

A flexible approach to
**Dermal &
Transdermal
Research
Services**

**THE FIELD OF DERMAL AND TRANSDERMAL RESEARCH
REPRESENTS AN EXCITING AND CHALLENGING AREA** for new
product and formulation applications. QPS has the experience and
resources to handle your Dermal and Transdermal research projects.

**TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!**

CALL +1 512 350 2827 **EMAIL** infobd@qps.com



Established Leader in Dermal and Transdermal Research Services

QPS offers Dermal and Transdermal Research Services for the development of a wide array of topical formulations including semi-solids (foams, 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 or iontophoresis).

Paul Lehman, having 40 years of experience in the field of dermatopharmacokinetics, leads the QPS Dermal and Transdermal Team. He has been a key opinion leader conducting over 600 clinical and *in vitro* preclinical studies for the pharmaceutical, toxicology, skin care, and veterinary industries.

Paul has been an integral partner with Dr. Thomas Franz (innovator of the Franz Diffusion Cell) since 1979, 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 *in vitro* permeation testing (IVPT) and the *in vitro* rate-of-release assay (IVRT) based on the FDA SUPAC-SS Guidance.

Research Study Capabilities

- ▶ IVRT/IVPT for US FDA ANDA bioequivalence submissions
- ▶ Membrane rate-of-release studies IVRT by SUPAC-SS and USP guidelines
- ▶ Percutaneous absorption kinetics (IVPT)
- ▶ Characterization of transdermal delivery systems for systemic delivery
- ▶ Comparison of formulations for topical delivery
- ▶ Analysis of systemic risk exposure from topical compounds, such as sunscreens and cosmetics

Regulatory Capabilities

- ▶ Study conduct according to GLP, FDA, EPA, OECD, COLIPA, or ICH guidelines

Bioavailability and Bioequivalence

- ▶ Systemic delivery (FIM, SAD, MAD)
- ▶ Systemic safety and risk assessment
- ▶ Chronic exposure
- ▶ Topical and transdermal BA/BE
- ▶ Dermal safety studies (irritation and sensitization (HRIPT))
- ▶ Adhesion for patch systems
- ▶ Clinical endpoint BE for topical products
- ▶ Vasoconstriction for topical corticosteroids

QPS is a Global CRO with locations around the world

