

# VALIDATION SERVICES

O'Neal offers turn-key services for commissioning, validation and operational start-up for pharmaceutical and medical device facilities. We can assist you with all aspects of commissioning and validation — facility, equipment, computer systems, process, cleaning, and sterilization. O'Neal also provides assistance in GLP, cGMP, MHRA, and QSR compliance; facility licensing for controlled substances, radiological materials, or animal research; and the handling of chemical or biological hazards.



*See reverse side for additional list of services.*

## ***Project Flow and Related Services:***

### ***Plan***

- Commissioning and Validation Master Plans
- Design Strategy for Compliance

### ***Design***

- Develop Test Protocols
- Identify Equipment Vendor Requirements

### ***Procure***

- Perform Equipment Supplier Audit
- Witness Factory Acceptance Testing

### ***Build***

- Coordinate and Witness Installation and Testing
- Develop SOPs for facility licensing or registrations

### ***Commission***

- Develop and Execute Commissioning Protocols
- Coordinate and Review Turn-over Packages and As-Built Drawings

### ***Validate***

- Develop and Execute Validation Protocol
- Coordinate Operational Training

### ***Operate***

- Assist with Operational Start-up
- Conduct Compliance Training

# VALIDATION SERVICES

## COMMISSIONING

- Facility Commissioning Plans
- Verification of Construction to Design Basis
- Verification of As-Built Drawings
- Documentation Control and Review
- Installation and Functional Check-Out
- Start-Up Support
- Review of Turnover Packages
- Safety Review
- Coordinate/Perform Training
- Integrate with Qualifications

## VALIDATION

- Validation Master Plans
- Validation Protocol Development
- Protocol Execution
- Facility Qualification
- Utility System Qualification
- Equipment Qualification
- Process Validation
- Cleaning Validation
- Sterilization Validation
- Lab Equipment Qualification
- Test Method Validation
- Computer System Validation
- 21 CFR Part 11 Solutions



## SUPPORT PROGRAMS & REGULATORY COMPLIANCE

### *Facility Audits and Design Review:*

- Pharmaceutical Product Manufacturing
- Medical Device Manufacturing
- Animal Research
- Impact Assessments
- Risk Analysis

### *Procedures and Policies for:*

- Controlled Substances
- Radiological (research / manufacturing, x-ray equipment)
- Animal Research
- Training Programs
- Biological Hazards (CDC Guidelines)
- Preventative Maintenance
- Bloodborne Pathogen Programs
- Chemical Safety (OSHA Guidelines)

### *Facility Registration / Licensing assistance for:*

- Controlled Substances (DEA and state)
- Radiological Materials (DNR and state)
- Animal Research
- FDA Registration

### *Procedure Development for:*

- Materials Storage and Control
- Equipment Operation and Cleaning
- Metrology and Calibration
- Preventative Maintenance Change Control
- Quality Assurance and Quality Control
- Document Control Systems