

***Integration of Technology, Chemistry and Design Space Principles in Wyeth Early Process Development Model***

***Michael K. O'Brien***, Wyeth Research, Pearl River, NY, USA

In response to the increased number of compounds entering the development pipeline each year and the pressure to reduce process development cycle times, Chemical Development at Wyeth Research has implemented a new early process development model. An organizational structure and associated workflow have evolved that integrate a multi-component technology platform with the research and development activities of our process chemists and engineers. Design space principles (QbD) and an enhanced utilization of Process Analytical Technologies (PAT) have been incorporated into this working paradigm.

New ways of working, our philosophy regarding QbD and PAT together with case examples to illustrate the Wyeth process development paradigm will be the subject of this presentation.