LIFE SCIENCES

ADVANCING YOUR SCIENCE

CMC PHARMACEUTICAL DEVELOPMENT SERVICES - CDMO/CRO

INTEGRATED LABORATORY SERVICES

BUSINESS PROCESS OUTSOURCING

Pace Analytical®

LIFE

CMC PHARMACEUTICAL DEVELOPMENT
CLINICAL TRIAL MATERIALS MANUFACTURING
GMP LABORATORY TESTING

SUPPORTING PHARMACEUTICAL INNOVATION WORLDWIDE

Pace Analytical® Life Sciences (PLS) provides CMC Pharmaceutical CDMO / CRO services to help improve human health. Our technical teams work together with our clients to bring novel treatments to market and to ensure the safety and efficacy of established treatments and therapies created by global innovators. We share a common goal to bring real value to people, healthcare professionals and health businesses around the world. Driven by our commitment to improve our health, we deliver services that offer hope–and a better, safer and healthier life for everyone.

CLIENTS WE SERVE

Pace Analytical enjoys close working relationships with our clients, and we are recognized as key service providers in our partnerships. Our customers range from new and innovative start-up companies through to the veteran industry leaders in the Pharmaceutical, Biopharmaceutical / Biologics, and oligonucleotide industries. We are one of the top-10 Pharmaceutical development and testing laboratories in the United States, routinely working with 8 of the top-10 global pharmaceutical companies.

Our investment in state-of-the-art facilities and highly trained personnel emphasizes our commitment to deliver positive customer experiences across all channels of our business. We are dedicated to providing not only the best in Pharmaceutical Development, Clinical Supplies Manufacturing, and GMP Testing Services, but also the most reliable–and we are well-equipped to handle almost any project regardless of scope or complexity.

OUR FACILITIES AND OUR SERVICES

Our early-phase preclinical teams develop robust, stage-appropriate drug products with concomitant process understanding by leveraging analytical methods, physicochemical, biophysical, and/or biopharmaceutical characterization. Our teams have proven expertise with small molecules, biologics (such as proteins, peptides, antibodies, antibody drug conjugates) and gene therapies (such as RNA and DNA oligos).

Our drug development services advance candidates from early pre-formulation and tox studies to an IND filing and on through the clinical phases. Our GMP clinical supplies manufacturing capabilities support clients needs through phase IIIa, and include sterile injectables, ophthalmics, capsules, tablets, solutions/suspensions, and topicals. Our specialized technologies for solubility enhancement (spray drying, nano milling, and hot-melt extrusion) and stability enhancements, like lyophilization, provide options to improve product performance.

Technology transfer to Pace Life Sciences' state-of-the art GMP testing facilities enables our clients to seamlessly and confidently advance their programs through commercialization in a manner compliant with regulations and industry standards. Our FDA-registered laboratories that provide manufacturing support, submission-ready methods validation reports, finished product release testing, ICH Stability programs, raw materials clearance programs, extractable-leachable studies, and full microbiology laboratory support.

BASIC RESEARCH | LEAD OPTIMIZATION | PRECLINICAL DEVELOPMENT | FILE IND | CLINICAL DEVELOPMENT PHASE 1, 2, AND 3 | FILE NDA | FDA APP

PHARMACEUTICALS
BIOPHARMACEUTICALS
BIOLOGICS | OLIGONUCLEOTIDES
CDMO/CRO

LIFE

WHY PARTNER WITH PACE ANALYTICAL?

Strategic partnering with Pace Analytical is a key accelerator for getting your products to market on time and on budget. We provide a real and tangible difference to your customer experience by combining all essential service elements:

- **Comprehensive scope of services:** A broad scope of services to support you through every step of the development, commercialization, and marketing of your products; all tailored to meet your needs.
- **Capacity:** Pace is committed to providing services to all clients, large or small. Our sites work together to provide support, resources, and reduce delays in your development timeline. Our flexible response to demand provides various service models to allow for economical options to meet business demands.
- **Quality:** Our facilities have long histories of successful regulatory agency, client, and third-party audits. Audits are welcomed, either virtually or in-person, and demonstrate confidence that PLS is a qualified service provider
- **Reliability:** We integrate all critical path components to ensure that programs advance while meeting rigorous scientific demands with flexibility to address dynamic challenges and aggressive timelines.
- **Culture of Service:** Our programs are focused on a partnership that includes effective project management with thorough technical insight and problem-solving. You retain control of your program and benefit from our experts who collaborate and check in regularly.
- **Satisfaction:** Our customers tell us that we out-perform our competition. We take pride in the work we do and honor our commitments so you can honor yours.

PACEPORT ONLINE DATA MANAGEMENT

PacePort® is our industry-leading, web-based application that provides GMP Laboratory clients with instant access to important laboratory information–anywhere, anytime!

PacePort provides secure access to data packages for every late-phase project within hours of the final signatures from our Quality Assurance review group. Every page is in high-resolution, in color, easy to read, easy to understand and completely audit-ready. Use PacePort to access every final report and the protocol, procedure, method and data package that supports it.

ROVAL | PRODUCT LAUNCH | PHASE 4 SUPPORT | MANUFACTURING SUPPORT | PRODUCT LINE EXTENSION SUPPORT | POST APPROVAL CHANGE SUPPORT

PROVIDING COMPREHENSIVE SERVICES TO INDUSTRY

From balancing workflows to drug development and manufacturing, progress depends on your ability to solve complex problems. We are your trusted experts to provide simplified solutions through our network of scientists and laboratories.

For more than 40 years, Pace Analytical® has operated one of the largest full-service commercial development and contract laboratory networks in the nation, providing support for thousands of industry, consulting, and regulatory professionals in many industries. Our investments in facilities, technology, training and staffing, demonstrate our commitment to providing comprehensive, consistent and reliable professional services. Pace Analytical has more than 3,000 employees in over 90 locations nationwide.

When your team needs additional support, our scientists are ready. Often, we are invited to work side-by-side with our partners in their facilities, at their sites, as integrated members of their teams. Our Scientific Professional Services teams provide:

INTEGRATED MANAGED SERVICES - Professional Staffing, Regulatory Compliance (SDS authoring), Regulatory Consulting

FACILITY / SITE SERVICES - Cleanroom Certifications, Facility Monitoring, Equipment Service Contracts, Laboratory Relocations

BOSTON, MA - CRO
- 22,500 FT^2
- BIOLOGICS / OLIGO CHARACTERIZATION
- SOLID STATE AND API CHARACTERIZATION
- FORMULATION DEVELOPMENT
- TOX STUDY SUPPORT
- TEST ARTICLE PREPARATION

SALEM, NH - CDMO
- 30,000 FT^2
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY / SOLUBILITY ENHANCEMENT
- ANALYTICAL DEVELOPMENT
- STERILE FILL-FINISH GMP MANUFACTURING

SAN DIEGO, CA – CDMO
- 5,500 FT^2
- BIOLOGICS/PROTEINS/PEPTIDES
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY/LONG-ACTING FORMULATIONS
- STERILE FILL-FINISH GMP MANUFACTURING

OAKDALE, MN – CRO (HEADQUARTERS)
- 50,000 FT^2 OF LABORATORY SPACE
- FDA-REGISTERED, DEA-REGISTERED
- CHEMISTRY / MICROBIOLOGY
- ICH STABILITY PROGRAMS
- SPECIALTY SERVICES

SAN GERMAN, PR - CRO
- 22,000 FT^2 OF LABORATORY SPACE
- FDA-REGISTERED, DEA-REGISTERED
- CHEMISTRY / MICROBIOLOGY
- ICH STABILITY PROGRAMS
- NEAR SHORE PROGRAMS

PHILADELPHIA, PA - CDMO
- 33,000 FT^2
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY / SOLUBILITY ENHANCEMENT
- ANALYTICAL DEVELOPMENT
- TABLET/CAPSULE GMP MANUFACTURING

SOUTH NEW BERLIN, NY - CRO
- 12,500 FT^2
- FDA-REGISTERED
- CHEMISTRY
- ICH STABILITY PROGRAMS
- SPECIALTY SERVICES

Pace Analytical®

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