DRUG SUBSTANCE SERVICES

DSI INPHARMATICS
A ProductLifeGroup Company

The DSI API consulting team goes beyond assisting and guiding and does the hands-on work for your program. The team offers over 175 years of combined experience supporting all phases of small molecule and peptide clinical development and manufacturing, coupled with an international network of CMO's and experience applying current ICH guidance and interacting with Agency CMC regulatory authorities.

DRUG SUBSTANCE DEVELOPMENT AND MANUFACTURING

From salt selection to route selection for Phase 1 through process validation and commercial manufacturing and API regulatory readiness for filing, DSI provides invaluable hands-on development, manufacturing support and strategic API regulatory guidance.

DRUG SUBSTANCE PROCESS SELECTION, SCALE UP DEVELOPMENT AND PLANT IMPLEMENTATION

- Apply DSI's large, international API CMO network toward identifying appropriate development resources – right team, right location, right price.
- Provide direct technical guidance of contracted chemical process development
- Assist in identifying processes that match current or anticipated needs
- Ensure the scalability of manufacturing processes to suit the anticipated scale of manufacturing
- Optimize processes to balance robust control of quality with cost-efficiency
- Guide development of intended commercial processes in view of current ICH guidance to support process robustness and a strong filing
- Evaluate existing manufacturing processes for suitability for intended use

DRUG SUBSTANCE MANUFACTURING SUPPORT

- Provide direct oversight for lab to plant and plant to plant technology transfers
- Assist with preparing requests for proposals and selecting contract manufacturers
- Evaluate facilities and CMO suitability and fit to project
- Hands-on management of contract manufacturing through Phase 1, validation and commercialization
- Direct involvement in preparing manufacturing documentation
- "Person on-site" support during manufacturing as needed
- Provide troubleshooting and support for the recovery of batches impacted by unexpected circumstances.
- Support technical deviation investigations and identification of CAPAs
- Assist in identifying and selecting alternate-source and replacement manufacturers
- Real expertise managing commercial manufacturing operations: Scheduling, process and operational efficiency, and capital installations
- Cost of goods estimation, analyses of capacity requirements and capacity of allocated equipment
- Assist with strategic planning for the security of API supply.

DRUG SUBSTANCE REGULATORY AFFAIRS SUPPORT

- Evaluate sponsor API CMC status, identify and assist with closing gaps in readiness for all clinical phases through fining and commercial launch
- Ensure that ongoing API programs are shaped to comply with the evolving regulatory developments and guidance.
- Author, review and edit regulatory filing content with an emphasis on scientific soundness
- Assist with selection and proposal of regulatory starting materials, including authoring Agency briefing book content
- Assist with a strategy for significant CMC changes and prepare associated agency briefing books and comparability reports
- Represent sponsor in CMC meetings with Agencies

Contact Us

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