integrated analytical
SOLUTIONS

A GENESIS DRUG DISCOVERY & DEVELOPMENT COMPANY

OVERVIEW OF SERVICES

GD3 Genesis
Drug Discovery & Development

Chemistry
- Venenum Biodesign Chemistry
- NEDP New England Discovery Partners
- BioBlocks
- Organochem — Accelerate Your Business

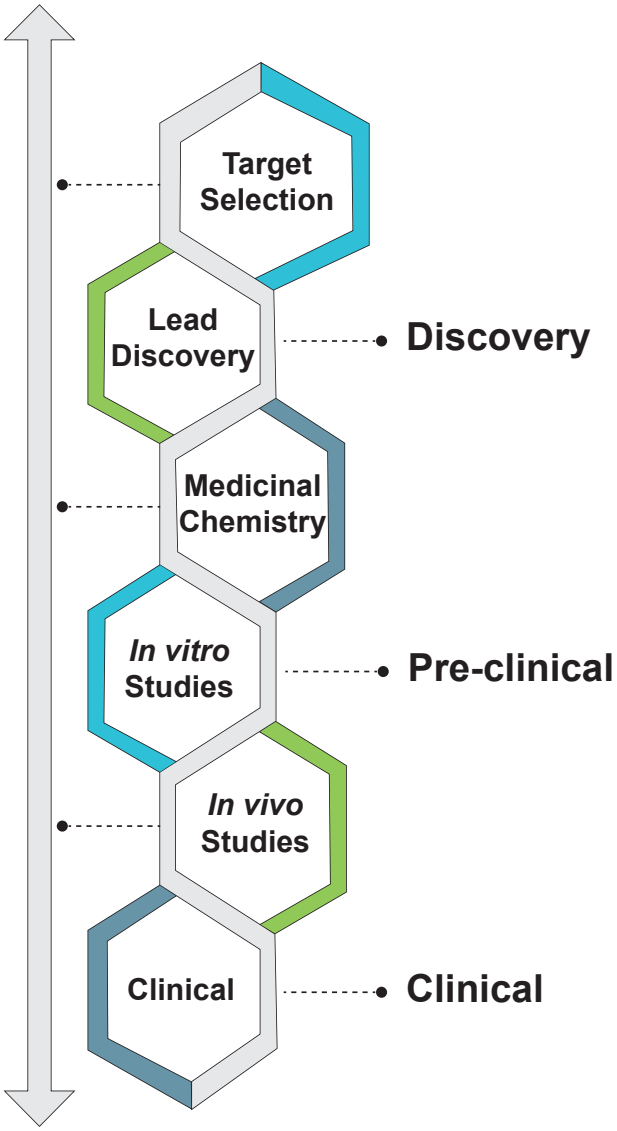
Biology/ Bioanalytical
- ias integrated analytical SOLUTIONS
- Venenum Biodesign Biology
- Pharmoptima
- Ingenio Diagnostics

Disease Modeling
- Invivotek
- nexus pharma

Preclinical-Toxicology
- Comparative Biosciences Inc.

Clinical
- STATKING Clinical Services
- JSS RESPONSIVE RELIABLE RESULTS

Genesis Drug Discovery & Development (GD³) is is a fully integrated CRO providing services to support drug discovery programs of our clients from target discovery through IND filing and managing Phase I-IV clinical trials. GD³ portfolio includes services for HTS and assay development, synthetic organic and medicinal chemistry, DMPK/in-vivo pharmacology and safety pharmacology, toxicology as well as clinical trial services for the regulatory approval of novel drug and medical device products.



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Integrated Analytical Solutions (IAS)

GxP-Compliant Contract Research Organization

IAS was founded in 2004 to support the growing demand for high-quality contract analytical services in the San Francisco Bay Area. From the beginning, we set out to provide to our clients the highest level of service grounded in a culture of scientific curiosity, open communication, and trusted relationships. This philosophy has helped us grow from a team of 2 scientists in an incubator lab to a current staff of 13. Through referrals and word-of-mouth, our clients have grown to include companies and academic labs around the world.

Though our company and client roster have grown, our approach remains the same. We are scientists serving a community about which we know and care. We are proud to cultivate loyal customers because of how we do business. Beyond simply delivering excellent R&D services, IAS strives to build lasting relationships with its clients, fellow services providers, and scientific consultants.

Services

IAS is a Good Laboratory Practice compliant (GLP), contract research organization focused on delivering fit-for-purpose solutions and the highest quality data. We provide expertise in:

- **Bioanalysis**
    - o Research Track
    - o Qualification Track
    - o Validation Track
- **Drug Metabolism**
    - o In Vitro Metabolism Assays
    - o Metabolite Identification
    - o Drug-Drug Interaction (DDI) Assays
    - o Protein Binding Assays
    - o Plasma Stability Assays
- **Analytical Chemistry**
    - o Release and Stability Testing of Non-commercial Products
    - o Nonclinical Dose Formulation Analysis (NCDFA)
    - o Physicochemical Profiling
    - o Assay Development Services

Bioanalysis

We specialize in GLP and non-GLP bioanalytical services using liquid chromatography with tandem mass spectrometry (LC-MS/MS) and immunoassay methods. We support pharmacokinetic (PK) and toxicokinetic (TK) evaluation of pharmaceutical and biopharma products. Our team works with you to determine the right bioanalytical approach for each stage of development and every size budget.

We are dedicated to developing methods for our client's most challenging drug candidates and biomarkers. The bioanalytical workflow system at IAS includes best practices for sample log-in, study scheduling, sample analysis, and data reporting. For regulatory or research purposes, the data we deliver will always meet client, internal, and applicable compliance standards

Research Track: *Bioanalysis for PK Screening*

DEVELOP

IAS provides cost effective solutions for your discovery-research bioanalysis with time-tested approaches to bioanalytical method development for new chemical entities (NCE's). Clients receive a snapshot of pharmacokinetic data quickly, efficiently, and economically. In most cases, we're able to deliver a bioanalytical report to you within seven days of receiving your samples.

The Research Track approach is appropriate for:

- Early PK screening
- Cassette PK studies
- Analyzing plasma samples from pharmacology efforts

Qualification Track: *Bioanalysis for Lead Optimization/Selection*

As selected compounds show promise, it may be necessary to further characterize the overall suitability of their bioanalytical methods. We offer various levels of bioanalytical method qualification to provide you with the assurance that a method has the desired level of accuracy, precision, sensitivity, and stability for a particular stage of development. At this level, bioanalytical methods for lead candidates and critical biomarkers are further optimized and qualified to support pivotal PK, dose range-finding, toxicokinetic, and tissue distribution studies.

Validation Track: *GLP Bioanalysis*

Ensuring a method performs according to established criteria with each set of test samples is paramount for data intended for regulatory submission. At this stage of development, bioanalytical method validation and test sample analysis will be under the control of our Quality Assurance Unit. We validate bioanalytical methods following European Medicines Agency (EMEA) and the Food and Drug Administration (FDA) guidance. We analyze your test samples according to the FDA GLP regulations and IAS Standard Operating Procedures (SOPs).

We provide full support for test samples from the following studies:

- Discovery PK studies
- Cassette PK studies
- Biomarker Studies
- Toxicokinetic studies
- Pharmacology studies
- Clinical studies (Phase I-IV)
- Tissue distribution studies
- Drug-drug interaction studies
- Bioavailability (BA) & Bioequivalence (BE) studies

Drug Metabolism

Our drug metabolism capabilities include high-throughput screening (HTS) and lead optimization for drug metabolism testing from off-the-shelf assays to compound-specific investigations. We offer economical solutions for providing metabolic stability data for all of your early discovery screens. The data we provide will facilitate the prioritization of your discovery compounds.

Our highly trained scientific staff provides expert guidance for metabolite identification and drug-drug interaction studies. Findings from these studies are critical to selecting appropriate species for in vivo toxicology studies and developing clinical testing strategies.

In Vitro Metabolism Assays

Our *in vitro* metabolism screens are an efficient approach to evaluating the stability and clearance of your test compounds in the presence of drug-metabolizing enzymes.

Assay Capabilities

- Liver, intestinal and renal microsomes
- Liver, intestinal and renal S9
- Cryopreserved hepatocytes
- Reaction phenotyping using recombinant enzymes

Assay Features

- Time profiles may be customized for each experiment
- Support for investigations in all relevant species
- Reaction conditions tailored to meet your needs for Phase I and II metabolism

Metabolite Identification

IAS offers expert capabilities for identifying metabolites that may cause unintended side effects. The data acquired from these experiments are interpreted and scrutinized by our most experienced scientific staff. You can expect very detailed reports containing elucidated/proposed metabolite structures and sites of modification on the precursor molecule.

Metabolite ID Capabilities

- *In vitro:* analysis performed in samples from concentrated *in vitro* reactions
- *In vivo:* analysis performed in selected matrices from PK, Tox, and clinical studies

Drug-Drug Interaction (DDI) Assays

Understanding compound interactions with co-dosed medications is critical to the drug development and market approval process. IAS provides DDI data to steer you toward drug candidates with reduced potential for adverse events and toxicity.

CYP450 Inhibition Studies

- IC50 determination
- Single point inhibition studies

Protein Binding Assays

Our protein binding assays aim to improve your understanding of your compound's efficacy, distribution, elimination, and safety profiles.

Protein Binding Capabilities

- All species of plasma/serum
- Equilibrium dialysis
- Single protein studies available

Plasma Stability Assays

Our plasma stability assays determine the extent to which your compound is a substrate for plasma enzymes which may degrade a research compound and alter its desired effect. This data can have implications for both PK screening and bioanalytical procedures. IAS offers plasma stability assays across multiple species of plasma.

Analytical Chemistry

Whether you are looking for specialized analytical methods or routine analytical release testing, our team of highly specialized scientists provides a personalized, collaborative approach to develop budget-appropriate methods. Let us solve your project challenges and bridge your research to product development.

Our Analytical Chemistry methods include:

- High-Pressure Liquid Chromatography (HPLC)
- Absorbance & Fluorescence
- Mass Spectrometry

Release and Stability Testing of Non-commercial Products

We offer Good Manufacturing Practices (GMP)-compliant services to support clinical Active Pharmaceutical Ingredients (API) and drug product release and stability. Our systems meet the most rigorous standards for quality.

IAS scientists will develop and validate analytical methods that perform based on their intended purpose while our QA staff ensures this work complies with both internal and regulatory requirements. This two-pronged approach ensures the integrity of your data and the fitness of systems used to generate it.

Nonclinical Dose Formulation Analysis (NCDFA)

Although regulatory guidance on preclinical method validation for formulation sample analysis is currently limited, our approach to NCDFA method validation and sample analysis is specifically designed to be consistent with the principles of GLP. Dose formulation analysis is performed to assess test article concentration, formulation homogeneity, and stability.

Physicochemical Profiling

The early characterization of lead compounds facilitates the selection of a commercially viable drug candidate. Physiochemical testing can be used to avoid time-consuming and expensive problems during preclinical and clinical drug development.

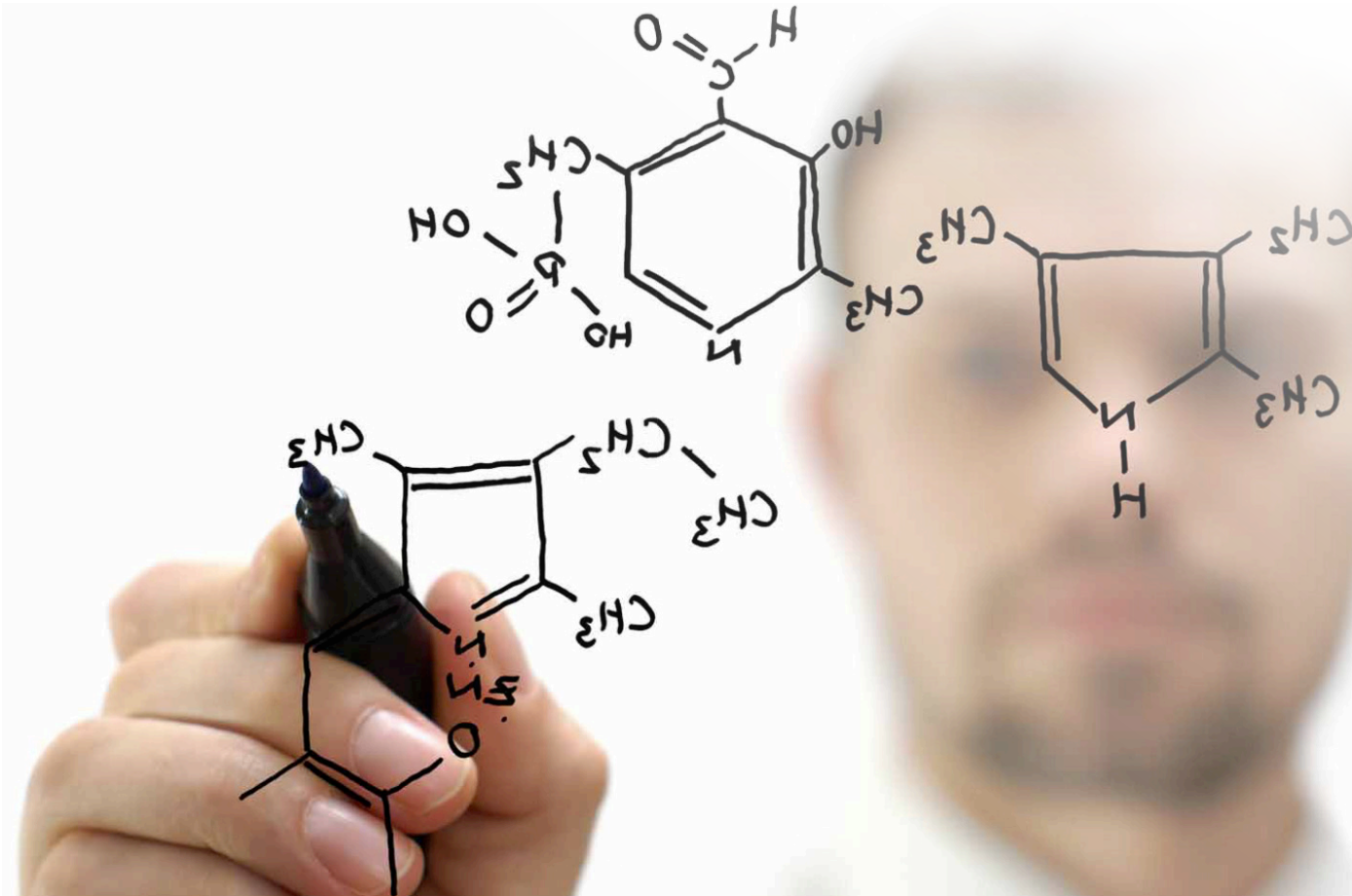
IAS is here to assist these efforts by supporting the following studies:

- Thermodynamic and kinetic solubility studies
- pH solubility and stability studies

Assay Development Services

We thrive on discovering fit-for-purpose solutions for an array of client requests. By harnessing the power of our instruments and the expertise of our scientific team, we deliver custom assays to meet client needs in the following areas:

- **Biomarker Analysis**
- **Analysis of client-processed samples**
  - o Cell-based assays
  - o In-vitro ADME studies
- **Methods to Support Controlled Release and Interaction Studies**
  - o Medical devices
  - o Nano-particles
  - o Drug delivery systems
  - o Polymers

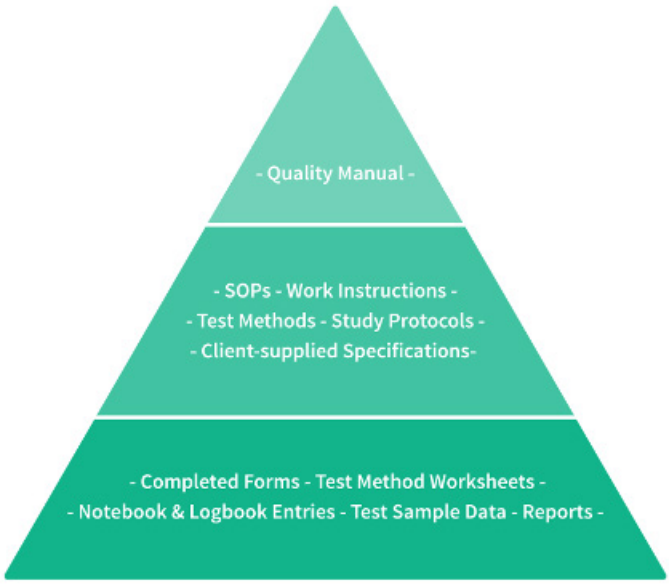


Quality Management System

Commitment to Quality starts at the Top

Our Quality Management System and the deep experience of key staff enable the IAS team to work hand-in-hand with clients to navigate and overcome regulatory hurdles. We are on a mission to provide best-in-class GLP bioanalytical and GMP analytical services and are always audit-ready!.

We are dedicated to the continuous improvement of our Quality Management System. Ongoing activities to ensure that we remain current in our approach to quality include:



- Comprehensive training program
- Responsive to deviations and non-conformities
- Scheduled routine internal audits
- Implementation of corrective actions
- Rigorous sample management program
- Validated computer systems and qualified equipment

Our Quality Agreements and Statements of Work explicitly define responsibilities and deliverables. We offer:

- QA oversight of critical records, including protocols, laboratory records, reports
- Systems to ensure data integrity, traceability, security, and archiving
- cGMP and GLP Compliance:
  - o Fully compliant with FDA Current Good Manufacturing Practice (cGMP) Regulations 21 CFR Parts 210 and 211
  - o Fully compliant with FDA Good Laboratory Practice (GLP) Regulations 21 CFR Part 58 and OECD Principles of Good Laboratory Practice

We welcome sponsor audits. Specific SOPs and full Quality Manual are available upon request.

Scientific Management

James Beasley, Ph.D.
Managing Director

Dr. Beasley joined the GBG team in 2011. He oversees a team of scientists that support the research efforts in GBG's pre-clinical drug discovery programs in therapeutic areas such as metabolic disorders, oncology, and infectious disease. Dr. Beasley's Discovery Biology team specializes in the development, optimization, and execution of assays in the ultra-high-throughput screening (uHTS) of Venenum's 5.7 million member compound library. The team also develops and performs assays, including several ADME-Tox assays, necessary to profile the small molecule therapeutic compounds produced by medicinal chemistry. Dr. Beasley serves as a member of the GBG Executive Council.

Dr. Beasley began his career with VENENUM Biodesign as the Discovery Biology Team Leader. In 2014 he was promoted to his current position as Director of Discovery Biology.

Dr. Beasley brought 12 years of experience in the Drug Discovery industry. He previously held positions with Ligand Pharmaceuticals as a Senior Research Investigator, Pharmacopeia as a Senior Principal Scientist, and DGI Biotechnology as a Senior Scientist.

Dr. Beasley received his BS in Chemistry from University of Texas at Austin in Austin, TX. He earned his PhD. in Chemistry at University of North Carolina at Chapel Hill in Chapel Hill, NC. Dr. Beasley completed his post-doctoral fellowship at Princeton University in Princeton, NJ.

integrated analytical
SOLUTIONS

1000 Waterview Drive
Hamilton, NJ 08691
510-649-9016 • 609-227-0255

1265 65th Street, Suite 1
Emeryville, CA 94608
510-982-5611

www.ianalytical.net

For Inquiries, please contact:

Biochemistry &
Bioanalytical Division

Toll Free: 1-844-272-8234
Info@gd3services.com • www.gd3services.com