

Tim is Executive Director and Team Leader for the CMC Advisory Office (AO) at Pfizer. The Advisory Office is a collection of Pfizer experts that provide regulatory & technical guidance to project teams to mitigate risk & integrate CMC policy with product strategies. The AO also leads Pfizer in developing and advocating regulatory and quality policy positions (internally and externally) in partnership with Pfizer's Quality Organization.

Tim currently serves as the PhRMA topic lead on ICHQ9's revision EWG and previously as a EWG member on the ICHQ11 regulatory guidance document for drug substance, Rapporteur for ICHQ11 Q&A Starting Material IWG, member of ICHQ7 IWG Q&A team, and ICHQ3C EWG. He continues to support other ICH efforts (such as Q12, Q13, and the QDG); and on the PhRMA Global Quality and Manufacturing team (GQM). Tim is one of Pfizer's participating Boards of Directors for the International Consortium for Innovation and Quality (currently Vice Chair of IQ) and Co-Chairs the ISPE Global RQHC – Regulatory and Quality Harmonization Council.

He began his career at Marion Merrell Dow in chemical research where his responsibilities involved developing new API processes, manufacturing the first GMP API bulk, technology transfers, etc. In 2000, Tim joined Pfizer, where he continued with process chemistry development responsibilities (Phase II, III and manufacturing). In 2009, he joined Regulatory Chemistry and Manufacturing Controls (GCMC) in support of QbD and Q11. He holds a PhD from The Ohio State University.