

Preclinical Dermatology Services



**QPS is the Right Place for your
Topical and Transdermal Studies**

Recognized Experts in Dermal ADME

QPS has worked with a large number of pharma and biotech companies all over the world to help them conduct both clinical and laboratory research on emerging and final topical and transdermal products. QPS experts will assist with product development from early preclinical through late phase clinical stages. These companies know that our staff and resources are second-to-none when it comes to study execution with exacting standards and advanced expertise.

Area of Expertise for Topical & Transdermal Product Development: The Franz Diffusion Cell

Developed in 1975 by Dr. Thomas Franz, The Franz Diffusion Cell has become the recognized standard for *in vitro* rate-of-release testing as per FDA SUPAC-SS Guidance. Paul Lehman, co-developer of the Franz model's utility and methodology since 1979, leads the QPS Dermal and Transdermal Research Laboratory Team. For thirty-six years in academia, industry and the FDA, Mr. Lehman and Dr. Franz have guided the advancement of dermatopharmacokinetics for pharmaceuticals and toxicological risk assessment. Methods they have developed have repeatedly been adopted as industry standards for both *in vivo* and *in vitro* investigations of percutaneous absorption. QPS upholds this legacy through our Dermal and Transdermal Research Laboratory, where the value of *in vitro* release and penetration studies is realized.

Your Product from Early R&D to Final Formulation, Streamlined

Extremely capable and specialty-focused project teams will shepherd your formulation's progress from study concept and design, protocol development, and study conduct for R&D or GLP submission to a Regulatory Agency, all the way through to the final report. Careful attention to detail—the product of 36 years of experience—is provided at each step: expert study conduct, analytical method development and validation, sample analysis, statistical evaluation, and quality control. To ensure compliance with GLP and international regulatory standards, our quality control and quality assurance staff monitors all studies from inception through final documentation.

Unparalleled Experience

No other facility in the world offers as much experience working with human skin, animal skin, or model membrane studies as the QPS Dermal and Transdermal Research Laboratory (QPS DTRL). With over three decades of experience and co-founder Paul Lehman at the helm, QPS DTRL can assist you with any product in development. Our team is highly trained by Mr. Lehman for *in vitro* release testing (IVRT) and *in vitro* percutaneous absorption studies (IVPT). We excel at evaluating skin absorption for novel topical compounds and formulations, transdermal delivery systems, generic versus innovator products, chemicals with toxic exposure issues, and

cosmeceutical and cosmetic products. The *in vitro* human skin percutaneous absorption model is the best known replacement for animal topical pharmacokinetic studies.

QPS is Your Dermal and Transdermal Specialist

Capabilities Utilizing the Franz Diffusion Cell

- Percutaneous absorption kinetics
- Drug retention or distribution within the skin
- Characterization of transdermal delivery systems for systemic delivery
- Comparison of formulations for topical delivery
- Membrane rate-of-release studies according to SUPAC-SS guidelines
- Analysis of topical systemic risk exposure from a noxious compound
- Conduct according to GLP, FDA, EPA, OECD, COLIPA, or ICH guidelines

Bioanalytical

- Method development, validation and transfer
- Sample analysis by LC/UV or LC/MS/MS

Scientific Affairs

- Protocol development
- Statistical analysis
- Complete final reports

For more information on QPS' Dermal and Transdermal Research Services, please contact:

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