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Camargo Vice President of CMC Services Leads 505(b)(2) Roundtable and CMC Focus Group at 2012 AAPS Annual Meeting

(Cincinnati, OH; October 10, 2012) – Industry-leading CMC strategy and management expert Lynn Gold, Ph.D., vice president of chemistry, manufacturing and control (CMC) services at Camargo Pharmaceutical Services, will discuss effective development pathways for drug products being developed with new delivery technology at the 2012 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, October 14-18.

Gold will present on effectively and efficiently translating new drug delivery technology into a product on the market at the "Innovation in the 21st Century: Large Pharma – Small Drug Delivery Company Collaborations" roundtable Tuesday, October 16, at 9 a.m. in room W178 at McCormick Place at 2301 S. Lakeshore Drive, West Building, in Chicago.

According to Gold, the drug development industry's biggest challenges when introducing regulatory pathways for new technologies, such as 505(b)(2), is to successfully engage partners and help companies understand the Federal Drug Administration's (FDA) requirements for the new technology. The 505(b)(2) process uses a new drug application (NDA) that contains full safety and effectiveness reports, yet allows some of the information required for the FDA approval to come from studies not conducted by, or for, the applicant.

In addition to her presentation, Gold will lead the CMC Focus Group Annual Business Meeting at AAPS. She is co-chair of the CMC focus group, and encourages members in CMC-related fields to participate in open, dynamic communications with colleagues tackling similar challenges. The focus group is affiliated with the Regulatory Sciences section, the Analysis and Pharmaceutical Quality section, and the Manufacturing Science and Engineering section, all of which assist in developing future programming for AAPS meetings. The CMC focus group is a forum that discusses technical and regulatory CMC topics associated with the development of pharmaceuticals.

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Gold will be available for questions or interviews at the Camargo exhibit booth, #4800.

About Camargo Pharmaceutical Services

Camargo Pharmaceutical Services is your full-service drug development partner specializing in the 505(b)(2) process. Before development even begins, we verify profit potential by working with your team to develop a comprehensive program and timeline complete with important milestones and cost objectives. We manage every facet of the plan throughout your development continuum, from feasibility assessments, formulation and testing the drug product, to conducting preclinical and clinical studies, to final submission. Connect with Camargo on LinkedIn, the President's blog or visit www.camargopharma.com for more information.

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