Center For Pharmaceutical Integration-LLC

- ***A consulting group of more than 20 Ph.D level highly qualified & experienced pharmaceutical professionals from the Pharmaceutical & Biotechnology industry . Main emphasis on CMC.***

- ***Founded: May 2012***

- ***Founders :***

  - Dr. Mick Banks

  Ex. Vice President, Pharmaceutical Sciences , Pfizer,

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OUR CORE BUSINESS

- **Chemistry and Manufacturing Controls across the spectrum of drug development to commercialization (from Pre Clinical to Phase 4)**
- **All scientific disciplines and CMC activities**
- **Small Molecules & Biotechnology Products**

What does this Encompass?

Active Pharmaceutical Ingredient (API)

Analytical Development

Analytical Control

Formulation , Drug Delivery and Development

Clinical Supply & Commercial Manufacturing and Packaging

Regulatory CMC Documentation & Filings (IND,NDA,ANDA)

Core Scope of CMC Services

What is our Expertise & Experience ?

- A group of over 20 Ph.D level experts with a collective experience of CMC in excess of 500 years
- Attained Director or VP level positions
- Experience across multi-national , start-up and generic companies or with regulatory agencies (FDA/MCA)
- Peer recognized scientific and technical expertise across CMC disciplines with several holding key positions in Professional bodies (AAPS, ACS, ISPE,USP,FIP, IPA)
- Hands on experience of early and late development compounds to successful regulatory filings in all major markets (USA, Europe, Japan, Far East)
- Located in the USA, Europe and India

Key Focus Areas

- Early Development
  - Development of strategy and provision of technical support covering API synthesis, pre-formulation, formulation, drug delivery & analytical development . Assembly of IND submissions (CTD documentation) and interactions with the FDA/MHRA/EMEA

- Late Development
  - Generic Drug Development and 505B2 applications
  - New Drug Development
  - API synthesis and Dosage Form Design to commercialization

- Quality and Technical Audits
  - Due-Diligence
  - GMP & GLP Audits

What do we offer ?

- **Customized pharmaceutical solutions for startup, virtual companies, investment institutions to meet your unique needs and budgets.**
- ***CMC expertise from pre-clinical through the spectrum of drug development to commercialization***
- **Large and small molecule technical evaluation, drug development program design and operational management**
- **Technical advice and hands on support in developing filings and interactions with Regulatory Agencies**

How do we operate ?

- Close interaction with each client to fully understand the project scope
- Provide a customized solution for each project with the right expertise and experience to deliver efficiently and effectively
- Highly responsive and cost conscious to provide value and quality to meet each client's expectations

Our guiding principals

- Scientific and technical scrutiny
- Responsiveness & nimbleness
- Openness
- Value
- Delivery (to milestones & agreed budgets)

Our Most Recent Projects

- Successful IND submissions including technical advice, writing of documents , facilitation of interactions with FDA (including face to face meetings and resolution of questions) for three clients
- Resolution and progression of complex API Syntheses to critical investment milestones
- Support to Generic and 505(b)2 development strategy
- Preparation of a business development proposal for a Drug Delivery system for commercialization (Strategy/Risk Mitigation)
- Development of platform for the Production/Distribution of Clinical Comparators to enhance clinical trial operations

Our Most Recent Projects

- **Customized training on the following subjects:**
  - **Technology transfer of small and large molecule projects**
  - **Technology Integrations of CMC functions post Mergers and Acquisitions**
  - **Lyophilization Technology**
  - **Post Approval Changes of Dosage Forms and Drug substances**
  - **Semi-Solid Dosage Form development**
  - **Pharmaceutical Process Development**
  - **GMP compliance and CAPA**
  - **GMP Plant Audits and Data Integrity management**
  - **Tablet and Capsule Development**
  - **Quality by Design Applications**
  - **Biosimilar Development**
  - **Process Validation**

CRO-CMO knowledge and experience base

Many Contract Research & Manufacturing Organizations in USA, Europe, and India offering:

- **CMC laboratory development activities**
  - *API, Analytical, Formulation*
  - *Specific technologies (e.g. nano-technology, lyophilization)*
- **GMP manufacturing capability**
  - *API (small molecules and biotech) , sterile & non sterile dosage form and clinical supply packaging*
- **Scientific and Technical expertise**
- **Value and reliability**
- **Regulatory competence**

Contact Details

Thank You

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