FDA CONNECTION GROUP INC
YOUR CONNECTION TO THE FDA

Capability Statement

www.fdaconnection.com

FDA Connection Group, Inc. is a 3rd party FDA consulting group specializing in analytical, clinical, regulatory, and compliance affairs specific to FDA. Our Team meets and exceeds Good Clinical Practices, Good Manufacturing Practices, Good Laboratory Practices, Quality System Regulations, International Conference on Harmonization, and International Organization for Standardization (GCP/GMP/GLP/QSR/ICH/ISO) requirements for the Pharmaceutical, Medical Device, and Biologic industries.

CAGE: 8VUG8 | **DUNS:** 025358310 | **Phone:** (571) 246-3142

Core Competencies

We Specialize In:

- **GCP, GMP, GLP**
- **IND Investigational New Drug**
- **CAPA**
- **NDAs/ANDAs**
- **PMAs PreMarket Approvals**
- **PLAs/BLAs**
- **510(k)s**

Differentiators

- Over 100+ years experience
- Provide superior customer care to our clients
- Respect and value our relationships with all parties
- Deliver quick efficient site visits and written documentation
- Together, bring your company into compliance
- We provide, timely, accurate, professional and thorough results

Company Snapshot

Gov. Business POC's: Nate Williams
Phone: (571) 246-3142
E-Mail: n.williams@fdaconnection.com
Address: 7830 E Camelback Rd Unit 410 Scottsdale, AZ 85251
Work Area: Nationwide
Socio-Economic: Minority-Owned Small Business

Past Performance

Arizona State University | **Value:** $75,000
Location: Phoenix, AZ | **Dates:** 10/2020
Job Detail: Clinical Trial Monitoring Services for 4 Trials all in Phase 2 | Assist writing IND/CMC required to start 4th Clinical Trial

R3 Stem Cell | **Value:** $40,000
Location: Phoenix, AZ | **Date:** 08/2020
Job Detail: Write Feasibility/Cost Analysis Report for Birth Tissue Recovery Center | Write Clinical Trial Plan/IND for initial meeting with FDA in efforts for Clinical Trial Phase 1 approval

ReGen Factor Pty Ltd | **Value:** $65,000
Location: Melbourne, Australia | **Date:** 12/2020
Job Detail: Write Clinical Trial Plan/IND for initial meeting with FDA in efforts for Clinical Trial Phase 1 approval

Primary NAICS & PSC Codes

541714 - Research and Development in Biotechnology (except Nanobiotechnology)
325413 - In-Vitro Diagnostic Substance Manufacturing
325414 - Biological Product (except Diagnostic) Manufacturing
541380 - Testing Laboratories
541611 - Administrative Management and General Management Consulting Services
541618 - Other Management Consulting Services
541690 - Other Scientific and Technical Consulting Services
541715 - Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)
541720 - Research and Development in the Social Sciences and Humanities
541990 - All Other Professional, Scientific, and Technical Services
561990 - All Other Support Services
561990 - All Other Support Services
R408 - Support - Professional: Program Management/Support
R499 - Support - Professional: Other
R699 - Support - Administrative: Other
R799 - Support - Management: Other

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