



**Dow Pharmaceutical Sciences, Inc.**

The D in Topicals R&D

Since 1977

# Consulting Services

Helping you evaluate drug candidates, formulations, processes and packaging



Petaluma, CA Facility

## Consulting Services

- Drug Candidate Screening and Feasibility Assessments
- Dosage Form and Packaging Recommendations
- Formulation Evaluation and Selection
- Manufacturing Process Critique and Scale-up

Whether an early-stage start-up or a mature company, development of a topical product brings challenges related to selection of an appropriate drug candidate, choice of formulation, appropriate packaging and development of a robust process that can be scaled-up to commercial size batches. Our professionals have faced most of these challenges and can help you avoid potential pitfalls, thereby adding speed to your development timeline and decreasing your costs.

### Drug Candidate Screening and Feasibility Assessments

Based on years of experience in formulating topical drug products, we can review compound structure and pre-formulation data to help you screen and select the most promising drug candidate(s). As part of the screening process, we can prepare simple formulations and test them for skin penetration in our *in vitro* laboratory. Our model uses freshly excised human skin, obtained following elective surgery, which is far superior to cadaver skin. We also screen for corneal/scleral, buccal, or vaginal tissue penetration using the relevant tissue *in vitro*.

### Dosage Form and Packaging Recommendations

Based on your target indication and the physical/chemical properties of your API, our clinical, formulation, and skin biology experts can help you select the most appropriate and commercially viable dosage forms (gel, cream, ointment, solution). We also can make recommendations for the most appropriate packaging for your dosage form and therapeutic indication.

### Formulation Evaluation and Selection

If you already have a formulation, we will assess the solvent system and other excipients and recommend changes to improve drug release and delivery, chemical and physical stability, cosmetic elegance, patient acceptability, and potential for FDA approval. Increased delivery of drug to the target tissue will decrease the concentration needed, thereby decreasing the cost of goods while potentially improving the toxicology profile.

### Manufacturing Process Critique and Scale-up

At Dow we manufacture Phase 1 and 2 clinical supplies. We have considerable experience helping clients scale-up their products at various commercial manufacturers. With topical products, problems may occur when going from small-scale to large-scale commercial batches. We have seen and solved most of these problems. Our scientists will evaluate your formulation process and may suggest changes to avoid scale-up problems. We can provide man-in-the-plant technology transfer and trouble-shooting services to assure that scale-up is successful.

To Learn More: Please contact Teresa Johnk, Director of Business Development at (415) 246-6018, for additional information. We encourage you to visit our facilities and evaluate our operations.

