

ENABLING PRODUCT QUALITY ASSURANCE VIA EFFECTIVE FORMULATIONS MANAGEMENT

In any laboratory environment, it is critical to have a tight formulations control process. A robust formulations management plan can help ensure product quality, meet specifications, and reduce manufacturing costs to ensure profitability!



The more regulated the industry segment is, the more stringent the formulation requirement becomes. Strict guidelines are put in place to ensure product quality, effectiveness, and safety. In this paper, we will address the challenges associated with product formulation processes and discuss how a Laboratory Information Management System (LIMS) can address those challenges.

Product Formulation Challenges

Homemade formulations, which lack adequate controls, checks and balances, do not allow for consistency across batches. If you were preparing a simple formulation for a smoothie using fruits, sweetening agents, yogurt and ice, you may have a good idea about the quantities needed to make the smoothie. Products made on different days of the week may have some variances, but may still taste very similar. The difference in consistency and quality between

homemade batches is due to the inability to use highly accurate measuring instruments, clearly documented processing steps, specific production conditions (temperature, time etc.) and quality checks. This is not the case for most of the formulations used in the industry for production. Here, the degree of control used in formulations for product manufacturing is of great significance and directly impacts product consistency, quality, reliability, and safety.



Typically, formulations do not involve chemical reactions or synthesis; they are done by measuring liquids by volume and solids by weight. Even though there are no chemical reactions involved, there are many aspects of chemistry present in a formulation, i.e. the thermodynamics of mixing, phase equilibria, solutions, surface chemistry, colloids, emulsions and suspensions. Even more important is how these principles are connected to adhesion, weather resistance, texture, shelf life, biodegradability, allergenic response and many other properties. Often, formulations development is being done by fairly

rudimentary trial and error methods. Although that can work for one-off formulation development, a robust system needs to be in place for routine large-scale development operations.

Critical in Regulated Industries

In heavily regulated industries (such as Biopharmaceutical), it is imperative to have good control of the formulation process. It is essential to properly document the development, testing, approval and lifecycle management of formulations. Only those products with formulations that meet regulatory approvals can be distributed. Routine commercial product manufacturing is then based on this specific proportion of ingredients, processing steps, conditions, controls and quality specifications.



For example, the rate of dissolution and bioavailability of a solid dosage drug product can vary significantly based on its formulation considerations and processing parameters. Imagine a platform where comparing slight variations within multiple formulations will allow a scientist to compare the results side-by-side and determine the next steps.

It is important that a finished product will have a high degree of uniformity, and lack variance between batches, which increases the overall quality. That is only possible with the

considerable effort and expertise of the formulating scientist. Painstaking documentation of formulations development and testing may be involved. For appropriate manufacturing based on well-defined processes it is also critical to consider the many variables that can affect composition, physicochemical properties, stability and utility of the products. It is also critical to consider the cost component so that it is marketable against the competition.

Records Retention is Essential

Maintaining detailed documentation on development research and the ability to search through historical records is essential to the formulations process. Mining and reuse of legacy information is critical in the process of knowledge management and can save tremendous amounts of time and money.



For formulation of a new product, it is indispensable to have a robust documentation and information management platform. When lab scale experiments are performed, proper documentation and the ability to generate intelligence from them, will avoid wasting time and resources. For low margin industry/products, it makes most sense to carefully consider the ingredient and processing costs from the start. This can eliminate mistakes by having an option to check historical records

of trial formulations, their output, product results and costing.

Without a universal method of documentation, storage and retrieval, collating and searching for any useful information becomes a true nightmare. Information may be stored on individual computers or shared hard drives. In the worst case, the information may not be found.

Only a robust electronic system, that offers complete historical search capabilities based on user-defined parameters, can really benefit an organization. This type of formulations management platform will eliminate the need for scientists to document anything outside of the system and offer a comprehensive set of capabilities for developing and managing formulations.

LIMS To The Rescue

Implementing a LIMS solution with robust formulations management capabilities can address many of the challenges in managing the formulations process. It will make life easier for scientists and managers in properly managing all product formulation needs from early initiation through to the retirement of a formulation. Having the right tools in place can make a huge difference in your product quality and ultimately your profitability. Some key formulation capabilities to look for in your LIMS system include:

- Robust capabilities for sample and specifications management, and product testing/analysis during different stages of formulation
- User friendly interface that allows for change of ingredient quantities within a formulation and the ability to see the

impact of those changes on the physical properties or cost

- Formulation templates that are reusable to save time and effort
- The ability to move formulations from one stage to the next with clear management approval
- Accommodation for varying sample calculation requirements
- Complete historical data search and indexing capabilities.

Summary

Getting your formulations process right means increased product quality, enhanced time to market, and reduced cost, providing you with a competitive advantage. Unfortunately, the idea to purchase a LIMS solution with robust formulations management capabilities is often overlooked when deciding upon a formulations strategy. LIMS is often thought of as a complex “Information Technology” solution, used by scientists for sample management and product testing. Contrary to that misconception, a LIMS solution is critical for any type of laboratory environment that requires management and documentation of complex scientific information for product development and sample testing. A robust, modern, highly configurable LIMS solution with integrated formulations management capability will play a critical role in managing the process for determining the right formulation.

Learn More

To learn more about how LabVantage can help organizations with Formulation Management, please visit us on the web at www.labvantage.com, call (908) 707-4100, or e-mail us at lvinfo@labvantage.com