



**Q Pharma, Inc.**  
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**Patrick P. Den Boer, CEO, Q Pharma, Inc.**

## Vital Statistics

**Year Founded:** 1994

**Key Personnel:** Patrick P. Den Boer, Chief Executive Officer; Raymond Roggero, Chief Operating Officer.

## Who We Are

Q PHARMA WAS ESTABLISHED IN 1994, as a systems validation firm. Validation continues to be a mainstay at Q Pharma but is now accompanied by two additional business units. The PDMA Services business unit, established in 2000, focuses on satisfying PDMA regulations. The Logistics Services business unit, established in 2006, focuses on fulfillment logistics. These business units service the Pharmaceutical, Biotechnology, and Medical Device industries. We also provide solutions to companies that provide products and services to the life science industry, therefore are subject to FDA regulations.

## Services Offered

### Validation Solutions

Validation Solutions provide all aspects of regulatory validation across the product lifecycle. We develop and execute detailed Validation Master Plans, SOPs, audit reports, protocols, and test scripts to ensure that the compliance of each system, facility, or process validated is thoroughly documented.

#### Validation and Qualification Domains

- Process Validation
- Cleaning Validation
- Equipment Qualification
- Computer System Validation
- IT Infrastructure Qualification
- Facility/Utility Commissioning and Qualification
- Analytical and Microbiological Methods Validation

### PDMA Solutions

PDMA Solutions ensure maintenance and compliance at any stage of a PDMA program. Our highly qualified experts guide our customer's through the steps required to comply with PDMA regulations.

#### PDMA Solutions include:

- PDMA Consulting
- Sample Accountability
- Audits and Assessments
- Practitioner Validation
- Training and Certification
- Scanning and Data Entry

### Direct Marketing Solutions

Direct Marketing Solutions provide services to implement a successful multi-channel marketing campaign, either brand specific or company-wide.

#### Direct Marketing Solutions include:

- DTR Fulfillment
- DTP Fulfillment
- OTC Fulfillment
- Literature Fulfillment
- Direct Mail
- Patient Assistance Programs
- Teledetailing & Telesampling
- Website Development and Hosting

### Logistics

Logistics Solutions provide the ability to acquire, transport, and store drug and medical device products according to specific guidelines. Efficient supply chain and proper logistical procedures can cut costs and increase efficiency.

#### Logistics Solutions include:

- Trade Distribution
- Compliant Warehousing
- Import/Export Services
- Storage/Fulfillment of Medical Devices

### Project Management

Project Management Solutions provide services to plan, organize, staff, direct, and control projects.

#### Q Pharma's Project Management Solutions include:

- Project Management Training
- Cadence PM Training
- Provider for the Project Management Institute (PMI)
- Progressix PM Training
- Outsourced Project Management

### Medical Device

Medical Device Solutions ensure maintenance and compliance with Medical Device regulations. Our highly qualified experts will guide our customer's through the steps necessary to comply with FDA regulations.

#### Medical Device Solutions include:

- Medical Device Quality Systems
- Medical Device Validation
- Quality Systems Regulations
- Medical Device Submissions
- Application of Medical Device
- Regulations to Pharmaceuticals
- Consulting Services
- Storage/Fulfillment of Medical Devices
- Tracking/Maintaining Medical Device Licensing

### Regulatory Compliance

Regulatory Compliance Solutions provide compliance consulting, vendor auditing, writing documentation, developing quality management systems, training and certification.

#### Regulatory Compliance Solutions include:

- GMP, GLP, GCP, QSR, ISO, Healthcare, and PDMA Consulting
- Quality Management System Development and Audits
- Quality Manual Generation
- Audits and Gap Analysis
- Tracking/Maintaining Drug Licenses
- Medical Device Consulting
- Storage/Fulfillment of Medical Devices
- Tissue Regulations
- Nutraceutical Regulations

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