

## FOR IMMEDIATE RELEASE

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### **DPT Laboratories offers customers new service preparing regulatory “Common Technical Documents”**

**SAN ANTONIO** (Feb 26, 2008) – DPT Laboratories has added preparation of the chemistry, manufacturing and controls documents (“CMC”) in the “Common Technical Documents” (“CTD”) format as an optional service that streamlines the documentation process for customers applying for approval of new drugs.

This new service provides preparation of chemistry, manufacturing, and controls Modules 2 and 3 documentation for customers throughout formulation and process development in the common format established by the International Commission on Harmonization for submitting new drug applications with U.S. Food and Drug Administration, as well as similar regulatory agencies in the European Union and Japan.

“An increasing number of pharmaceutical companies are choosing to format the documentation in the CTD format throughout development on an ongoing basis, rather than waiting until the end of the drug development process and having to reconstruct years of paper work,” said Kay Mary Harrell, senior director, Regulatory Affairs for DPT. “Drafting the documentation in the CTD format from the beginning of development and/or manufacturing can shorten the already lengthy drug approval process. At the end of the process, the customer has a submission-ready CMC section.”

DPT’s regulatory services involve those responsible for the research and development, quality and regulatory aspects of a project earlier in the process and help to meet the increased expectations of the FDA and other regulatory agencies.

Customers also benefit from:

- Smoother product launch,
- FDA commitments aligning with DPT standard operating procedures and specifications,
- Documents prepared by persons directly involved in the process and familiar with DPT systems,
- Timely and efficient preparation of documents,
- Documents that meet specifications of the FDA and other regulatory agencies, and
- Documents designed to be incorporated into electronic submissions.

“The drug development process is a long and costly process, and we can believe that we can increase the efficiency of the CMC module preparation,” Harrell said.

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**About DPT**

With facilities in San Antonio and Lakewood, N.J., DPT, a DFB company, is recognized globally for unparalleled semi-solid and liquid technical expertise. DPT is a contract development and manufacturing organization (CDMO) and is the industry source for semi-solid and liquid development and manufacturing services for the world's leading pharmaceutical, biotechnology, and healthcare companies. With four cGMP facilities and over 1 million square feet of state-of-the-art manufacturing, packaging, and distribution space, DPT offers full service outsourcing solutions including stand-alone development, site transfers, turnkey production, packaging, and worldwide distribution.