Vendor and Contractor Identification and Management

Selecting and efficiently managing vendors that are reliable, as well as technically competent, is one of the best tools available for minimizing the time needed to develop and register a drug or healthcare product. Contract manufactures, laboratories, and suppliers require diligent oversight and management so as to prevent development delays and cost overruns and to ensure the quality of products and deliverables.

A Deeper Department

A Regulatory Drug Development consulting business that (works exclusively with) serves the needs of small emerging biotechs, most of whom do not yet have major products approved and on the market (to improve performance in strategy and leadership). Whether advocating CMC strategy, directing CMC operations or developing CMC submission content that represent the best interests of emerging biotech, we focus on the critical CMC and Regulatory issues and build programs that enhance development.

Manufacturing Cost Estimates & Cost of Goods Analysis

The real costs of manufacturing in the pharmaceutical industry are difficult to determine. Our industry-experienced professionals, will help you uncover, analyze and in many cases reduce your real costs of API and Drug Product manufacturing.

For synthetic APIs, our analysis includes: a thorough literature search, patent inquiry, analysis of synthetic routes and yields, starting material analysis, manufacturing facility and/or specialized processing requirements, labor requirements, etc. We'll prepare a detailed manufacturing cost estimate that along with the essentials above will include detailed consultation and discussion on the challenges inherent in the identified routes, material options and the anticipated cost of the final API/intermediate.

For biologically produced APIs (large molecules and secondary metabolites), we consider the process provided or a feasible process model derived from literature.

For drug products, we consider the formulation provided or use a formula from published regulatory documents to estimate the cost of making the product form(s). Packaging costs in any trade dress can be estimated, including the cost of serialization.

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CMC DRUG DEVELOPMENT AND OPERATIONS MANAGEMENT

Services

DSI's Three Levels of Cost Analysis Services

1. Cost estimate of API or Drug Product by a single process with basic background information and discussion of the basis of the estimate
2. Cost estimate of API or Drug Product with a discussion of a process, consideration of alternative processes, including background information and discussion of the basis of the estimate with supporting tables and graphs
3. Cost estimate of API or Drug product with a detailed discussion of the estimate, slides for a presentation, and research into specific issues. (Requires an in-depth discussion with client to mutually agree on all deliverables.)

We provide access to our cost model(s) for client-driven "what-if" analyses of the impact of yield efficiency, throughput, and key material prices.

Cost Analysis Benefits

- Understand the challenges of selected processes
- Analysis of specific manufacturing and equipment requirements for material development and production
- Identify starting material supply costs and sourcing challenges
- "Make vs. Buy" Critical Analysis
- Geographic location variables in manufacturing (global analysis)
- Guidance on most cost effective process for desired production volume
- Focus on "Cost Drivers" (appropriate development efforts to drive down overall costs)
- Provide a comprehensive understanding of final API or Drug Product cost estimates

Clients

- Established Pharmaceutical Companies
- Emerging Pharmaceutical & Biotech Companies
- API Sourcing Professionals
- Generic API Manufacturer

Selecting and efficiently managing vendors that are reliable, as well as technically competent, is one of the best tools available for minimizing the time needed to develop and register a drug or healthcare product. Contract manufactures, laboratories, and suppliers require diligent oversight and management so as to prevent development delays and cost overruns and to ensure the quality of products and deliverables. We work with vendors and clients to identify appropriate and place the required management processes to minimize the risks and maximize the value that these service providers can produce.

Our network of contract manufacturing organizations (CMOs) allows us to identify the most suitable service providers for your compound and dosage form and ensure optimal performance within your time and budget parameters. Throughout the process, DSI experts advise on formulation and design, handle site inspection/monitoring, design/review protocols and identify the best method validation strategy to ensure compliance with FDA and ICH guidelines — a critical step for first-cycle review.

CMC DRUG DEVELOPMENT AND OPERATIONS MANAGEMENT

Active Pharmaceutical Ingredient (API) Vendor Management

- CMO sourcing
- Specifications and test methods
  - Method validation
  - Evaluation of process impurities
  - Stability testing and results analysis

Clinical Trial Materials Management

- CMO management and technical direction
- Formulation oversight
  - Raw material selection and characterization
  - Pre-formulations (chemical/physical properties testing and evaluations)
  - Formulations (chemical/physical properties testing and evaluations)
  - Methods development and validation
  - Impurity profiling
  - Release specifications and testing
- Manufacturing and release of clinical batches
- Packaging and labeling of clinical supplies
- Container/closure systems testing and evaluations
- Stability protocols, specifications, tests and results

WHAT CAN DSI DO FOR YOU?

Regulatory Affairs

- Regulatory Agency Representation
- Regulatory Strategy Development
- Management and Preparation of Regulatory Submissions
- Responses to Regulatory Challenges
- Breakthrough Therapy Designation Requests
- Gene and Cell Therapy Product Review

CMC

- Integrated CMC Development
- Materials Characterization and Formulation Development
- Process Development, Optimization, And Validation
- Analytical Method Development, Optimization, and Validation
- Stability Program Design and Management

QA

- Design, Implementation, and Remediation of Quality Systems
- Compliance, Vendor Qualification, and Mock Pre-approval Audits (Mock-pais)
- Management of Compliance Situations

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