cGMP SERVICES

FROM FORMULATION DEVELOPMENT TO FILL & FINISH AND STABILITY STUDIES

MANUFACTURING SERVICES

IDRI is a non-profit organization performing formulation development and fill & finish services in newly constructed, state-of-the-art labs and cGMP facilities located in Seattle's South Lake Union neighborhood.

AT IDRI, WE PROVIDE

- Formulation development services with a focus on liquid, emulsion, and liposome formulations based on small molecules and proteins
- cGMP drug product manufacturing for preclinical, Phase 1 and 2 clinical studies with a batch capacity of up to 15,000 vials of drug product in compliance with U.S. and EU regulations
- Analytical development services including bioassay development
- Stability studies performed in compliance with ICH guidelines

FILL & FINISH

The filling is done with an automated filling, stoppering and capping machine. A hand-fill operation is available for smaller lot sizes, if desired. Our services are individualized and performed with flexibility per our customers' needs.

QUALITY CONTROL & STABILITY STUDIES

Manufactured drug product lots are release and stability tested by our Quality Control team. Analytical development and pre-formulation / formulation development services are executed by IDRI's highly skilled Research & Development and Quality Control staff.

Stability programs at IDRI encompass:

- Accelerated stability
- Long term stability
- ICH compliance
- Method transfer and/or development as needed
- Storage conditions
  - ≤ -65°C
  - -25 to -10°C
  - 2 to 8°C
  - 22°C
  - 35°C
  - 37°C

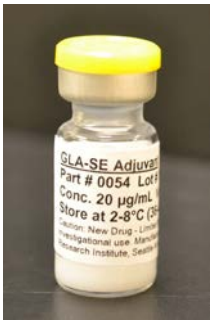
Products

Small molecules and proteins formulated as parenterals in:

- Liquids
- Emulsions
- Liposomes

Pre-clinical to Phase 2 manufacturing for:

- Pharmacology, toxicology & characterization studies
- Phase 1 & 2 clinical studies



Analytical Methods

Drug substance specific methods

USP/generic methods

- Biochemical
- Chromatography
- Physico-Chemical
- Microbial

cGMP SERVICES

SERVICES

- Formulation development
- Analytical development
  - –Method verification
  - –Method qualification
- Manufacturing
  - –Engineering run for pre-clinical purposes
  - –cGMP run for Phase 1 and 2 clinical studies
  - –Labeling of small lots (<2,000 vials)
- Release testing
- Stability study
- Project management

IDRI OFFERS EXTENSIVE EXPERIENCE

At IDRI, we have more than 20 years of technologic and scientific excellence. We collaborate with organizations throughout the world to find solutions to some of the world's most perplexing health problems. In addition to our state-of-the-art manufacturing facility, we have formed a strong, experienced and committed team ready to find answers to your manufacturing questions.

Our focus is exclusively on fill and finish services and supporting activities, which allows us to find the fastest and most flexible route to meet your manufacturing and clinical objectives.

cGMP MANUFACTURING

- Vial Sizes: 2 mL - 100 mL
- Fill volume: 0.3 - 100 mL
- Capacity: Up to 15,000 vials/batch
- Filling: Semi-automated or fully-automated
- Nitrogen purge

ABOUT IDRI

- 501(C)3 NON-PROFIT INSTITUTION FOUNDED BY STEVEN REED IN 1993
- HEADQUARTERED IN SEATTLE WITH NEARLY 100 COLLABORATIONS WORLDWIDE
- 120+ EMPLOYEES, OF WHICH ~40 HAVE ADVANCED DEGREES AND ~90 WORK IN RESEARCH AND DEVELOPMENT

PLEASE CONTACT US TO OBTAIN ADDITIONAL INFORMATION

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