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**Camargo President and Vice President Lead 505(b)(2)  
Symposium and CMC Focus Group at 2011 AAPS Annual Meeting**

**(Cincinnati, OH; November 14, 2011)** – [Camargo Pharmaceutical Services](#), an end-to-end drug development service provider specializing in the [505\(b\)\(2\) process](#), had a large presence at the 2011 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting through a symposium presentation, exhibiting at the trade show and leading a key focus group. The annual meeting took place in Washington, D.C., October 23-27, 2011.

Camargo President and CEO [Ken Phelps](#) presented the symposium, "Development of Drug-Drug Combination Products via 505(b)(2) Approach." The symposium covered the accelerating trend in drug product development following the 505(b)(2) strategy because of the increasing technical challenges and costs in new chemical entity (NCE) discovery and development.

"In 2009, there was a record number of [505\(b\)\(2\)](#) approvals: 33 NDA approvals via 505(b)(2) or 56% of all new drugs approved. Some predict that by 2012, about 80 percent of all drug approvals will be 505(b)(2)s," Phelps said. "The shift is unmistakable because the process allows us, for pre-clinical through Phase I-III, to utilize existing public information to alter the timing and content of the studies from the traditional drug development process – thereby greatly improving cost and speed through clinical development."

The timing and content of these pre-clinical and clinical studies alter the sequencing of chemistry, manufacturing and control (CMC) activities, including formulation and design, site monitoring, protocol design and review, and method validation strategies. Camargo has invaluable strategic leadership in these areas through its vice president of [CMC services](#), [Lynn Gold](#), Ph.D.

Gold led the CMC Focus Group Annual Business Meeting at this year's AAPS Annual Meeting. She is also co-chair of the [CMC focus group](#) that encourages members in CMC-related fields to participate in open, dynamic communications with colleagues tackling similar challenges.

The group is also affiliated with the [Regulatory Sciences](#) section and the [Analysis and Pharmaceutical Quality](#) 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.

"We're very proud of Camargo and the people who represent this company," Phelps said. "In the future, we will continue to be a leader in developing drug products via the 505(b)(2) approval pathway and share our CMC, clinical and regulatory expertise at principal industry events like the AAPS Annual Meeting."

***About Camargo Pharmaceutical Services***

Camargo Pharmaceutical Services is an end-to-end drug development service provider specializing in the 505(b)(2) approval pathway. Camargo works with companies to develop comprehensive programs, managing every facet of the plan from formulating and testing the drug product, to conducting clinical studies and FDA application submissions. Connect with Camargo on [LinkedIn](#), the President's [blog](#) or visit [www.camargopharma.com](http://www.camargopharma.com) for more information.

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