DS InPharmatics, Inc.

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NUMBER OF EMPLOYEES
30

DATE FOUNDED
2007

CORPORATE CAPABILITIES

General Company Description

DS InPharmatics (DSI) offers one-stop, full-service Chemistry, Manufacturing, and Controls (CMC) Development and Regulatory consulting resources to emerging pharma and biotech companies.

Our exceptional value begins with our multidisciplinary teams of development, manufacturing, quality, and regulatory affairs specialists. Our CMC consultants combine in-depth product development knowledge with risk-based submission authoring and regulatory strategies for all product phases.

This breadth of field-tested expertise provides you with a single, integrated source for efficient problem-solving strategies. Whether your needs are comprehensive or tightly focused, our experienced CMC consultants will help keep your drug development program on track and on budget.

CMC Operations/Product Development

- Supply Chain
  - Select, qualify, establish and manage CMOs and vendors
  - Process transfer and scale-up strategy, management and budget
- Product Development
  - Formulation development and justification
  - Establish and justify specifications, optimize methods
  - Develop stability programs. Perform data review
- NDA Filing and Product Launch
  - CMO/sponsor preparation, strategy and execution
  - Regulatory gap analysis and risk assessments
  - Define CQA and CPPs, validation strategy, protocols, and execution
- Virtual QA Management
  - MBR generation; batch record, investigation and CAPA review and recommendation
  - Audits and Mock PAIs
  - Develop and manage document systems
- Regulatory Affairs
  - Marketing applications (NDA,BLA, MAA)
  - Investigational applications (IND, IMPD)
  - Pre-meeting packages
  - Agency liaison

Facilities

Projects executed cost effectively through DSI's remote secure systems and on line interactive communications or at a client's site.

Major Services

CMC Healthchek™ Designed for managers who are engaged in planning future development and regulatory strategy. DSI provides an objective gap analysis and risk assessment of a CMC development program (DS, DP, and Quality Systems), allowing clients to proactively address gaps before they become a regulatory or investment issue. Clients receive a written report summarizing the CMC program components and highlighting any critical/major/minor weaknesses or potential problems as well as suggested remediation, allowing the client to make appropriate risk based decisions to keep drug development programs on track.

Markets Served

DSI is a valued partner to small and mid-sized pharmaceutical and biopharmaceutical companies. We have the expertise needed to guide drug development programs to success from start to finish, offering smarter, faster ways to accelerate drug development programs. For large multinationals, our alliance of specialists allows us to fill specific, in-house gaps with targeted solutions.

DSI INPHARMATICS

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