David L. Hughes

David L. Hughes brings to the pharma CMC consulting arena over 30 years of experience as a scientific leader in process chemistry and CMC at Merck. As an industry-recognized expert in all facets of API drug development, he was a key driver in the development of numerous drug candidates from early stage through registration and launch, including Primaxin, Fosamax, Cozaar, Emend, and Cancidas. He has in-depth expertise with current global regulatory and compliance requirements, including cGMP, ICH guidelines, PGI assessments, and QbD.

His consulting firm, sp3 Pharma Consulting, specializes in guiding clients through CMC issues on API in all phases of development, with a particular emphasis on integrating science across all areas of pre-clinical development to ensure flawless execution on worldwide regulatory filings.

Dave has 115 publications, 17 patents, and 22 invited lectures, and served on the Board of Editors for *Organic Syntheses* from 2008-2013, editing volume 90 (2013). Dave was recently honored as the recipient of the 2014 ACS Award in Industrial Chemistry and received the ACS Heroes of Chemistry award in 2006 for leading the team that designed and developed the manufacturing route for the anti-fungal drug Cancidas.