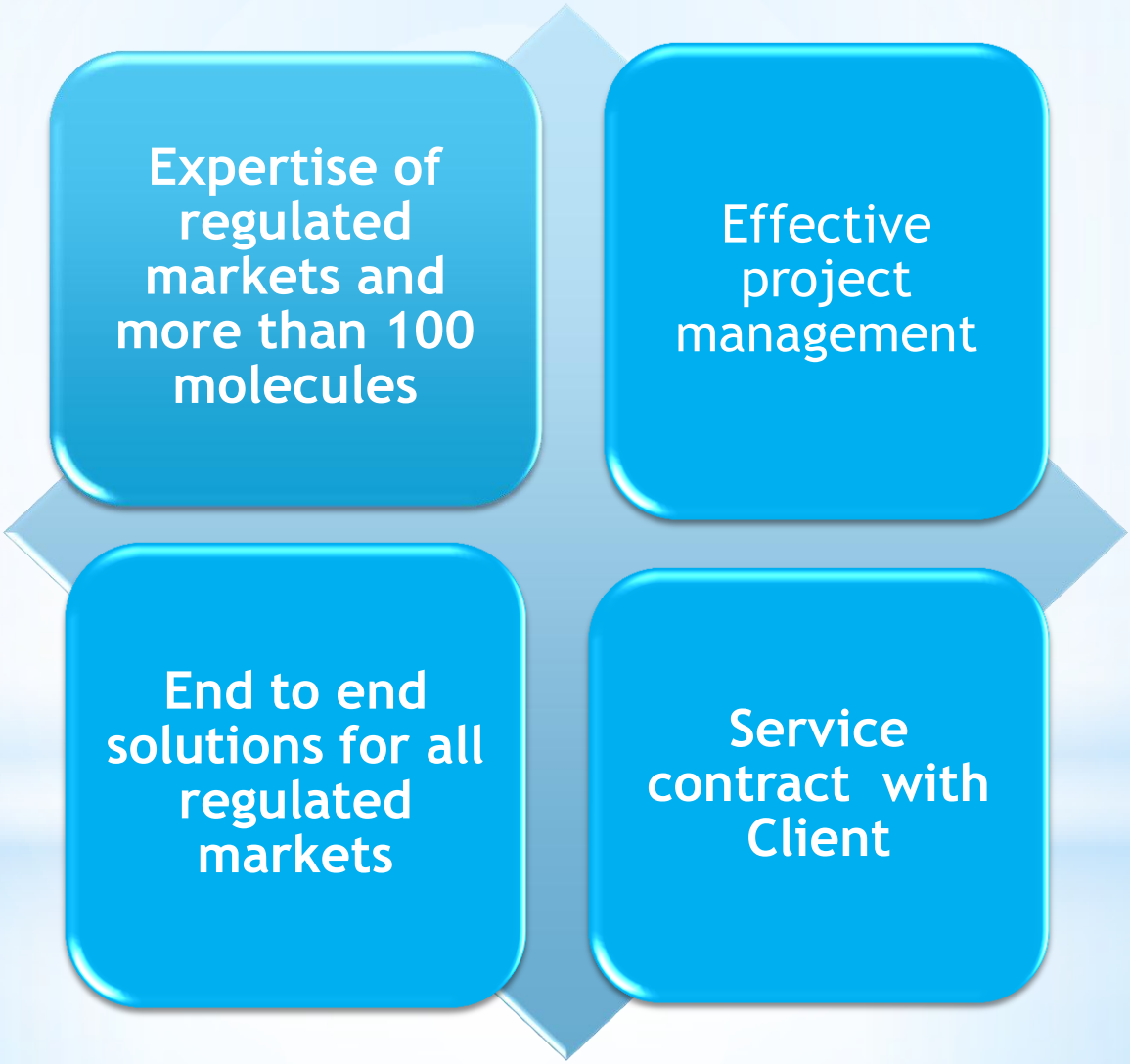
Arti Potdar M.Pharm, Ph.D.(Pharmaceutics)

Jan 2013 to date- Pharma technical consultant

Jul 2006 - Dec 2012: ZYDUSCADILA HEALTHCARE LTD., AHMEDABAD, Vice President, Formulation Development, Pharmaceutical Technology Centre
Nov 2005 - Jul 2006: TRIS PHARMA, USA
May2000 - Oct 2005: SANDOZ PVT LIMITED, MUMBAI, Group Leader, Sandoz Development Centre, India
May1999 - Apr2000: ALKEM LABORATORIES LIMITED MUMBAI, Sr. Development Scientist, Formulation Development
Apr1989 - May1999: LYKA LABS LTD. MUMBAI, Sr. Officer Formulation Development
Sep1988 - Mar1989: INGA LABORATORIES LTD. MUMBAI, Formulation Development Chemist
Jun1985 - Sep1988: ELDER PHARMACEUTICALS PVT.LTD. MUMBAI, Production Pharmacist

The director of our organization is Dr. Arti Potdar who has 25 years of experience in formulation development and regulatory submission of various dosage forms across the globe, working for the US, EU, Japan, Brazil, SA, and ROW markets. She has pharmaceutical industry experience from various positions at Alkem, Sandoz, Tris Pharma US, and Zydus Cadila as well as sound knowledge of Intellectual Property Rights (IPR) and product development using Quality-by-Design (QbD) concepts. She is versed in product development, process development, process optimization, process scale-up, process validation and Technology Transfer. She possesses an understanding and knowledge of pharmacokinetics and in-vitro dissolution, specially with respect to bio-equivalence studies—and Technology Transfers to different countries.
Dr. Potdar has demonstrated project management skills and a strong understanding of regulatory requirements, cGMP & compliance for the US and EU markets. Additionally, she excels at team building and problem solving with troubleshooting and leadership skills.
Specialties: formulation development (immediate release, modified release, Novel Drug Delivery Systems (NDDS) as per QbD); project management; Technology Transfer; problem solving; troubleshooting; team building; and auditing for compliance.

Expertise


Expertise of regulated markets and more than 100 molecules
Effective project management
End to end solutions for all regulated markets
Service contract with Client

Services


R&D Support
QBD Training
Tech transfer support
Services
CGMP audits
System and
Process validation
Bioequivalence support
Regulatory support

*R&D SUPPORT

All IPR generated during the project is owned by the client

* Trouble shooting for process and stability improvement
* Redevelopment for cost reduction; pharmacopoeia or cGMP; or for change of API, excipients
* Improvement of taste masking formulations

*PROJECT MANAGEMENT

All IPR generated during the project is owned by the client

* One point contact
* Proactive daily or weekly communication
* Flexibility of work plan priority as per client need
* Weekly or biweekly update report via teleconference
* Quarterly evaluation of FTE program
* Video conferencing services
* Monthly visit to client site, as well as on – need visits
* Timely deliverables

Services

* PHARMACEUTICAL DEVELOPMENT

* Tablets: Modified release, orally disintegrating, bilayered, coated, extended release, delayed release
* Pellets: Extended release, delayed release, fluid bed drug layered, spheronization extrusion
* Powders: Oral solution, suspension
* Liquids: Syrups, drops, suspensions/ emulsions, sugar free systems
* Parenteral Dosages: SDV, MDV, ampolues, lyophilized systems, pre filled syringes, dry powders
* Topical Dosages: Creams, emulsions, ointments and gels
* Taste masking

* BIOEQUIVALENCE SUPPORT

* Guidance for Design of Bioequivalence study and protocol
* CRO identification
* In vitro in vivo correlations
* Scientific support to formulation development teams in the areas of pharmacology, pharmacokinetics
* Maintaining Biopharmaceutics database, providing updated scientific knowledge according to regulatory guidelines.
* Providing scientific support to formulation development teams in the areas of pharmacology, pharmacokinetics

*QBD TRAINING

* Quality target product profile preparation based on innovator
* Risk management plan and identification of critical quality attributes in the product
* Risk identification of critical material attributes of various API's and excipients and their effects on drug product CQAs
* Identification of affects of critical formulation factors and process parameters on drug product CQAs and experimental design
* A risk based approach to process optimization
* QBD – based product development report

*Tech transfer support

* A three phase process in which Intelliscend supervises the development of the product and the submission of tech pack documents

1. Phase 1
   * Provide details of innovator, API, excipients, tooling, packaging etc
2. Phase 2
   * Intelliscend will prepare or assist customer R&D in preparing all tech pack documents including the batch formula, manufacturing process, product specifications, testing procedure, API documents, RM documents, packing material specifications, tooling dimensions and equipment list
3. Phase 3
   * Manufacturing of three exhibit/registration batches of each strength and charge the product on stability

Tech transfer documents

- Master formula card
- Information of active substance
- Excipients information
- Packaging material information
- Tooling information
- Drug product information
- Finished product information
- Preparation of tech transfer documents and transfer to customer

Clients

Intend to be of service for -

* Small and Mid size Indian pharma companies (oral dosage forms) venturing for regulated markets US, EU, Brazil, Japan, etc.
* US Companies seeking formulation development and tech transfer
* EU Companies seeking formulation development and tech transfer
* Brazil and Japan companies seeking formulation development and tech transfer
* ROW companies seeking formulation development and tech transfer
* Indian companies seeking formulation development and tech transfer

Edge

EXPERIENCE

- Scientific knowledge
- Expertise of more than 100 molecules and various dosage forms.
- Good knowledge of regulatory requirements of regulated, semi regulated and Indian markets

RELIABLITY

Due to effective project management we are able to provide end to end solutions for product development

ACCOUNTABILITY

- We are committed to serving as effective and responsible stewards of our clients' trust. We are efficient and results-oriented.

WORKING LIKE EXTENDED ARM OF YOUR R&D , IMPROVING THE QUALITY OF PEOPLE AND GETTING THE PROJECTS DONE ON TIME !!!!!!!!!

Contact details

Contact :

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