



## 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.

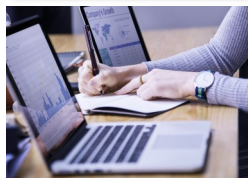


**CAGE:** 8VUG8 | **UEI:** C3A4PAHVBLU1 | **Phone:** (571) 246-3142

## Core Competencies

### We Specialize In:

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



## Past Performance



**Arizona State University** | **Value:** \$75,000  
**Location:** Phoenix, AZ | **Dates:** 2020-Present  
**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:** \$200,000  
**Location:** Phoenix, AZ | **Date:** 2020-Present  
**Job Detail:** Writing SOPs for R3 Therapeutics' developing Lab, Processing Center, and Clinical Trial Site | 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:** 2020-2022  
**Job Detail:** Write Clinical Trial Plan/IND for initial meeting with FDA in efforts for Clinical Trial Phase 1 approval



**Letco Medical** | **Value:** \$200,000  
**Location:** Decatur, AL | **Date:** 2021-Present  
**Job Detail:** Audit API Supplier Specialty Process Labs | Full Regulatory/Compliance Audit with semi-annual follow-up

## Company Snapshot

**Gov. Business POC's:** Nate Williams

**Phone:** (571) 246-3142

**E-Mail:** [n.williams@fdaconnection.com](mailto:n.williams@fdaconnection.com)

**Address:** 7830 E Camelback Rd Unit 410  
Scottsdale, AZ 85251

**Work Area:** Nationwide

**Socio-Economic:** Minority-Owned Small Business

## 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

## 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

**Nate Williams**  
Gov Business POC's

**(571) 246-3142**

**n.williams@fdaconnection.com**

**7830 E Camelback Rd Unit 410 Scottsdale, AZ 85251**