Products and Services for The Development Lab

Development scientists are constantly facing tighter timelines for completing increasingly more complex product evaluations with decreasing resources.

Partnering with Proveris allows a cost-effective manner to more thoroughly evaluate a wider range of factors of existing research methods and products with shorter timelines. More critical factors can be evaluated on multiple devices and formulations to ensure an optimized combination is selected and thoroughly tested.

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 allow 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.

Reference Product Characterization for Generic Developers
Understanding the reference product performance and the bio-equivalency target are the most important, yet most challenging tasks.

Human Actuation Studies
Identifying the actual range of force and other key factors that can be achieved by humans in both general and specific demographic groups is critical to establishing the correct product specifications as well as the associated testing protocols.

Robust Method Development and Optimization
The Proveris Quality by Design (QbD) and Design of Experiments (DOE) principles are applied across initial research and eventually extended throughout the development process across the entire protocol.

Typical parameters include:

- Shot Weight
- Spray Pattern
- Plume Geometry
- Droplet Size Distribution

Method Verification and Validation
Once the method development protocols are completed, depending on the project requirements, verification or full validation steps can be undertaken to ensure that the analytical methods are suitable and can provide documented evidence of acceptable product performance.

Method validation can be initially performed on a single lot to eliminate lot-to-lot variability. Once completed, multiple lots can be tested on multiple systems by multiple operators to test robustness.

Validation protocols are typically based on ICH and FDA quality guidelines [using guidance documents and Q2 (R1) as references].

Key steps include:

- Method Precision
- Intermediate Precision
- Accuracy
- Reproducibility
- Sensitivity

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)

Product and Services for the Development Lab

We're Committed to QUALITY in All We Do

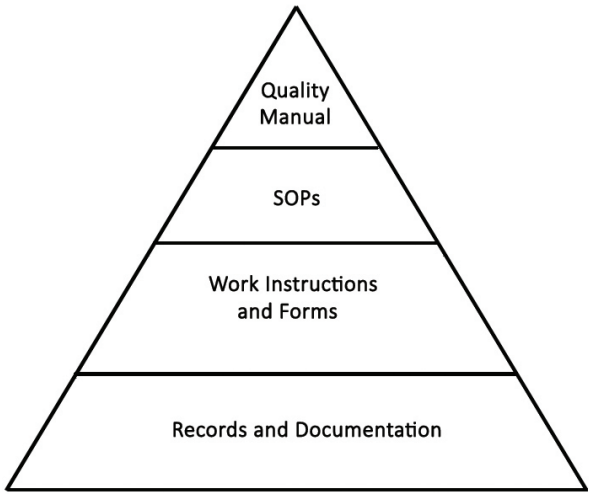
Proveris's laboratory staff follow the highest quality standards in developing our protocols and implementing our procedures. Our projects deliver services and documentation that are thorough, robust and easily transferred.

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 selection is based on optimally testing each parameter, including device actuation for testing and reproducible intermediate shots to endure consistency and accuracy.

pMDI Devices

Nasal Sprays

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