

# Dermal and Transdermal Research Services



**QPS is the Right Place for  
your Skin Studies**

Paul Lehman, a well known name in the field of topical and transdermal pharmacokinetics and bioequivalence testing works with QPS to oversee various aspects such as global regulatory requirements, including EMA, FDA, and OECD. He has lent his rich experience of over 33 years in this field. He has been a Principal Investigator, Sub-Investigator, Principal Scientist or Study Director for more than 600 clinical and *in vitro* preclinical studies for the pharmaceutical, toxicology, skin care, and veterinary industries. His bibliography currently includes 44 published manuscripts, 5 book chapters, and over 125 poster and lecture presentations.

Paul has been an integral partner with Dr. Thomas Franz (innovator of the Franz Diffusion Cell) since 1980, developing and validating *in vitro* and *in vivo* models for topical formulations. The Franz Diffusion Cell is the industry standard for *in vitro* percutaneous absorption kinetics of topical and transdermal products using *ex vivo* human skin. This model and associated methodologies support drug development in the preclinical, clinical, and post-approval phases, including the *in vitro* rate-of-release assay (IVRT) based on the FDA SUPAC-SS Guidance.

QPS offers dermal and transdermal research services for the development of a wide array of topical formulations including semi-solids (lotions, gels, emollients, creams, and ointments); transdermal delivery systems (patches and semi-solids); cutaneous and intradermal injections; wound dressings; and innovative delivery systems (micro-needles and iontophoresis). Our dermal and transdermal research services include:

### **Bioavailability**

- ❑ Systemic Delivery (FIM, SAD, MAD)
- ❑ Systemic Safety and Risk Assessment

### **Bioequivalence**

- ❑ PK for Transdermal Generics

- ❑ Cutaneous Safety (Irritation and Sensitization)
- ❑ Adhesion for Patch Systems
- ❑ Clinical Endpoint BE for Dermal Products
- ❑ Vasoconstriction for Topical Corticosteroids

### **Safety**

- ❑ Primary Irritation
- ❑ Cumulative Irritation
- ❑ Sensitization Assessment (HRIPT)
- ❑ QTc
- ❑ Chronic Exposure studies

### **Efficacy**

- ❑ First in Human
- ❑ Phase II – Phase IV

### **Unique Study Designs**

- ❑ Topical Drying Time
- ❑ Person-to-Person Transfer
- ❑ Surface Deposition
- ❑ Hand Wash and Shower Efficiency

The field of dermal and transdermal research represents an exciting and challenging area where novel techniques for skin permeation enhancement and development of methods to lessen skin irritation are actively being pursued. QPS has the experience and resources to handle your dermal trials and get your product to market. Choose QPS for your next skin trial! Should you want to discuss your questions in more detail with one of our dermal experts, please contact us directly at: [info@qps.com](mailto:info@qps.com)



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