AdeptPackaging
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A Systematic Approach to Distribution Qualification

Comparing People-Driven Versus Process-Driven Systems

An Adept Packaging White Paper

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Comparing People-Driven Versus Process-Driven Systems

Is your company people-driven or process-driven? Companies or departments tend to initially develop as people-driven; that is, they rely on the experience and expertise of individuals to manage projects. This reliance on individual expertise can be acceptable for a time, but eventually people-driven organizations experience issues due to:

Time Limitations – People can only work a limited number of hours; therefore, people-driven decisions and operations will be restricted by the availability of individuals.

Limitations of Skill – A people-driven function can only be as good as the people doing the work, with boundaries on skill and knowledge.

Agent/Principal Conflicts – People-driven functions run the risk of individuals making decisions in their best interests rather than to benefit the organization as a whole.

Because of these challenges that arise in people-driven systems, companies must migrate to process-driven systems to obtain consistent results. A process-driven approach allows companies to deliver above average results, even if workers without specific project expertise are used to complete the work.

A validation or qualification department can be used as an example to demonstrate the benefits of a process-driven organization. Qualification of packaging in the distribution environment is a critical step in bringing life science and CPG products to market. A distribution qualification system will assess the environment that the packaged product will be distributed within, develop tests protocols that simulate the environment correctly, and ensure results are compared

accurately against success criteria. Failure to qualify packaging correctly will result in adding risk to user or consumer safety and can significantly impact time to market.

Distribution Qualification Process

Performing a distribution qualification can be a complex endeavor. One of the major obstacles to successfully execute a qualification is the time it takes. Consider how long it takes to write a validation protocol from scratch. Often in these cases, rework occurs, hours are spent researching a distribution environment, that has been previously researched in past projects. In some circumstances, tests are conducted only to have QA dispute the methods used. These are examples of delays that extend the time it takes to qualify packaging and ultimately impacts speed to market. These challenges and delays are a result of a people-driven organization.

In addition to the factor of time, user safety can be significantly impacted by utilizing a people-driven system. When it comes to user safety, we are under obligation to reduce risk of harm as much as possible. Unfortunately, lack of consistency and inexperience can increase the risk of products being unsatisfactory for use; due to, for example, incorrect sample sizes being used to infer population data, tests not accurately simulating actual use, or the incorrect inspection of test product are completed.

In the period between January 1, 2018 to October 1, 2018, the FDA reported 69 recalls of medical devices due to packaging issues (US Department of Health and Human Services). Some examples for the reasons for recall include,

- ✓ "The LDPE bag packaging for various highly polished hip and knee implants may adhere to the highly polished surface, leaving residue or material from the LDPE bag on the implant after it is removed from the bag."
- ✓ "A defect in the seal of the pouch contained in kits caused the pouch to leak within a limited portion of the kit."

These recalls elicit the question of whether the issues could have been detected prior to launch if a rigorous distribution qualification process had been deployed prior to commercialization.

The FDA reported 69 recalls of medical devices due to packaging issues

-US Department of Health and Human Services

Validation Protocols

Validation protocols are an integral component of a distribution qualification. Because of the complexity associated with writing a validation protocol, this component of distribution qualification lends itself heavily to the process-driven over people-driven approach. When companies take a people-driven approach to validation protocols, they often experience challenges such as:

- ✓ Inconsistency
- ✓ Outdated methods
- ✓ Uneven Workload Distribution

Inconsistency

Within the Validation world, consistency can be a challenge. When departments are composed of people that bring experience from previous jobs, are new to the field, or even contracting for a short period of time, consistency becomes an issue. The problem with this is that the variance in opinions and processes can lead to different paths in validation. For example, some will perform a rub test on labels and other will not, citing vibration testing as sufficient. Neither route is necessarily wrong but could raise questions or doubts about the company's methods and lead to inconsistent results in addition to introducing risk post commercialization.

Outdated Methods

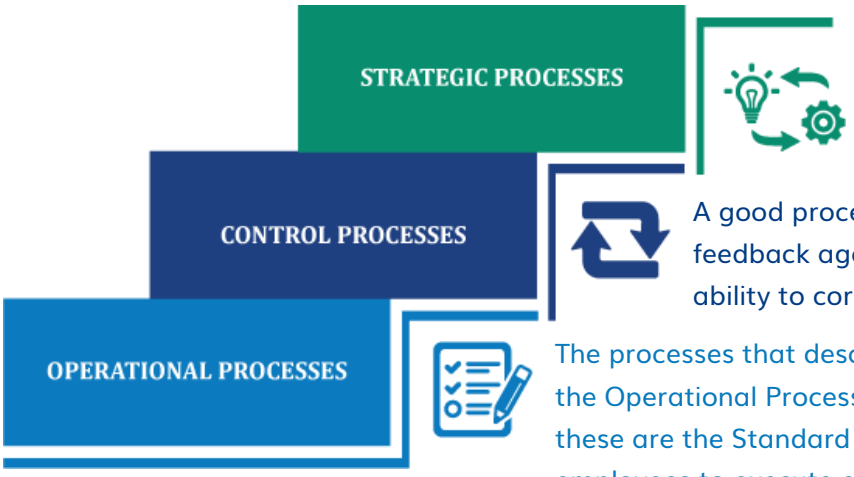
If a department has an undocumented practice of using previous protocols as templates, or the person conducting the tests is not familiar with the latest regulations, companies run the risk of missing tests that may be required now that were not previously. For example, tests may be conducted using a protocol from a vial qualification as a template for combination device qualification; wherein the engineer may forget to include device functionality testing for the combination device protocol.

Uneven Workload Distribution

Another part of the problem is understanding the department's workload. There are plenty of tools that will help a manager distribute the workload evenly to employees but being able to interpret how long it will take someone to create a protocol will vary if there is no set structure. To support the business, the Validation department must be able to predict work load assignments and mitigate issues of uneven workloads that can arise from a team with diverse backgrounds.

In summary, people-driven distribution qualification systems will ultimately cause delays to product launches and increase risks to safety incurring challenges that are not present in process-driven systems. However, just documenting a current process does not make an

organization process-driven. The documentation needs to be developed into best practice through the utilization of operational, control and strategic processes.



The highest level of a process is where data is converted to information and decisions made on that information.

A good process will receive constant feedback, and measure feedback against metrics. The process then must have an ability to correct if metrics are indicating deviation.

The processes that describe the primary activities of an organization are the Operational Processes. In the case of a distribution qualification, these are the Standard Operating Procedures (SOPs) that are used by employees to execute everyday tasks. When writing SOPs it is important to determine industry best practices.

Documented Systems and Processes

A documented distribution qualification system overcomes the issues detailed above and helps ensure products are launched safely and on time. Having a developed and approved system supports the organization in the following ways:

- ✓ Providing the Opportunity for Training – A system can be used to teach new associates the correct way to undergo the process, thereby reducing new employee onboarding and helping to create consistency and repeatability in the workplace.

- ✓ Increasing Efficiency – Because activities and workflows are documented, time is not wasted on working out who needs to provide approval, or what step is taken next. A documented process will also allow different members of a team to take over projects with minimal delay.

- ✓ Removing Ambiguity – Decisions and activities are based on best practices and are not fully dependent on the experience of individuals.

Procedures should be updated in a timely manner and whenever appropriate. Procedures are a key part to have consistent, compliant, and effective protocols. Reviewing procedures should be meaningful, something beyond structure and grammar. All test guidelines referenced in the procedure, ISO, ASTM, USP and ISTA, should be checked regularly for updates. It is also good practice to review the company's product portfolio and pipeline to ensure the procedures are equipped to handle everything that is produced, or planning to be, at the facility.

To enhance quality standards, templates can be utilized to bridge gaps from procedures to protocols and reports. Working from pre-vetted boiler plates will guide employees to always present their work in the same manner with all the crucial regulatory required elements. This creates an information flow that is consistent and easy to understand. Templates will also reduce the time it takes to produce a protocol/report. When they are finally being routed, the people reviewing will be able to see everything in a familiar layout and will make it easier for them to approve. Decreasing the time to write protocols by reducing errors and creating an air of familiarity for everyone involved is key to successful work. If the department has laid the groundwork upfront, identifying the key inputs, the rest of the workload will be easier to manage.

Partner with Adept

We have explored the benefits of creating a process-driven distribution qualification system, and given some tips on how to create a process, but how can Adept help?

Adept Packaging employs a range of experts, from various backgrounds; from Consumer Products to the Medical industry. Our collaborative team makes it our mission to stay on top of industry regulations and pass that knowledge on to our clients.

Adept Packaging has developed tools to help companies navigate complex environments like these. ProTrack (Distribution, Development, and CMO) is designed to streamline the process' all companies encounter on a daily basis.

Our proven Distribution ProTrack modules swiftly install customized packaging programs for the most demanding and heavily regulated supply chains. Distribution ProTrack is specifically designed with templates, tools, and procedures to counteract the issues described above. This is especially helpful for departments that lack the workforce to put these things in place.

If you're looking to streamline your distribution qualification process, contact us to learn more about Distribution ProTrack.

www.adeptpackaging.com

Sources

US Department of Human Services
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=78942