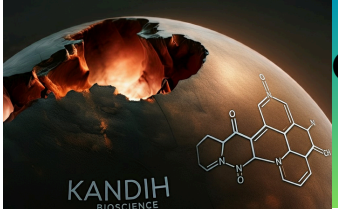

CAPABILITIES STATEMENT

ADVANCING MEDICAL SAFETY

KANDIH BIOSCIENCE
Toxicology and Regulatory Consulting

KANDIH BioScience is a woman-owned business dedicated to driving innovation in the healthcare industry by delivering comprehensive regulatory and strategic development services for drugs, biologics, medical devices, and cosmetics

Key Expertise:

- **Protecting Human Health:** Our toxicology specialists ensure product safety by meeting rigorous regulatory standards and consumer expectations.
- **Navigating Regulatory Hurdles:** We streamline compliance with national and international regulations, including those from the FDA, EPA, REACH, and OECD, ensuring an efficient path to market approval.
- **Safeguarding the Environment:** Our environmental consulting team conducts site assessments, qualitative testing, and remediation planning to promote sustainable practices to minimizing environmental impacts

CORE CAPABILITIES

PROJECT MANAGEMENT

- **Testing Services**
  - Design studies and oversee execution.
  - Manage sample collection and reporting
- **Regulatory Toxicology Study Design**
  - Develop study strategies and manage CRO partnerships.
  - Review preclinical study protocols and reports.
- **Laboratory Identification and Audits**
  - Select and audit labs for GLP compliance.
  - Recommend improvements for regulatory adherence.
- **Provide Logistics Support**
  - Manage sample and test article handling.
  - Coordinate study site and lab logistics.
  - Ensure data quality and protocol compliance.
- **Study Monitoring-Clinical and Non-clinical**
  - Conduct site visits and monitor compliance.
  - Review data, address deviations, and ensure integrity.
- **Study Close-Out and Report Generation:**
  - Ensure protocol-compliant study completion.
  - Generate comprehensive study reports

CERTIFICATIONS

STATE: SBR, SBE, MBE, DBE
FEDERAL: WOSB, WBE

GENERAL INFORMATION

Company Name	**Kandih Group, LLC**
DBA	**Kandih BioScience**
CAGE Code:	
UEI ID	**T9Q7HEENL936**

NAIC CODES

- **541715, 541690, 541714, 541620**
- **541380**

REGULATORY AFFAIRS

- **Regulatory Consultation**:
  - Develop regulatory strategies and ensure compliance.
  - Conduct gap analyses and due diligence.
- **Regulatory Submissions (eCTD)**
  - Prepare and submit INDs, NDAs, and amendments.
  - Ensure compliance and engage with FDA, EMA, Health Canada.
- **Literature Review & Documentation**
  - Develop Investigator's Brochures and risk assessments (WoE for carcinogenicity, environmental risk assessment)
  - Prepare scientific reports and publications.
- **Quality Assurance**
  - Ensure GLP/GMP compliance and conduct audits.
  - Develop SOPs for regulatory adherence.

SAMPLE PASTPROJECTS

- **Subcontractor – Technical Research Institute (NIAID Support) -** Reviewed study designs, protocols, and reports in pathology, toxicology, bioanalytics, PK, and IND summaries.
- **Subcontractor – SCITECK (GAP/BARDA Support)-** Assessed regulatory strategies for Scopolamine and developed large animal models for nerve agent countermeasures.
- **Paradigm Biopharma, Ltd -**Designed toxicology/ pharmacology assays, monitored studies, and advanced compound research.
- **Plakous Therapeutics, LLC-** Developed preclinical studies, regulatory strategies, and ensured compliance with FDA/EU/global standards for biologics and devices.

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SCAN ME

A trusted partner for organizations seeking comprehensive toxicology and safety consulting services.

KANDIH BIOSCIENCE