DRUG PRODUCT SERVICES

DSI leverages seasoned professionals to take your program from bench scale to commercial optimization. By understanding the challenges of scale-up and production, as well as the characteristics of most manufacturing process trains, we can help you plot an efficient course for your drug product program.

DRUG PRODUCT FORMULATION DEVELOPMENT

DSI's early involvement in the drug development process saves you substantial time and money. By utilizing proven methods in your development planning and execution, you can assure an efficient scale-up and process transfer.

Drug Product (non-sterile) development expertise includes:

- Immediate, controlled, extended-release tablet and capsules
- Oral liquids and dosing systems for solutions, and suspensions
- Functional and solvent coating
- Abuse deterred formulation and DEA scheduled products
- Pediatrics including chewables, orally disintegrating, powders taste masking
- Topical and transdermal

Our Sterile development expertise includes:

- Pre-filled syringes and vials
- Ophthalmics
- Suspensions and viscous solutions
- Small and large molecule formulations
- Car-T, Cell lines
- Validation of sterile manufacturing

DRUG PRODUCT MANUFACTURING SUPPORT

DSI's experience with Contract Manufacturers allows you to gain insight into the workings of vendors as well as a collaborator in ensuring your compliance manufacturing needs are met on time.

DSI can lead process improvement or remediation efforts including FMEA, Risk Assessments, CAPA remediation, improving process capability, statistical analysis with your chosen vendor.

We offer "person in plant" services to monitor critical experiments or manufacturing operations. This can also prove to be a valuable part of any firm's due diligence efforts in assessing facility and process assets.

We can apply our significant experience working with CMO's and CDMO's to source a vendor who fits best for you to help ensure they meet deliverables, value and quality expectations.

DRUG PRODUCT REGULATORY AFFAIRS SUPPORT

By remaining current with the regulatory landscape, we can save time and money by ensuring your development program is meeting the latest expectations. This includes recent regulatory requirements addressing supply chain risk for adulterated raw materials (melamine, nitrosamine, BSE, TSE) and serialization of packaging.

DSI can piece together the CMC documents and data from your development program to tell the story of how the product was developed into a coherent Pharmaceutical Development report. This will be invaluable during pre-approval inspections and when drafting CMC sections of filings for marketing approval.

Contact Us

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