

# quality

## What is quality validation?

Gavin teams distinguish themselves by high quality work

### Validation Excellence

If you think discussion of quality in a validation contractor is a waste of time, you may be in for some real tough lessons in your business life. At Gavin Pharmaceutical Services, we have seen the disastrous consequences of sloppy, incomplete, low quality (but usually very high priced) "validation services" by many competitors. Most of those experiences have been with large, well known firms in the business. That is why we want to talk about our approach to quality validation service.

### Philosophy of Excellence

"*Excellence in Service*" has been our theme since our founding in 1991. Of course, we do not always accomplish all that we want, but this philosophy drives us hard. It compliments our "sweat the details" approach to high quality validation service.

### No Validation Contractors Allowed

Recently, I met a validation manager from a large pharmaceutical firm. He explained that his company had established a "no validation contractors allowed" policy. The reason for the policy? It had nothing to do with a regulatory policy, or confidentiality protection, or cost. The reason is a history of poor quality service. How do you know if you are getting poor quality service? Here are a few things to look for.

**At a Glance**

Service: *Quality Validation Service*  
 Compliance: *21CFR Part 211*  
 Capability: *Full Capability*  
 Best at: *Customer Satisfaction*  
 Project Scope: *Full or Partial*  
 Contact: *Blair Conley*  
 Sales: **1-800-700-5147**

### Validation Quality Tests

Compare your experience in validation:

#### 1. Comprehensive Understanding

Does each validator take the time to learn and understand the system, equipment or process under validation, before the protocol is written and executed?

*Failure to understand is the #1 fault among contractors in this business.*

#### 2. State of Control

Do they understand and apply State of Control theory and practice?

*If not, it isn't genuine FDA validation!*

#### 3. Cookbook and Boilerplate?

Popularized by contractors, validation by cookbook and boilerplate can be mindless, inadequate, and lead to major product failures. You know you are getting it when the protocol tests features you didn't buy.

*This is all many contractors know!*

#### 4. Failure Notification and Resolution

Real validation testing results in failure. Does your contractor just list failures as deviations in a validation report? Do you find out about it months later, after the contractor whose work was defective is paid and gone? Are you left to fix it and repeat the validation? *This is what most contractors do!*

### Gavin Quality Distinctives

Here are a few ways Gavin service is distinguished from our competition:

#### *Understand First, Then Validate*

You will see it right up front in our planning estimation. We call it research. It is what we do first, because we don't know how to do quality validation any other way. Once we understand how something works, we decide how to best test it. By the way, we also analyze the design, because many problems start with faulty design.

#### *Scientific Validation*

Validation was conceived as a scientific exploration, using experimental methods. That's a completely different mindset than the cookbook plan. That is why we are more likely to find and resolve problems than our competitors. We will be delighted to explain the difference in more detail.

#### *Customer Service: We Don't Stop*

When our validation testing finds the defects, we tell you about it right away. Our "Validation Alert" system lets you know what the problem is now, before the contractor is gone. Not only that, we will work with the contractor, vendor, or troubleshoot the problem ourselves. When it is fixed, we even stick around to retest. You get stuck with a finished job. If this discussion hits home, give us a call today.

#### Act Today

Call to discuss your project today!

**1-800-700-5147**

