

## BIO

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CDR Jeff Yuen is a well-respected domestic and international speaker with nearly 30 years of compliance and regulatory experience; Jeff was a peace officer/investigator with the State of California, Food and Drug Branch and a Consumer Safety Officer for the US FDA respectively. During his tenure with the US FDA, he was rapidly promoted to the rank of Commander in the US Public Health Service while serving as a member of the following teams:

- FDA’s Pacific Regional Biotech Team (pre-cursor to ORA Team Biologics);
- Los Angeles District Drug Team; and
- Foreign Inspection Cadre.

CDR Yuen served as District Drug Team Leader and Drug Pre-Approval Manager during his time with US FDA. CDR Yuen specialized in both high priority drugs (PAI) and biologics (ELA and BLA) inspections. He is well widely recognized as a CGMP and compliance expert by industry and CDER Office of Compliance in the area of sterile drug manufacturing particularly with regard to inspection of biotech products, aseptic filling, quality systems, and process validation. CDR Yuen is the recipient of numerous US Public Health Commendation and Achievement medals including a “Hammer Award” presented by Vice President Al Gore’s Office for his participation and leadership in the area of innovative biotechnology/FDA industry outreach programs.

Since leaving the FDA in 1998, he was founder of Jeff Yuen & Associates, Inc., a well-recognized and well-respected independent regulatory compliance consulting firm specializing in FDA matters such as the following: developing domestic and international regulatory and compliance strategies in the area of PAI/BLA and A/NDA PAI preparation, simulated FDA mock inspections, conducting CGMP gap assessments, conducting due diligence audits, troubleshooting technical issues and interpreting compliance problems, evaluating existing and future compliance risks and liabilities, and providing CGMP training seminars.

On January 5, 2014, CDR Yuen was named EVP, Global Quality for AAIPharma Services Corp. with responsibilities for a global organization with facilities in Wilmington and Durham, NC, Edison, NJ, Germantown, WI, Charleston, SC, and Weert, The Netherlands.

CDR Yuen possesses a BS in Biological Sciences from UCI, a Masters in Public Health from UCLA, and an MBA from National University. CDR Yuen is a past President of the PDA - Southern California Chapter and former Board Member for the Institute of Validation Technology's Journal of CGMP Compliance. CDR Yuen was nominated and awarded "Distinguished Alumni for the School of Biological Sciences – University of CA, at Irvine. CDR Yuen remains a member of the BIOCUM's FDA Committee, UCI's Biotechnology Advisory Board, and PDA-TRI teaching faculty.