The BioDuro Advantage

BioDuro’s CMC services have a reputation for scientific and operational excellence in supporting preclinical and clinical programs for pharmaceutical and biotech clients. Maintaining the knowledge and experience of formulation development, manufacturing and supporting analytical in one location allows for effective integration of program components leading to timely delivery of drug product to clinical sites.

BioDuro provides exceptional formulation development and clinical supply manufacturing to our clients. From simple API-in-a-bottle, to high performance solubilization enabled and controlled release formulations using techniques such as hot-melt extrusion and spray-drying, our development expertise will provide the right answers for your clinical trial material programs.

- From preformulation to formulation development to scale-up and cGMP manufacturing, BioDuro offers expert solutions to advance drug candidates from late discovery to clinical development.

- Seamless and efficient transfer of product and process know-how across formulation, analytical and manufacturing teams is streamlined by close internal collaboration and with clients facilitated by dedicated program managers.

- Recognized for our ability to resolve bioavailability challenges: 100+ solubility-enhanced formulations developed over the last ten years using hot melt extrusion and spray dried dispersion.

- Laser-focused on customer satisfaction with flexible and responsive teams driven by tenacity and accountability in delivering drugs to the clinic.

In pursuit of your success. www.bioduro.com
Integrated Drug Product Development at BioDuro San Diego

CMC Services

Formulation Development
- BioDuro Solution Engine:
  - Rapid parallel screening of solubilization processes and excipients, utilizing mg levels of precious API
  - API characteristics and interactions used to select approaches and formulations with the highest likelihood of success
  - Concurrent in-vivo/in-vitro performance assessment provides superior risk management throughout the development process
  - Process for selecting less toxic vehicles for pre-clinical dosing studies
  - Screening process leads to predictable scale-up from feasibility to pilot-scale manufacturing of Clinical Trial Material
- Screening of drug candidates for late discovery/early toxicology studies
- Physical, chemical and biological characterization of API
- Generation and screening of formulation prototypes
- Drug excipient compatibility studies
- Lead generation identification
- Scale-up and process development
- Technology transfer to manufacturing

cGMP Manufacturing
- Process development and technology transfer
- Engineering batch manufacturing
- Batch record generation
- Materials management
- Equipment installation, calibration, cleaning and maintenance
- cGMP drug product manufacturing
- Packaging and labeling
- Distribution to clinical sites

Analytical Development
- Method development and optimization
- Method transfer
- Phase appropriate method validation
- Testing of non-GMP stability samples
- Residual solvents analyses
- Cleaning method development and validation

Quality Control
- Release testing of raw materials, API and drug product
- Generation of raw material and DP specifications
- Cleaning verification testing
- In-process testing
- cGMP stability testing
- Equipment calibration and maintenance
- Environmental monitoring