PrimaPharma

Commercialization Capabilities

PrimaPharma "Solution"

- Our team of scientists, engineers and quality experts work directly with the customer to identify necessary technical and regulatory tasks for a successful clinical trial, FDA submission and commercial launch/distribution
- PrimaPharma has proven track record of successful FDA approved drugs, devices and biologics for use in commercial and clinical applications
- We maintain a team of outside contractors, including suppliers, testing laboratories and various manufacturing capabilities to provide additional support if required
- Partnership opportunities

Company History

- Privately held CDMO since 1992 located in San Diego, California
- Aseptic liquid filling, injectables, ophthalmic and OTC's
- New management team organized in 2009
- Currently FDA Drug and Device registered facility
- California State Food Drug Branch Drug & Device
- ISO 13485: 2003 currently certified by BSI (notified body)
- 34 full-time employees

Management Team

- Mark Livingston, President & CEO (2009)
  - Former Executive: Danco Laboratories
  - Co-Founder; predecessor entity, Sorrento Biochemical, Inc.
  - Former President/CEO Motels of America, Inc
  - Former President Road Runner Sports, Inc
  - Former CEO Price Quest, Inc
- Anthony Dziabo, V.P. Product Development, Regulatory Affairs & Quality
  - Formerly V.P. R&D Allergan and Medtronic
  - 23 U.S. Patents
- Larry J. Braga, V.P. Operations (2009)
  - Formerly Genentech (currently Roche), Collagen Corporation (currently Allergan), and Rhone Poulenc Rorer (currently Sanofi-Aventis)
  - 3 U.S. Patents

Management Team

- Nayaz Ahmed PhD, RAC (US, EU), CQA, Director, QC – Analytical Services & Product Development
  - Former consultant at Cargil
  - Former Scientist at LKT Labs
  - Former member, NIH/NCI Peer Review Committee
  - Member of SCI Advisory Board, Biopep Solutions, Inc.
  - 4 US Patents

- Arshad Chaudry, Director of QC, Microbiology & Validations
  - Member of PrimaPharma management team (20+ years)
  - Over 20 years experience microbiology and pharmaceutical product development
  - Member of management team responsible for obtaining approval of several drugs & medical devices

Management Team

- Sarah Dziabo, Associate Director Quality Assurance
  - 15 years experience in cGMP operations including technical writing, document control, GMP auditing, Quality Systems, ISO 13485, ISO the lab one, FDA inspections, Manufacturing support and project management.
  - Former Medtronic Cardiopulmonary
  - Former Alsuis medical device
  - Former Micro Quality Labs
- Hampar Karageozian, Chairman of the Board
  - Formerly Sr. Vice President of Research at Allergan
  - Founder of Four Pharmaceutical Companies
  - Currently CEO of Allegro Ophthalmics
  - Over 30 worldwide patents

Manufacturing Expertise

- Commercial NDA, ANDA and PMA products
  - Liquids, solids, vials, syringes, btc, & tubes
- Clinical manufacturing-small scale runs
- Clinical labeling & packaging (blinded, randomized trials)
- Formulation development
- Analytical testing development & validation
- Microbiological development & testing
- Regulatory support for FDA application submission-CMC packages

Manufacturing Capabilities

- Manual aseptic filling for small lot sizes up to 5,000 units under ISO Class 5 conditions (process approved for commercial or clinical products)
- Semi-automated aseptic (RABS) nested tray filling, syringe or vial
- Terminal sterilization by steam, dry heat or irradiation
- Semi-automated non-sterile filling for larger batch sizes >10,000 units (Nasal Pump)
- Formulation expertise to support sterile emulsions, sterile powders (API's), sterile lipids, sprays, gels, peptides, MAB's and recombinant proteins

Laboratory Capabilities

- Analytical Chemistry
  - UPLC
  - GC
  - FTIR
  - UV Vis
  - KF
  - Viscometer
- Microbiology
  - Sterility Testing
  - Bioburden
  - Endotoxin
  - Aseptic Process Qualification
  - MLT
  - Facility Environmental Monitoring

Process Development

- Aseptic Manufacturing
  - Drug Products
- Formulation Development
- Blow, Fill, Seal
- Syringe Filling
- Emulsions
- Suspension
- Gels
- Sprays
- Unique Container/Closure Systems
- Scale Up & Build OUT (GMP Compliance)
- Network of Approved Contractors (Gamma, E-Beam, Analytical Chemistry, CRO's, Regulatory. Etc.)