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### Roger Nosal

Principal Pharmaceutical Consultant  
(Formerly VP & Head of Global CMC at Pfizer)

06371 (CT) USA



*Roger Nosal PharmaCMC  
Regulatory Consultants*

Tel: +1 860 625 1072

Email: [rogernosal@outlook.com](mailto:rogernosal@outlook.com)

Roger Nosal is currently Principal Consultant with *Roger Nosal PharmaCMC Regulatory Consultants* and serves as Head of Regulatory Strategy for *NGT BioPharma Consultants*. Prior to September 2022 he was Vice President & Head of Global Chemistry, Manufacturing & Controls at Pfizer where he was accountable for development, preparation & prosecution of global regulatory CMC applications for new commercial products & investigational applications (small & large molecules, combination products, vaccines including the COVID-19 mRNA vaccines and gene/cell therapies).

Roger is currently Rapporteur for the ICH QDG and has served as PhRMA representative to several ICH EWG & IWGs. Roger was instrumental in development & implementation of Quality by Design & was awarded the ***Pharmaceutical Discovery, Development and Manufacturing Forum Award*** from **AICHE** for outstanding contributions to advancing QbD in 2013. He has been an invited speaker/expert panelist (>230) on a myriad of CMC development/regulatory topics including technical innovations (continuous manufacturing, PAT & adaptive controls). Roger's 41 years of experience at G. D. Searle, Monsanto, Pharmacia & Pfizer, includes 28 years in regulatory CMC & 13 as a Medicinal & Process Chemist and author of 24 patents.

