# ANALYTICAL SERVICES

DSI can oversee the development, application, and investigation of analytical methodologies for use in the control of starting materials, drug substances, and drug products. This spans the full lifecycle of methodology including design, development, optimization, transfer, validation, and ongoing updates. After 14 years, we continue to support some of our earliest clients through the ups and downs of drug development.

## METHOD DEVELOPMENT AND OPTIMIZATION

With an average of more than 30 years of experience each, the types of test method and products that DSI's consultants have experience with is extensive and continuously expanding. Our Analytical Development Team has comprehensive methods development and validation experience in a wide range of analytical methodologies for small molecule drugs, generics, biologics, biosimilars, orphan drugs, and over-the-counter (OTC).

- Diverse active ingredients including small molecules, peptides, proteins, and oligonucleotides
- Traditional dosage forms including tablets, capsules, lyophilized and liquid, parenteral and oral solutions, alternate dose forms such as soft chews, semi-solid gels, nasal, inhalable products, and liposomes, stem cells and as well as bioanalytical methods and PK/ADME samples.
- Chemical and chromatographic assay and related substances methods, residual solvents, nitrosamine risk assessment and elemental impurities methods, physicochemical characterization methods, structural analysis methods, microbial enumerations and sterility/container closure integrity tests, compendial monograph and general chapter methods, biochemical release and characterization tests.
- Forced degradation and method qualification
- Generation of dissolution development and discriminating dissolution studies for solid oral dosage forms.
- Stability study trend analysis and interpretation on shelf life expiration dating

## METHOD QUALIFICATION AND VALIDATION

All methods display some variability. It's important to know how much. Your release and stability data does not truly make sense until you understand the limitations of the method(s) that generated it. How reliable (accurate and precise) is it? Over what range of conditions can the method be run and still give trustworthy results? What are reasonable system suitability ranges to set to ensure that method problems are caught before they become serious and affect data generation and timelines. DSI's consultants will work with your analytical labs to ensure smooth execution of studies including:

- Method validation per compendial/ICH/VICH requirements
- Method transfers of manufacturer methods to and between CDMOs to ensure that drug substances and excipients can be tested externally for release.
- Verification of compendial monograph methods and qualification of product-specific methods derived from compendial general chapters.
- Method equivalency studies to replace compendial drug product methods with equivalent or superior in-house methods.
- Bioanalytical methods validation to support clinical studies.

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## INVESTIGATIONS AND EVALUATIONS

CDMOs that primarily perform release and stability testing frequently do not have the analytical and methodology expertise or inclination to perform thorough investigations when anomalous data or method performance is observed. Sometimes the most convenient explanation is proposed to resolve an investigation quickly, rather than thoroughly investigating other possible causes that are better supported by the data, to understand why a problem occurred so it can be prevented in the future. DSI's experienced consultants work closely with your analytical and manufacturing labs to coordinate investigative strategies, to flag data anomalies, evaluate viable hypotheses and generate data-supported and QA approvable investigation reports and corrective/preventive actions (CAPAs).

Examples include:

- Analytical investigations of Out of Specification and Out of Trend results in release and stability tests
- Impurity isolations and characterizations of newly- occurring degradants
- Investigation of stability trends and establishment of drug substance and product shelf lives
- Generation of Elemental Impurity, Nitrosamine and Genotoxicity Risk Assessments
- Verification of dosing solution stability for prepared clinical materials
- Evaluation of extractables and leachables content of parenteral products

## ANALYTICAL REGULATORY AFFAIRS SUPPORT

Obtaining first-time approval of NDAs, BLAs, ANDAs and JINADs, and getting prompt authorization via INDs and IMPDs to commence clinical studies as well as addressing Agency concerns in complete response letters (CRLs) and other filings is a matter of presenting the appropriate data-driven story to demonstrate that the products' manufacture, characterization, testing, and stability is under control and well understood. Presenting the available data to make the strongest case to regulatory authorities requires not only analytical expertise but the experience to present the right data in the right fashion to support the IND/NDA claim being made or to respond to the Agency's questions.

- Technical review of analytical sections of regulatory filings.
- Evaluation of characterization and impurity qualification data to ensure that the structure and degradation mechanisms of the product are adequately understood.
- Generation of specification justifications for drug substances and drug products based on available release and stability data, manufacturing process capabilities, maximum daily dosages and regulations/industry standards.
- Establishing product-specific control strategies for finished products e.g. for degradants, genotoxic and synthesis impurities, extractables/leachables.
- Establishment or justification of product shelf life through evaluation of available stability data.
- Generation of responses to Agency queries, including CRLs and preparation/review of regulatory responses.


## Contact Us

DSI, a PLG Company
P: 855-805-8402
solutions@dsinpharmatics.com