

# QSPEC focus on Pharmaceuticals

QSPEC Solutions is your single source for pharmaceutical engineering services. We know how to optimize stringent processes and handle validation issues. Our experience with industry documentation requirements, cGMP procedures, and SOP's ensures that a system designed by QSPEC Solutions meets all your specialized requirements for both quality control and regulatory compliance.

## Areas of Expertise

### Utilities Systems

WFI / Purified Water Systems  
RO Systems  
Waste Systems  
CIP Skids  
Autoclaves  
HVAC Controls  
Clean Steam Generators

### Manufacturing

Liquid & Dry Compounding  
Bioreactors / Fermentors  
Filtration Systems  
Centrifuges  
Lyophilizers  
Incubators  
Inoculators

### Filling/Packaging

Sterile & Non-sterile Fillers  
Tablet Machines  
Cartoner Machines  
Printing & Bar-coding Systems  
Vision Inspection Systems  
Labeling System  
Stopper Washers  
Tunnel Sterilizers

## Related Skills and Services

### Project Management, Design and Definition Skills

QSPEC Solutions is thoroughly familiar with GAMP project management techniques and requirements. We approach all projects with GAMP in mind.

Whether your design and definition project is for a stand-alone machine or an entire facility, QSPEC Solutions visualizes the most efficient solution.

### cGMP Requirements, SOP Development, Protocol and Validation Services

QSPEC Solutions is practiced in dealing with FDA requirements and finding the most efficient ways of meeting them.

QSPEC Solutions has decades of experience with regulatory compliance and test procedures. We've become experts in supplying this documentation for our customers.

### Machine, Line & Plant Controls

QSPEC Solutions provides general industrial control services for pharmaceutical applications. This includes PLC program design and implementation, operator interface (HMI) design and programming, and custom software solutions. QSPEC Solutions has experience with a wide variety of DCS systems, PLC's, PC's, and software.

### Batch Systems

QSPEC Solutions knows how to apply major brands of batch systems to achieve flexible yet consistent production results. We manage the entire project, from batch modeling and recipe definition to phase validation. Batch systems can greatly reduce validation costs. PLC and DCS systems require validation any time the program/configuration is changed. Using a validated batch system, a new recipe or modified recipe doesn't require system validation.

### Database Interface

QSPEC Solutions designs systems that collect data and interface it into standard databases where it is readily available to IT and management. We provide reports that present the information you need to know in clear and concise formats that are 21 CFR Part 11 compliant.

### Network Design / Implementation

Today, industrial controls often operate over enterprise networks. This presents both opportunities and challenges. A well-designed enterprise network efficiently delivers data where and when it is needed, while a combination legacy system can slow down performance. QSPEC Solutions has the technical expertise to deliver the full benefits of enterprise communications along with a reliable, real-time control system.

