

# CAPABILITY STATEMENT



## ■ Company Overview

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Senan Group partners with leaders in Business, Technology and the Regulatory Compliance functions to tackle their most important challenges, see and capitalize on their greatest opportunities. Senan Group is a leading provider of regulatory compliance products and services for the 21st century. We specialize in providing solutions with IT Compliance, Risk Management, Testing and Digital Transformation within regulatory industries and IT Compliance in Bridgewater, New Jersey. We have over 20+ years' experience of helping our customers comply with the FDA, MHRA, and other regulations. We bring together traditional compliance, cloud compliance, cyber security, and GDPR/Data Privacy to build comprehensive compliance solutions for our clients, in the Federal/Public and Private Markets.

## ■ Contract Vehicles & Certifications

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- Business Size: SBA Certified Small Business
- Minority
- Small Disadvantaged Business
- UEI Number: QLCTZD2ZLBA6
- GSA
- 8(a) Upcoming

## ■ NAICS Codes Supported

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- **541511** Custom Computer Programming Services
- **541512** Computer Systems Design Services
- **541513** Computer Facilities Management Services:
- **541714** Research and Development in Biotechnology
- **541519** Other Computer Related Services
- **54171** Research and Development in the Physical, Engineering, and Life Sciences
- **541611** Administrative Management and General Management Consulting Services (IT/TELECOM)
- **517112** Wire Telecommunications Carriers
- **611430** - Professional and Management Development Training

## ■ Solutions

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### DATA INTEGRITY PROGRAMS AND REMEDIATION

- Data Integrity Programs Review
- Implementation of Data Integrity Programs

## ■ Company Information

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- Senan Group LLC
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- **Facebook:** <https://www.facebook.com/senangroupllc/>
- **Instagram:** <https://www.instagram.com/senangroupllc/>

- Implementation of Data Integrity Controls
- Review of Audit Trail Data using forensic standards
- Periodic Review of Data Integrity Effectiveness
- Implementation of Data Integrity Programs

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## ■ AUDIT AND INSPECTION READINESS

- Design Audit and Inspection Readiness programs
- Implement Audit and Inspection Readiness programs
- Perform Third-Party Assessments and Audits

## ■ CLOUD COMPLIANCE FOR REGULATORY USE

- SaaS Validation for GxPregulatory use
- IaaS Qualification for GxPregulatory use
- Cloud Design Strategy for GxP Applications
- Migrating GxP Applications to the Cloud

## ■ ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING FOR REGULATORY USE

- Develop AI and ML Regulatory strategy
- Design AI and ML Models
- Develop Regulatory Test for AI & ML Implementation
- Implement Predictive Compliance Models
- Application of AI Models for Risk Management

## ■ ROBOTIC PROCESS AUTOMATION

- Program Management for RPA
- Develop RPA Regulatory Strategy
- Design RPA Models
- Develop Regulatory Tests for RPA Implementation

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## ■ CYBER SECURITY SERVICES

- Security Risk Consulting
- Security Assessment and Audit
- Security Programs Design & Implementation
- Vulnerability Management
- Penetration Testing
- Incident Response

## ■ IT SARBANES-OXLEY COMPLIANCE

- SOX Risk Assessment
- SOX Controls Rationalization
- Controls Automation
- SOX Controls Testing
- SOX Third-Party and SSAE/SOC Report Analysis & Testing

## ■ DATA PRIVACY & GDPR COMPLIANCE

- Data Privacy & GDPR Programs Design
- Data Privacy & GDPR Programs Implementation
- Data Privacy Assessment
- GDPR & Data Privacy by Design
- Third-Party Data Privacy and GDPR Compliance

## ■ ERP (SAP, Oracle, MS Dynamics) RISKS & CONTROLS

- Ruleset Development
- Ruleset Maintenance
- Firefighter Log Management

## ■ Our Solutions Engagement Models

### ■ TURNKEY SOLUTIONS



- Scope the project with the client
- Deliver complete solutions to the client
- 100% Satisfaction
- Guarantee inspection ready

### ■ SERVICE-BASED MODELS



- Manage Services Models (Flexible)
- Manage Services Models (Fixed)
- 100% Satisfaction

### ■ RESOURCE AUGMENTATION



- Scope the project with the client
- Provide resources to deliver under clients or Senan Group direction
- 100% Satisfaction

## ■ Sample Prime Past and Ongoing Experience



zoetis

VIFOR  
PHARMA

Pfizer

NOVARTIS

molex

MERCK  
INVENTING FOR LIFE

KVK TECH

Johnson & Johnson

Genmab

ES  
eagle scientific ltd

Bristol-Myers Squibb

bluebirdbio

Biogen

AMYLYX

amneal

BlueRock  
THERAPEUTICS

KEROS  
THERAPEUTICS

Organogenesis  
Empowering Healing

