

packaging validation

Years of practical, FDA Inspected operations and validation experience

Sterile, Non–Sterile, Liquid, Powder, Filling, Closing, Labeling

Packaging Validation Nightmares

Several years ago, the president of Gavin Pharmaceutical Services, then Director of GMP Compliance with a major pharmaceutical firm, conducted a post-validation audit of a pharmaceutical filling and packaging line. The “validation” was by a major Architectural and Engineering contractor, whose name is well known in the industry. It was no surprise to our president that the “validated” line was running hopelessly out of control.

Another Black Eye for Validation

Profusely leaking containers were easily traced to severely burned induction seals (a technique using radio frequency to induce sealing heat in a specially designed cap liner). Not surprisingly, this validation was another case of expensive “FDA eyewash”. A huge, fill-in-the-blank protocol had been unwittingly approved by management, and executed thoughtlessly by the validation contractor. Little attention was paid to the packaging science involved. No appropriate tests to prove the line operation were done. It’s a sad but common story of today’s validation.

At a Glance

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

Packaging Validation Excellence

Gavin Pharmaceutical Services, led by a president with years of extensive high quality pharmaceutical filling, packaging, and labeling experience, employs scientists and engineers with a combination of academic training, validation training, cGMP training and packaging training to bring excellence to your packaging validation project. We follow a very simple, but often neglected formula for validation success: we first master a complete understanding of the packaging process, from the packaging science to the product to the machinery. Only then can we design appropriate tests which are capable of assessing the line performance.

What Do You Want?

What do you want in your packaging validation project? If you just want to throw together a project by spending a lot of money, creating a lot of paper, and hoping the FDA doesn’t look at it too hard, please do not call us. We gladly refer you to our competitors, especially the large engineering firms. They are very good at that.

Packaging and Validation Expertise

Rather than throw a boiler plate protocol writer at your packaging project, try our combination of packaging and validation expertise. There is no substitute for our extensive experience in specifying, purchasing, installing, qualifying, validating, and troubleshooting filling, packaging, and labeling lines. From the simple project to the exotic, we can make your validation experience a happy one.

Got a tough Project?

That is a problem made for GPS. Even if no one has ever done it before, we will tackle your toughest project. We will apply our experience with sterile suspension filling, hygroscopic sterile powder filling, flexible package thermal sealing, high foaming liquid filling, corrosive product filling, in-line check weighing systems, containment systems, low oxygen headspace closing, partial closing for lyophilized product, high speed coding and verification, label control systems, and much more.

Act Today

For effective packaging validation, call today. Put our experience to work for you!

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