

# VALIDATION SUPPORT SERVICES



Validation is the cornerstone of Quality Assurance and our policy is to ensure that Quality Assurance is enhanced by our work.

Validation follows regulations and guidelines set forth by the US Food And Drug Administration (FDA) in the Federal Food, Drug and Cosmetic Act; Title 21 CFR Parts 210 and 211, Current Good Manufacturing Practices (cGMP) for finished pharmaceuticals and the Code of Federal Regulations (CFR), Part 820 for Medical Devices.

Validation is defined as the process of, *"establishing documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product meeting it's predetermined specification and quality attributes"*.

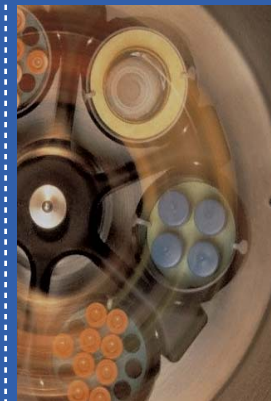
This is accomplished through the development of written protocols, definition of acceptance criteria, execution of the protocols, and documentation of the findings. The protocol represents an approved written plan to test, inspect, research and document results.



OVER 20 YEARS  
EXPERIENCE



Quality Compliance Partners, Inc.  
*Your Partners in Quality*



Expert Validation Services From The  
Ground Up

Contact Information:  
Bonnie Ward  
President and CEO



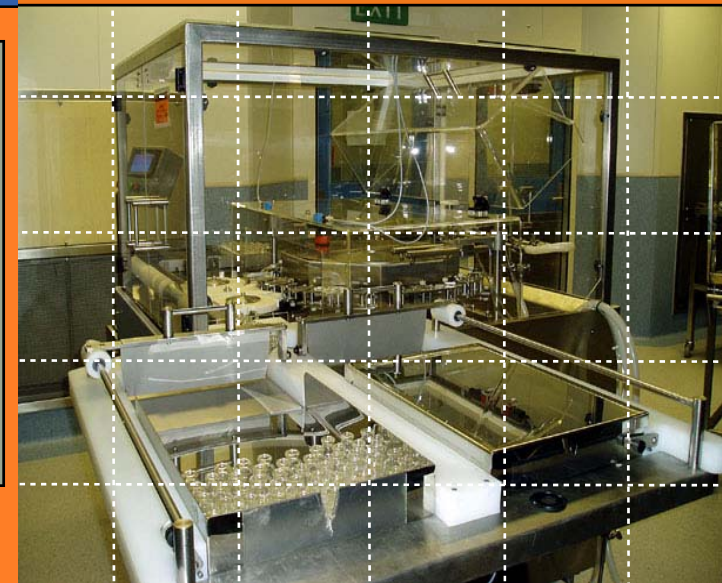
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(858) 605-1744

[www.qualpartners.com](http://www.qualpartners.com)

Or e-mail requests to:

[validation@qualpartners.com](mailto:validation@qualpartners.com)

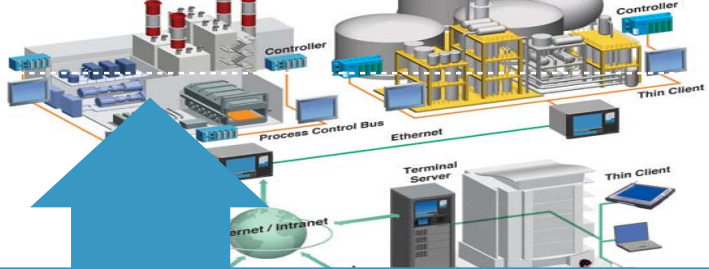


# VALIDATION SUPPORT

## ENSURING COMPLIANCE

**Qualification, Validation and Commissioning Services**

QCP, Inc. offers a wide range of project based services for your regulated company. We provide quality documents and services to support the GMP, GLP, GTP, and GCP regulatory guidelines. We will work with you to define the scope, deliverables and timeline which meet your requirements. We can provide a full team of qualified professionals or individual professionals based on your scope of work.



## MANUFACTURING SYSTEMS

**We Have the Right Crew for Your Project!**

**Evaluation / Qualification / Validation of Computerized Systems, Instruments, and Networks**  
**Systems Engineering / Specification Development**  
**21 CFR Part 11 Compliance (Assessment, Remediation, and Validation)**  
**Extensive Experience with the Development and Execution of Validation Plans, IQ, OQ and PQ Protocols, Test Plans and Scripts**

**Automation validation master planning and integration**  
**Hardware and software specifications**  
**System integrator audits**  
**URS generation & review**  
**FRS generation & review**  
**DDS review**  
**FAT and SAT test methodology definition**  
**FAT and SAT test protocol generation & review**  
**GAMP training**

**Striving to Ensure Quality Processes and Lifetime Relationships**

VALIDATION PLANNING COMMISSIONING SUPPORT EXPANSIONS PROCESS IMPROVEMENT METHODS VALIDATION LABORATORY TEMPERATURE MAPPING

## WHY QCP, INC. VALIDATION SERVICES

At QCP, Inc. we truly become a part of your project team, we are your advocate and partner providing comprehensive services. We work closely with our client internal staff and all contracted service providers involved in the qualification process to support project success. The results are an integrated project team leading to effective communication, project planning, and project delivery. As required we supply clients with financial and scheduling updates providing complete visibility and control throughout the Project process.

