QIS

**An Extension of Your Team**

Quality Implementation Services, Inc.

QIS, Inc. is a professional services organization dedicated to delivering customized solutions designed exclusively for your company's current regulatory challenges. When you choose QIS, you get tremendous value. We match your needs with specialized experts to produce compliant processes that are simple to use and easy to learn. Our core-objective is to always make sure your company is rewarded with successful regulatory achievements making your future always move quality-forward. QIS works in complete harmony with your team to create a time-savings environment to deliver intuitive and exceptional products based upon current regulatory requirements and industry best practices.

Whether you're a small, medium or large pharmaceutical, medical device, OTC or dietary supplement company, QIS can offer clear solutions to meet your company's regulatory compliance, laboratory, and technical writing goals.

# DEDICATION

## We Listen

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CEO
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# Success - Yours is Ours

The ability to maintain your company's processes and product in compliance is very challenging. QIS is committed to helping you successfully address your regulatory challenges.

We take pride in supplying:

- Practical approaches
- Effective communication of information
- Real-life solutions
- Listening skills & custom solutions
- Sound & contemporary advice
- Easy to work with professionals

## Regulatory Support

- Compliance & GAP Analysis Auditing (cGMP, GLP, QSR)
- Mock FDA Inspections
- Investor and M&A Due Diligence
- PAI Readiness
- Quality Systems Set-up & Optimization
- Document Control Systems
- Facility & Equipment Controls
- Material & Warehouse Controls
- Production & Process Controls
- Design Controls
- Project Management
- Regulatory Submission Planning & Execution (eCTD, 510k, PMA)

## Laboratory Compliance

- Lab Build-out, Implementation, Optimization
- Lab procedures & documentation
- Calibration & Preventive Maintenance Program Build, Implementation, Optimization
- Equipment & Instrument Qualification Build, Implementation, Optimization
- Sample Handling Controls Build, Implementation & Optimization
- Analytical Method Validation or Transfer
- USP Method Verification
- Contract Lab Qualification & Management Assistance
- Stability Programs Auditing, Writing, Editing, Review
- Laboratory OOS Investigation Assistance
- QC Data & Record Reviews

## Technical Assistance

### Technical Writing

- SOPs: Quality Assurance, Quality Control,
- Laboratory Controls, Clinical, cGMP, cGLP
- Equipment, Instrument Installation, Qualification Protocols & Reports
- Engineering Tests Protocols & Reports
- Analytical Test Methods
- Analytical Methods Verification & Validation Protocols
- Engineering Test Reports
- Design & Development Plans
- CMC Review & Submission Assistance

### Technical Reviews

- IND/NDA Submission Review
- 510(K) Submission Review
- eCTD Submission Review
- Data & Records
- Batch Records
- Validation Packets
- Stability Data
- Design & Development Records
- Complaint Handling
- CAPA
- Failure Investigations

## Training

QIS provides fully customized training programs in quality assurance, regulatory submissions, GxP, and FDA readiness for all levels of your organization.