PHARMACEUTICAL SERVICES

Quantex Laboratories serves the pharmaceutical, biotechnology, medical device and other life science industries. Our background of solving challenging analytical problems, combined with a vast range of skills, knowledge and experience, is designed to support your efforts through the discovery and development pipeline and into the marketplace.

We work in a collaborative and interactive manner with your project and product teams to design and implement projects which meet their specific objectives and time frame. Through this collaborative and interactive approach we help you leverage time, costs, experience, capabilities and resources to successfully achieve project and product development, analytical, quality and regulatory objectives. And, as you would expect from your own laboratories, our work is performed under strict compliance with cGMP requirements, based on formal written, detailed SOPs and stringent quality assurance practices.

Our focus is to serve as an extension of your analytical, manufacturing, quality and research and development teams. We are dedicated to building long-term relationships with our clients. And, we bring our history of experience, dependability, integrity, quality and responsiveness to every client. Our commitment has always been to be more than just a vendor to our clients. We focus at partnering with you, as a dedicated team member, interacting collaboratively with your internal teams, as *An Extension Of Your Team*, to successfully achieve project goals and objectives.

We provide an expansive range of services to support early to late phase projects, manufacturing, product release and support for investigating quality issues. These services include analytical method development, method validation, stability testing, impurities and residuals, extractables and leachables, product quality control and release testing, raw materials and excipients compendial testing and microbiological services.

Some of the pharmaceutical service we offer include:

- Method and Protocol Development/Validation. Chromatography (HPLC & GC with various detectors, GC-MS, LC-MS^n) Spectroscopy (FT-IR, AAS, ICP, ICP-MS, UV/VIS)
- Methods transfer
- Drug substance characterization
- Impurity Profiles
- Identification of impurities and residual solvents
- Elucidation of the degradation pathways
- Reference Standard Characterization/Qualification
- Raw Material testing
- Finished Product Testing
- Release testing
- Container Leachables/Extractables
- Package Suitability Testing
- Comparator studies
- Organic/Inorganic Analysis
- Trace and heavy metals

AN EXTENSION OF YOUR TEAM$_{SM}$

State-of-the-Art Instrumentation:

- HPLC: (UV-VIS, PDA, FL, RI, electrochemical detector, ELSD)
- LC-MS & LC.-MS/MS with APCI & ESI
- GC: direct injection, head space capability, (FID, TCD , NPD & ECD)
- GC-MS: direct injection, head space capability with El & CI ionization source
- Flame AA
- GFAA
- ICP & ICP-MS
- Mercury analyzer
- IC
- CE
- UV-VIS spectrophotometers
- Fluorescent spectrophotometer
- FTIR : Dual detector/HATR
- Karl Fischer (titrimetric and coulometry)
- Osmometer
- Autotitrator
- Polarimeter
- Melting point analyzer
- Brookfield viscometer
- Particle Counter

QUANTEX LABORATORIES®

For more information on our capabilities please contact our Business Development group at (609) 655-4047, extension 304

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