Products and Services for The Manufacturing Plant

Balancing production schedules with optimizing methods and reducing operating costs on methods that have been transferred is always an issue that is discussed but too many times delayed.

Partnering with Proveris allows a cost-effective manner to thoroughly evaluate existing SOPs and determine what areas should be evaluated to make procedures more robust. This must be done while taking into consideration what changes are allowed without affecting regulatory submissions.

Optimization of testing procedures has constantly shown to provide more comprehensive knowledge of the products while reducing variations and OOS issues. More detailed knowledge facilitates evaluations such as CAPAs, allowing them to be closed sooner and in a more complete manner. Production SOPs can be evaluated not only for system performance, but also for maintenance procedures to ensure maximum operating time, training programs, optimum timelines for upgrades and equipment lifecycle planning.

Proveris scientists have focused for over twenty years on helping their customers evaluate and deliver quality orally inhaled and nasal drug products (OINDPs). Our vast experience allows options to be discussed and protocols refined in shorter times and reduced budgets.

The Proveris Laboratory approach accelerates research timelines and provides robust methods for submission.

Partnering with Proveris Laboratories saves time and costs for evaluating procedures while maintaining challenging production schedules.

Method and Technology Transfer

In too many instances, the method that was installed with a system initially is applied to multiple products in the future. This results in methods being applied that were not optimized for each product. Evaluating a method before it is accepted can minimize issues in the future such as OOS and variances that require large amounts of time to understand and explain.

The Proveris practice of method evaluation thoroughly evaluates each aspect of a method, thereby developing a procedure that provides the most efficient transfer between multiple sites, various instruments, and operations.

Lot Evaluation

Executing methods on multiple product samples from multiple lots provides insight in the inherent variability of products across multiple lots. This allows the appropriate QC specifications and supporting methods to be developed and the robustness tested.

OOS and CAPA investigations

Our experienced and knowledgeable experts help with root cause analysis for OOS issues through data evaluation, recreating OOS, and using the evaluation to provide the information needed to close CAPA investigations.

Customized Protocol Development

Along with the comprehensive offerings noted above, Proveris Laboratories provides customer consulting services for new products as well as customers with unique research, development and production needs.

Accelerate Development with Proveris Laboratories

Device Selection and Screening | **Method Development** | **Method Verification**

In less than two months

Achieve the following with Proveris in less than two months with Proveris Laboratories:

- Device-formulation Selection
- Robust Method Development based on FDA recommended Quality by Design (QbD) approach
- Product understanding based on sound science
- Identify input variabilities influencing critical quality attributes (CQAs)

Products and Services for The Manufacturing Plant

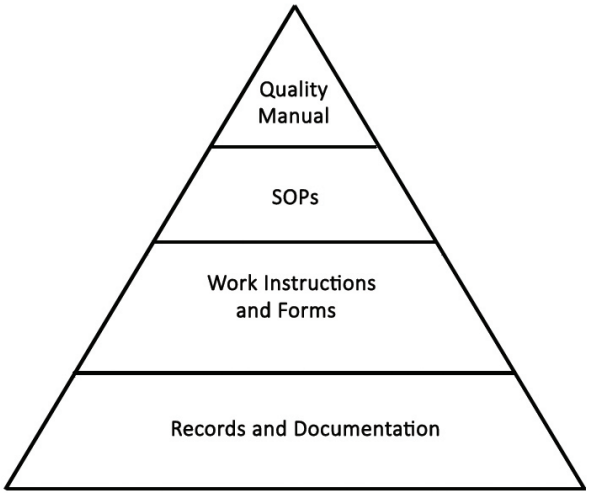
Proveris's laboratory staff follows the highest quality standards in developing protocols and implementing procedures. Our projects deliver services and documentation that are thorough, robust, and easily transferred.

Our quality programs are designed to document every aspect of key quality parameters including methods, equipment parameters, report design, and data review.

Proveris is certified to ISO 9001:2015

We understand global regulatory guidelines and our Quality by Design process offer documented evidence of protocols that meet the appropriate local and global requirements. This includes areas such as 21 CFR Part 11 compliance with complete audit trails of operator activities, instruments settings, calibration, and data measurement.

Partnering with Proveris allows scientists to focus on the research and not creating technology transfer documents.



Proveris incorporates core quality assurance functions in its business practices.

Integrated Suite of Equipment for Nasal and pMDI Devices

Equipment evaluation is based on optimally testing each parameter including system performance, training of operators, evaluation of method and SOP robustness, understanding the benefits of upgrades, and planning the optimum times for implementation.

pMDI Devices

Nasal Sprays

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