台美藥劑協會
Taiwanese American Association of Pharmaceutical Sciences (TAAP)

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Topic: An Introduction to CMC Regulatory Affairs: Lifecycle Management from Product Birth to Death.

Jennifer Schmitt is an Associate Director in Global Regulatory Affairs – CMC at Merck & Co. Inc. based in West Point, Pennsylvania. Jennifer earned her B.S. at the University of Delaware and M.S. from Villanova University, both in Chemical Engineering. Jennifer has over 22 years of experience in the pharmaceutical industry in small molecule process development, manufacturing and regulatory affairs. She started her career in global pharmaceutical technical operations at Merck. She held additional positions in manufacturing operations as an industrial engineer and coating production supervisor at Merck's pharmaceutical manufacturing facility in West Point. For the past 13 years she has worked in Regulatory CMC where she has supported both pre-approval initial registration and post-approval product lifecycle maintenance activities. In addition, during that time Jennifer spent 4 years focused on emerging markets projects where she served as the Merck Regulatory CMC lead for the Latin American region. In the emerging markets role, Jennifer was responsible for management of CMC dossiers for branded generics and fixed dose combination products developed at sites in India and Mexico. In addition, she led the CMC activities for business development and product licensing deals in Latin America. When she is not doing Regulatory CMC, Jennifer enjoys spending time with her husband John and her children John (15), Stephanie (13) and her wheaten terrier Arya (1). She enjoys cooking, jogging, traveling and playing the piano. Jennifer lives with her family in Audubon, PA.