Neopharm LABS

ACCURATE
ON TIME
RESPONSIVE

Neopharm LABS

OUR COMPANY

Founded in 1990, Neopharm Labs is a full service GMP analytical testing laboratory serving the global pharmaceutical industry as well as natural health products, medical marijuana, veterinary and cosmetics markets. From our government-accredited operations, we provide unique quality control and consulting services, as well as perform a wide variety of analysis, including fine chemistry, microbiology, sterility testing, method development and validation, technology transfer and stability studies. Over the years, Neopharm has successfully developed/validated/transferred in excess of 3,000 analytical procedures.

As a Health Canada certified laboratory, Neopharm benefits from Canada's unique profile as a participant to the Global Mutual Recognition Agreements (MRA's), covering drug/medicinal products, Good Manufacturing Practice (GMP), Compliance Program, with parties such as the European Community (EC), the European Economic Area – European Free Trade Association (EEA EFTA), as well as Switzerland and Australia. Countries where MRA's are in place will accept Certificates of Analysis (CofA's) produced by Neopharm for the local commercialization of foreign products.

Through the acquisition of Averica Discovery Services in 2016, our company is able to provide a full range of services at every stage of the drug development cycle. Averica, a Contract Research Organization (CRO) based in the Greater Boston region with specialized expertise in small molecule analysis and purification, supports chemistry teams by providing material and information required to transition programs from drug discovery to development. With extensive experience in pharmaceutical R & D, we provide a variety of chromatography-based services, including method development and qualification, impurity isolation and identification, scalable small molecule purification, and custom assay development.

Our goal is to be a partner of excellence offering a full suite of analytical solutions powered by experts who are dedicated to meeting the business demands of our customers.

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NEOPHARM LABS: EXPANSION INTO THE U.S.

ACQUISITION OF BOSTON-BASED AVERICA DISCOVERY SERVICES: EXPANDED RANGE OF SERVICES & SOLUTIONS FOR THE LIFE SCIENCES INDUSTRY

November 2016 marked a turning point for Neopharm Labs as we proudly announced our expansion into the U.S. with the strategic acquisition of Averica Discovery Services a Contract Research Organization (CRO) based in the Greater Boston area with specialized expertise in early stage contract research and analytical development. The addition of Averica to Neopharm Labs' portfolio provides an opportunity for our organization to expand its geographic reach into the U.S. allowing us to pursue our growth strategy and further increase the range of services into the region.

The highly complementary combination of these two companies is unique. The new entity provides a range of services at every stage of the drug development cycle, from R&D and method development and validation, to stability management and commercial testing in chemistry and microbiology. By acquiring Averica's specialized expertise in small API molecule analysis and purification, Neopharm is creating a company that will be a leader in the field of analytical services.

Dr. Jeffrey Kiplinger, President and CEO of Averica Discovery, joined our Executive Team as Vice President, Science & Innovation. Averica's Boston area laboratory continues to provide its current services with plans to expand service offerings and lab space. The location also serves as the U.S. sales office for Neopharm Labs.

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CUSTOMER VALUE CREATION = SERVICE + INNOVATION + QUALITY

Neopharm Labs combines innovation with an exceptional quality and service level in order to deliver personalized service solutions that are addressing our clients' needs. Our strategic imperative is to partner with our customers, leveraging our laboratory expertise, specialized customer service support from beginning to end of the analytical process and quality & regulatory support, in order to help our customers to maximize their speed to market and deliver safe, high-quality products to consumers.

Neopharm Labs is a full service GMP analytical testing laboratory closely collaborating with pharmaceutical, medical devices, natural health, veterinary as well as cosmetic clients. Our world-class laboratory is regularly inspected by government agencies such as the U.S. FDA and Health Canada, and has been qualified by several world-renowned Life Sciences industry leaders. Neopharm holds a Canadian Drug Establishment license since 1995 and possesses narcotics, precursors and controlled substances licenses.

Accuracy, flexibility and innovative ways are Neopharm's trademark that shape up our client oriented culture and leading position as a service provider for the Life Sciences industry.

QUALITY ASSURANCE & CONSULTING

Neopharm is committed to providing its clients with the highest quality in analytical (chemistry, chromatography, microbiology), consulting, stability, development and validation services. We strive to respect client timelines, as well as the accuracy and integrity of all data generated while performing tests or projects. We pride ourselves in ensuring our facilities, equipments, records and procedures are maintained in accordance with applicable regulatory and compendial requirements with respect to the Client's specifications.

QUALITY ASSURANCE CONSULTING

Neopharm offers consulting services for quality assurance and regulatory requirements to the pharmaceutical industry. We assist our clients in various aspects of their quality assurance programs, including assisting them in meeting GMP requirements, developing Standard Operation Procedures (SOP), preparing for regulatory inspections and managing product and license submissions.

CERTIFICATIONS

- Inspected by U.S. Food and Drug Administration (FDA) (No 483)
- Certified by Health Canada's Health Products and Food Branch Inspectorate (HPFBI)
- Inspected By Canadian Centre for Veterinary Biologics, Canadian Food Inspection Agency
- Controlled Drugs and Substances License permit
- Audited and qualified by many global pharmaceutical organizations

REGULATORY & CONSULTING

Neopharm's team includes industry veterans with significant regulatory experience and capable of assisting our clients with respect to assessing requirements and developing:

- Stability programs in accordance to ICH Q1A, WHO and other regulatory requirements
- Validation and method transfers
- Regulatory compliance for Canada, US, Central & South America, Europe and Asian markets

PRECLINICAL R&D ANALYTICAL SERVICES

PURIFICATION & CHIRAL SEPARATION

Our lab has multiple highly customized preparative chromatography systems that allow us to achieve fast turnaround and high recovery without sacrificing quality. Upon completion of a purification project, clients receive highly pure material, fully optimized methods, and detailed reporting to support ongoing preclinical development.

APPLICATIONS

- Compound for mechanistic studies, differential enantiospecific activity, structural biology, in vivo toxicology, advanced profiling
- Applicable to water sensitive, unstable, difficult to purify compounds
- Compounds with multiple chiral centers
- Targeted purification of a desired enantiomer or isomer. Racemize and recycle the distomer
- Achieve needed enantiomeric excess (ee) to >99%

BENEFITS

- Rapid chiral screening for feasibility assessment
- Fastest turnaround & highest recovery
- Detailed method reporting & analytics
- Turnaround in DAYS, not weeks or months – even at larger scale
- Controlled substance registrations - Schedule II-V compounds
- Success-oriented and highly responsive team with average 15 years pharmaceutical industry experience

IMPURITY ISOLATION & PROFILING

Impurity isolation, profiling, and identification offers critical information at any stage of process development or manufacturing. Our laboratory is capable of screening/profiling assays using accurate mass MS or of isolation and specific structure assignment, supporting CMC documentation and ongoing development of synthesis, scale-up, and production.

APPLICATIONS

- Structure Elucidation
- Isolation of low level impurities from bulk material
- Reference Standard production
- Isolation of material for toxicology profiling

ADVANTAGES

- Trace components to 0.01% of bulk
- Fast processing of feedstock to accumulate needed isolates
- Degradation and kinetic studies - understand formation, purge and fate
- Impurities in drug substance or drug product
- Specific impurity method development and optimization

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PRECLINICAL R&D ANALYTICAL SERVICES

ANALYTICAL METHOD DEVELOPMENT

Our scientists develop analytical methods that are robust and reproducible, and designed to generate quality results. We focus on methods that are fit for purpose and on tech transfer – we recognize that you work with many partners, and we work to develop methods that are easy to use and deploy.

APPLICATIONS

- Purity, potency (assay), impurities, chiral purity
- Stability indicating methods
- ICH Q11 support, e.g. for qualification of regulated starting materials (RSMs)
- Molecules with unique complexity or physical properties
- Robust methods for fast method transfer

METHOD DEVELOPMENT ATTRIBUTES

- System Suitability
- LOD, LOQ, Linearity, Precision
- Intermediate Precision
- Sample & Standard Stability
- Evaluation of Range
- Mass Balance

BENEFITS

- A strong focus on definition of purpose and need results in methods that support the entire development process
- Diverse chromatographies and detection systems facilitates work with tough compounds and projects
- Validation and release testing is rapid and seamless if the method development is done properly
- Preformulation & Custom Assays
- Solubility profiling in vehicle or buffers
- Solubility Excipient Screening
- Forced (Stress) Degradation
- PSA – Indirect Measurement Through EPSA
- Customized physical properties assays

METHOD DEVELOPMENT & VALIDATION SERVICES

Neopharm has two distinct validation departments; chemistry and microbiology. Each validation department is dedicated to the development, validation, verification, recovery and inter-laboratory transfer of analytical methods. Typical samples include raw materials, active pharmaceutical ingredients (API), finished products, cleaning and environmental samples.

CHEMISTRY

Methods are validated according to current ICH Q2 guidelines and client's requirements for:

- Extractable & Leachable Studies
- Elemental Impurities Testing as per USP < 232/233 > and ICH Q3D
- Determining the dosage of active ingredients and finished products
- Degradation studies for the development of stability indicating methods
- Dissolution studies for all types of solid dosage forms
- Quantification and qualification of residual solvents and impurities/related substances
- Cleaning methods validation: research and quantification of washing reagents and recovery on SS plates and other materials
- Identification of known and unknown impurities

We perform technological transfers of existing methods from other laboratories and also provide verifications of Pharmacopeias.

MICROBIOLOGY

We comply with all compendial requirements. Neopharm develops and validates microbiology methods for:

- Total Aerobic Microbial Counts
- Total Yeast & Molds Counts
- Pathogen Detection
- Antimicrobial Effectiveness Testing
- Sterility
- Bacterial Endotoxins
- Vitamins
- Antibiotics

CHROMATOGRAPHY & CHEMISTRY

Our skilled and competent Chemistry group uses a wide range of methods to test raw materials, finished products and packaging components in accordance with compendial procedures including but not limited to: USP/NF, BP, Ph. Eur, JP, CP, FCC, ACS, AOAC, AOCS, In-house and client supplied methods. Over the years, Neopharm has successfully developed/validated/transferred in excess of 3,000 HPLC, GC or other chemistry analytical procedures.

ANALYTICAL SERVICES PROVIDED

Our analysts can assist you with numerous routine and specialized techniques and provide support for regulatory submissions (i.e NDA, IND, CTA):

- UPLC, HPLC, GC and IC analyses
- Process and cleaning validations
- Physical and wet chemical analysis
- Residual solvents
- Stability storage and testing
- Method development and validation
- API Characterization
- Total organic carbon (TOC)
- Dissolution studies
- Spectroscopy
- Vitamin assays
- Antibiotic assays
- Enzymatic testing /ELISA
- Protein/Nitrogen analysis
- Volatile organic compounds
- Identification of impurities with LC-MS (Q-TOF)
- Container/packaging testing including leachables and extractables

SAMPLES ANALYZED

We perform analyses on many types of samples including but not limited to:

- Pharmaceutical, veterinary, cosmetics, antibiotics, enzymes, medical marijuana and natural health products
- Finished products: oral solid dosage forms (i.e tablets, capsules), liquids (i.e injectable, oral, topical, drops, syrup), semisolid dosage forms (i.e creams, gels, lotions, shampoos), pads, swabs and suppositories
- Raw materials: active pharmaceutical ingredients, fillers, binders, lubricants, colors and other excipients
- Container/packaging components: plastics, glass, foils, bottles, strip packs and cards
- In-process products: bulk mixtures of solids or liquids prior to filling into capsules, bottles, vials and syringes, or before compressing into tablets, including DSC analysis
- Utility systems: HVAC, water-for-injection (WFI), purified water, clean/pure steam, compressed air systems, nitrogen, etc.
- Gel capsule analysis meeting new USP requirements (gel strength)

INSTRUMENTATION

- UPLC – UV/visible, diode array
- HPLC – UV/visible, diode-array, fluorometric, electrochemical, conductivity, refractive index and ELSD detection
- GC – Flame ionization & thermal conductivity detection, on-column and headspace techniques for packed and capillary columns
- Dissolution baths with autosampler – USP or Ph. Eur methods I, II, III
- GC-MS, ICP-MS(2)
- Spectroscopy – infrared and UV
- AAS – atomic absorption spectrophotometer, FIAS and graphite furnace/flame
- LC-MS (Q-TOF)
- Viscosity/Rheometry
- Particle Size Analyzer (Malvern and others)
- Differential Scanning Calorimetry (DSC)
- Microplate reader UV/visible
- SDS Page for protein migration analysis

MICROBIOLOGY & STERILITY TESTING

Neopharm offers complete microbiology and sterility testing to help ensure the safety of various products and ingredients including pharmaceuticals, cosmetics, personal care products, vitamins, water, veterinary products, natural health products, etc. All analyses are performed in compliance with cGMP requirements using methods from relevant compendia and pharmacopoeia. Our experienced microbiology team can perform a wide range of compendial assays, including: USP/NF, AAMI, BP/Ph. Eur, AOAC, AWWA, FDA-BAM and Client supplied methods.

ANALYTICAL SERVICES PROVIDED

The following analyzes are performed in compliance with current GMP requirements:

- Antimicrobial effectiveness testing (AET)
- Bacterial endotoxin test
- Antibiotic-microbial assays
- Microbial limit tests (total bacterial, yeast & mold counts & pathogen detection)
- Microbial identification (aerobic & anaerobic bacterias, yeasts, molds)
- Water testing
- Disinfectant/Disinfection efficiency testing
- Biological indicators (sterilization, verification, count, identification)
- Microscopy
- Sterility testing (injectables, powders, medical devices, packaging, etc.)
- Particulate matter
- Vitamins (assay and ID)
- Pathogen detection
- Bioburden analysis; TAMC, TYMC
- Growth promotion
- Crystallinity
- Microbial ingress
- Packaging verification

FACILITY AND EQUIPMENTS

- Biosafety laboratory Risk Group 2 licensed (total of 8,000 Sq. Ft.)
- Sterility Room Grade B (Class 10 000/ISO 7) including two Grade A (Class 100/ISO 5) zones for more flexibility
- Microbiological ID systems
- Antibiotic inhibition zone reader
- HIAC/Royco particulate matter counter

STABILITY SERVICES

Neopharm offers a full range of stability testing and storage services to meet the performance needs of our clients. Our stability operations include 15,000 cubic feet of walk-in/reach-in chambers/incubators that meet the ICH guidelines requirements. We also support special storage conditions customized to a client's specific needs. A dedicated staff and specifically designed software provides total management of stability programs including timely reports, interpretations and recommendations.

STABILITY SERVICES INCLUDE:

- Full Range of Environmental Conditions for all ICH zones
  - 25°C/60% RH (ICH zone I and II conditions)
  - 25°C/40% RH (Permeability studies)
  - 25°C/80% RH (Permeability studies)
  - 30°C/65% RH (ICH zone IVa conditions)
  - 30°C/75% RH (ICH zone IVb conditions)
  - 40°C/75% RH (Accelerated stability)
  - 2°C to 8°C (Refrigerated conditions)
  - -20°C ± 5°C (Freezing conditions)
  - Photostability (ICH Q1B, Option II)
- Flexible incubators to perform stability studies under stress conditions (customized)
- All chambers are fully mapped, qualified, controlled and 24/7 monitored with alarm system (21 CFR part 11 compliant)
- Transport studies: Cycle test and Freeze/Thaw studies, including protocol and interpretation report
- In-use stability studies to simulate patient use of drug product
- Trend analysis by Arrhenius calculation by SlimStat software in order to optimize the development of product formulations
- Stability trends to compare different packaging materials and container closure systems
- Narcotics stability studies
- Customized data recording and reporting, including OOT trending, available upon request
- Storage available for short and long-term durations, alone or with analyses

REGULATORY & CONSULTING

Neopharm's team includes industry veterans with significant regulatory experience capable of assisting clients with respect to assessing requirements and developing:

- Stability programs in accordance to ICH Q1A, WHO and other regulatory requirements
- Regulatory compliance for Canada, US, Europe and Asian markets
- Design of customized Global stability testing protocols to support drug registration and to satisfy all regulatory requirements as per ICH Q1A and WHO Stability guidelines
- Matrix and bracketing designs for reduced stability testing of commercialized products as per ICH Q1D
- Projection of shelf-life with fully validated software for worldwide regulatory submissions with 95% confidence limits and ANCOVA calculations according to ICH Q1E guideline
- Stability packages as per SUPAC to support post market changes such as manufacturing site, container/closure and product formulation changes
- Annual reports including tabulation of results and graphical trend analysis by a validated statistical software respecting FDA SAS program

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