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It's all on the skin

Petaluma-based Dow Pharmaceutical Sciences, is among the few local companies offering complete topical formulation development services

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It's a niche market and Petaluma-based topical formulation developer, Dow Pharmaceutical Sciences, has situated itself comfortably into it. The field of topical medicine is a complex combination of science and art that Dow has been perfecting for the past 25 years.

Founded by Gordon Dow, PharmD (doctor of pharmacy), in 1977 as Dow Dermatologics, the once home-based business has grown into one of the few companies of its kind that provides complete development of topical products; taking them through clinical trials and up to application for Food & Drug Administration (FDA) approval.

"We like to say that we're the D in topicals R&D," says Steve Smith, Dow's vice president of marketing and business development. "A client comes to us with their drug and we develop it. They have their scientists do all the research, but obviously they can't sell a drug in a beaker. You have to put it into a cream, gel or ointment. That's when they come to us."

Topical formulations consist of everything from creams, lotions and gels to ointments, shampoos and suppositories that contain medicines to treat a variety of illnesses.

Application of topical products are not solely dermatological, but are also ophthalmic, otics, intra-oral, intra-rectal, vaginal and nasal.

Some of the formulations Dow works on are designed for over-the-counter use, such as Neutrogena T-Gel which Dow developed in the company's early years. Smith says that the majority of Dow's products, however, are



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prescription medications used to treat everything from acne to psoriasis.

Gordon Dow started the company as a small, part-time venture in San Rafael - a far cry from its current, modern Redwood Way facility. "The company was in three garages and a few school houses," says Smith. "We moved to a building on Petaluma Boulevard South in

1993, then to this location in 1998. This is a great-looking facility and our clients certainly don't mind coming here to visit."

Over the years, Dow has expanded from formulation development to labeling of clinical supplies, analytical chemistry, stability testing, regulatory and clinical affairs, and clinical studies. It's the company's ability to completely develop a product and focus on only topical products that puts Dow in a league of its own as a topical formulations company. "We are one of the few companies that does only topicals and does everything involved with their development," Smith says.

"It's a small niche, but we want to be very good at this niche. We're not like some car places that specialize in foreign as well as domestic cars. You can do everything, but do you do anything well? Topicals are our focus and our goal is to be the best topical product developer in the world."

Dow is well on the way to achieving that goal with clients all over the country, in Canada and Europe. "At any given time we're serving a lot of clients such as pharmaceutical companies, bio-techs and start-ups that are all trying to develop some sort of topical formulation - whether it's dermatologic or for nasal, ears, or mouth use. They don't have the internal capability to develop it themselves, so they come to us."

In addition to celebrating its 25th anniversary Aug. 16, recent major milestones for Dow have been the opening of a skin biology lab earlier this year and the 2001 acquisition of Solano Clinical Research, which serves as the company's clinical research branch. The skin biology lab is used for penetration studies, which include measuring a formulation's stability, skin penetration and retention. While the products are formulated in Dow's Petaluma facility, the Solano Clinical Research sites in Vallejo and Davis are where Dow conducts Phase I through Phase IV clinical trials.

According to Smith, the formulation development process takes a great deal of time; four years minimum. The process itself begins with a client and its already researched medication. The drug is then sent to a lab such as Dow, to determine how effective and safe it is. Then stability chambers subject formulations to different temperatures and humidity's. Smith explains that, "the test determines shelf life and how stable the drug remains in various situations over time."

From there, the drug moves closer to the FDA application process and on to clinical human trials. Phase I of the trials involves using the drug on a small number of volunteers to examine safety. Phase II incorporates a larger group of test subjects and involves evaluating the drug for safety and efficacy in a small sampling of patients who have a specific disease which the drug is designed to treat. During Phase II, effective dosages are determined.

"Phase III involves a bigger study performed at many different clinical study centers," says Smith. "These larger trials are the finals for FDA approval. We participate in these and can do them on site, but they also must be performed at several other sites."

Dow takes its clients through the entire process, or performs certain aspects of it, depending on what a customer needs. "There are some companies that formulate topicals and some that have their own bio labs, but I'm not aware of anyone in the area that can do it all. We do everything from beginning to end - or do parts of it depending on what needs to be done."

Smith continues, "Developing these formulations is a combination of art and science. It's based on a lot of experience. Our top chemists have over 100 years combined experience. Often a client comes to us with a problem, a certain molecule won't penetrate the skin or they don't know how stable it is. We can solve the problem for them and come up with a formulation that is stable. It can involve a lot of trial and error. Compared to the injectables and oral drugs industry, topicals are a smaller niche, but our goal is to be the best we possibly can."

(For information, call 793-2600 or visit www.dowpharm.com.)

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