PrimaPharma, Inc.
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PrimaPharma

Poised for Growth

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 Licensed
- ISO 13485 Quality Standard: 2003 certified by British Standards Institute (notified body)
- 32 full-time employees

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 regulatory authority 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 (NDA, ANDA, PMA)
- We maintain a team of outside contractors, including suppliers, testing laboratories and various manufacturing capabilities to provide additional support if required
- Partnership opportunities

Management Team

- Mark Livingston, President & CEO (2009)
  - Former President/CEO Motels of America, Inc
  - Former President Road Runner Sports, Inc
  - Former Executive; Danco Laboratories
  - Co-Founder predecessor entity; Sorrento Biochemical, 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 & Valaidations
  - 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
- 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

Process Development

- Aseptic Manufacturing
  - Drug & Device
- Formulation Development
- Blow, Fill, Seal
- Syringe Filling
- Emulsions
- Suspension
- Gels
- Sprays
- Unique Container/Closure Systems
- Scale Up & Build OUT (GMP Compliance)

Laboratory Capabilities

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

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, foreign language trials)
- Process Development
- Formulation development
- Analytical testing development & validation
- Microbiological development & testing
- Regulatory support for FDA applicationsubmission-CMC packages

Manufacturing Capabilities-Current

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

Manufacturing Capabilities-Growth

- High volume aseptic filling for lot sizes up to 50,000 units utilizing Restrictive Access Systems (RABS) for commercial or clinical products Bottle, Tip, Cap or Vials (Qtr 2 – 2017)
- Blow, Fill, Seal dedicated aseptic facility with capacity of 7,000+ 2mL units/hr
- Semi-automated aseptic (RABS) nested tray filling for syringe or vial (QTR 1 – 2017)

THANK YOU

PLEASE, CONTACT US FOR MORE INFORMATION

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