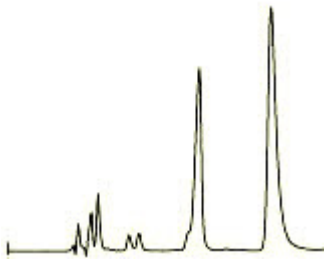
ANALYTICAL,
QUALITY & REGULATORY
SERVICES

Pallas Pharmaceutical Consulting LLC



Services are tailored to meet specific client requirements. Consulting can be provided on an advisory capacity or as a temporary extension of your management team

Frank Pallas

Skilled analytical chemist with thirty years' experience supporting the pharmaceutical industry.

Key accomplishments include a successful record of building, managing and growing contract analytical laboratory businesses to support R&D and product registration. Implemented cGMP and GLP compliant Quality Systems for Quality Control and Bioanalytical testing.

Mr. Pallas managed drug development programs, directed analytical activities and prepared documentation to support numerous regulatory submissions including INDs, and approved ANDAs and NDAs.

Consulting services are provided to assist pharmaceutical companies in successful product development and registration.

Area of Expertise

- **Pharmaceutical Analytical Chemistry**
  - **Drug Substance Characterization**
  - **Potency Determinations**
  - **Evaluation of Degradants/Impurities**
  - **Stability**
  - **Method Development, Validation and Troubleshooting**
  - **Special Expertise in HPLC and Separation Sciences**
- **CMC Strategy & Development**
- **Program Management for Pharmaceutical Development**
- **Preparation of Regulatory Documentation for INDs, NDAs and ANDAs**
- **Laboratory Design**
- **Analytical Equipment Qualification (IQ/OQ/PQ)**
- **Laboratory Management**
- **Quality System Development**
- **Compliance Auditing(GLP/cGMP/21 *CFR* Part 11)**

Service Offerings

Support for Established Pharmaceutical Companies

- **Expert method development, validation and troubleshooting support**
- **Product development program management**
- **Data analysis and report review**
- **Preparation of data packages and documentation for FDA regulatory filings**
- **Analytical laboratory work process evaluation**
- **Training programs (HPLC, general analytical techniques, and quality topics)**
- **Contract auditing to evaluate laboratory technical quality and GLP/cGMP compliance**
- **Assistance for inspection concerns and support for FDA general or pre-approval inspections**
- **Document scanning and management services to support regulatory submissions**

Service Offerings

Establishing New Analytical Capabilities for Emerging Companies

- **Establishment of R&D and QC Analytical Laboratory functions**
- **Facility and Laboratory Design**
- **Development of Quality Systems and Standard Operating Procedures**
- **Evaluation of needs and specification of analytical equipment**
- **Defining qualification requirements for analytical equipment and computerized data systems**
- **Organizational and personnel development**
- **Training programs**
- **Development of QC testing and stability programs**
- **Document control and record retention systems**

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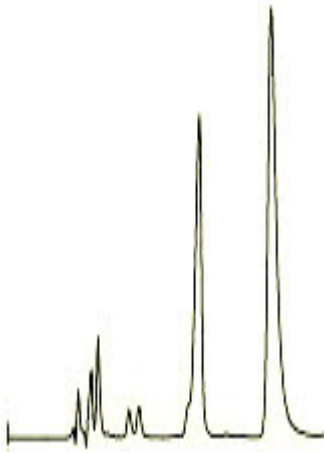

Pallas Pharmaceutical

Consulting LLC

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