CURRICULUM VITAE

JEFFREY THOMAS YUEN
RANK: Commander (0-5), PHS #64033

EDUCATION

National University, at Sacramento & Irvine
Masters in Business Administration — April 1989

University of California, at Los Angeles
Masters Degree in Public Health,
Specialization in Epidemiology — June 1986

University of California, at Irvine
Bachelor of Science, Biological Sciences
Graduated with Honors — June 1984

John F. Kennedy Senior High School
High School Diploma — June 1980

Academic Honors and Activities

Distinguished Alumni of the Year – School of Biological Sciences
(Lauds and Laurels)
Dr. Alfred B. Nejame Business Scholarship
UCI Dean's List - 6 Academic Quarters
Dean's Academic Achievement and Service Award
President's Undergraduate Research Fellow
Alpha Epsilon Delta Honor Society
Peer Academic Advisor - School of Biological Sciences
Student Speakers Forum
Who's Who Among American High School Students

PUBLIC HEALTH SERVICE AWARDS

- Recipient PHS Commendation Medal – 1998
- Recipient PHS Achievement Medal – 1998
- Recipient ORA/FDA Team Award of Merit - Pacific Regional Biotech Team – 1997
- Recipient Exemplary Team Outreach Award - San Francisco District Mgmt. Team- 1997
- Recipient Vice President Al Gore’s Nat’l Performance Review Hammer Award – 1996
- Recipient PHS Achievement Medal – 1995
- Recipient Unit Commendation Medal - 1994

PUBLIC HEALTH SERVICE AWARDS - continued

- Candidate for Stanley J. Kissel Health Services Officer of the Year – 1996
- Candidate for USPHS, C. Everett Koop Award –1996
- Candidate for PHS Achievement Medal – 1996
- Candidate for Commendation Medal – 1995
- Candidate for FDA Investigator of the Year - 1995

NON-PUBLIC HEALTH SERVICES AWARDS

- Awarded UCI's coveted Distinguished School of Bio. Sci. Alumni Award (2006)
- Nominated to City of Orange Chamber of Commerce Board (2005)
- Recipient of 1994 California Association of Food and Drug Investigators Peer Excellence Award presented in Santa Ana, CA
- Recipient of 1994 Certificate of Appreciation signed by Senator David Roberti presented in Westminster, CA
- Recipient of 1992 State of California, Department of Health Services, Food and Drug Investigator of the Year Award presented in Los Angeles, CA
- Recipient of 1992 State of California, Department of Health Services, Food and Drug Branch Team Effectiveness Award presented in Downey, CA
- Recipient of 1991 Association of Food and Drug Officials National Achievement Award presented in Buffalo, NY
- Recipient of 1987 Sacramento Valley/Sierra Hypertension Council, Dedicated Service in Community High Blood Pressure Control Activities Award presented in Sacramento, CA

PERTINENT PUBLIC HEALTH TRAINING

- PDA/FDA Conference on Validation for Biologics - Washington D.C., September 2000
- 23rd Annual GMP Conference, University of Georgia at Athens, GA, March 1999
- Validation of Process Chromatography, Institute for International Research, Philadelphia, PA, February 1999
- Preparing for PAIs, CGMPs and Post Market Inspections - PDA Boston, December 1998
- Vulnerabilities in Sterile Drug Processing - 3rd Annual GMP By The Sea Conference, Newport, Rhode Island, September 1998
- Critical Utilities Design Operation - ISPE/InterPhex, Long Beach, CA, September 1998
- FDA Out-of-Specification Seminar, Los Angeles District Office, August 1998
- FDA Review Process For New Product Applications - An Interactive Workshop, Irvine, CA, July 1998
- PDA Spring Conference, San Francisco, March, 1998
- PhRMA Spring Conference, Coronado, March 1998

PERTINENT PUBLIC HEALTH TRAINING - continued

- PDA Barrier Isolator Technology Symposium, March 1998
- Lab Symposium, San Diego, February 1998
- Well-Characterized Biotechnology Pharmaceuticals, San Francisco, January 1998
- Myers Briggs Training, FDA, Irvine, September 1997
- Inspectional Approach/Laboratory Inspections, Alameda, September 1997
- Chromatography Short Course, State of CA/FDA, Sacramento, July 1997
- Quality System Regulations/Design Controls for Medical Devices, May 1997
- Field Management Directive - 145, FDA, April 1997
- Zenger Miller Training, FDA, Irvine, CA, July, 1997
- Pre-Approval Inspections Training Course, FDA, Washington D.C., June 1996
- Hull Lyophilization Course, Irvine, CA, April 1996
- Government Performance and Results Act Summary Training, Irvine, CA March 1996
- BioMerieux Vitek Training, Irvine, CA, February 1996
- WestPharm Meeting, San Diego, CA, January 1996
- 4th Annual DIA Biotech Meeting - DIA, Newport Beach., CA, January 1996
- Interphex Meeting, Anaheim, CA, October 1995
- Orientation to International Inspections, Annapolis, MD, September 1995
- Quality Audits For Improved Performance, Irvine, CA, August 1995
- Advanced Biotechnology Course, FDA, Seattle, WA, May 1995
- Los Angeles District Investigator Basis Training, May 1995
- Pre-Approval Inspection Program, San Francisco, CA, May 1995
- Food & Drug Law & Evid./Inv. Interviewing/NLEA, Colorado Springs, CO, April 1995
- Advanced Officers Training, Criminal Justice Training Center, GWC, December 1993
- Sanitation Workshop for Food Processing, UC Davis, November 1988 & 1993
- Software, FDA, & Medical Device Training, Noblitt & Rueland, Irvine, CA, June 1993
- Special Problems in Food Protection, Sacramento, CA, May 1993
- Preclin. Eval. Biomaterials/Process Validation, NAmSA, Laguna Hills, CA, April 1993
- ISO 9000 and Medical Devices, Malloy, Noblitt, & Rueland, Irvine, CA, January 1992
- Food Labeling #320 - NLEA, FDA Training Course, San Francisco, CA, May 1991
- Seafood Sensory Evaluation Workshop, NOAA and FDA, Compton, CA, January 1991
- State of California, Department of Justice, Commission on Peace Officer Standards and Training Specialized Law Enforcement Basic Certificate, July 1989
- Criminal Justice Training Center, Golden West College, Basic Investigator Course (280 hours) Certificate, May 1989
- State of California, Department of Health Services, Food and Drug Branch, Introduction to Food and Drug Investigation (160 hours) Certificate, October 1988
- Chapman College and Department of Food Science and Nutrition, Better Processing School Certificate, August 1987

SUMMARY OF EXPERIENCE

1) **Jeff Yuen & Associates, Inc. – President and CEO** 1998 - 2014

Expert FDA compliance and regulatory consulting for the dietary supplement, pharmaceutical, and biotechnology industries

Extensive expertise and experience in small molecule and large moleculte biologics products

Extensive compliance experience in all dosage forms: tablets, capsules (hard and soft gel), injectables, transdermals, inhalation, otic, ophthalmic, creams/ointments, and powder finished dosage form products

Extensive experience in USP <797> (compounding pharmacies), Q7 (APIs), 21 CFR 211 (small molecules), and 21 CFR 600 (biologics)

Extensive experience in API operations (small molecule and biologics / fermentation / purification processes)

Extensive compliance experience and expertise in mammalian and microbial fermentation processes and operations

World respected expert in aseptic and sterile operations and GMP Trainer

2) **CML/AAIPharma - EVP Global Quality** 2014 - 2015
3) **La Jolla Biologics – VP QA/RA** 2013 – 2014

4) **Althea Technologies Tech. Advisory Board Member** 2008 - 2012
5) **Amphastar Pharmaceuticals Board Member** 1999 - 2002

6) **UCI Life Sciences Advisory Committee Member** 2008 - Present
7) **BIOCOM FDA Advisory Committee Member** 2008 – Present

8) **NNFA Dietary Supplement GMP Advisor** 2005 - 2008
9) **NNFA Dietary Supplement GMP Auditor** 1999 – 2004
10) **PDA/TRI Faculty Member** 1998 – 2005

11) **U.S. Public Health Service -**
Lt. Commander Inactive Reserve 1998 - 2001

SUMMARY OF EXPERIENCE - continued

12) **U.S. Public Health Service**
Food and Drug Administration

Consumer Safety Officer/Investigator	1997 - 1998
Rank: 0-5, Commander	
Member ORA/FDA Foreign Inspection Cadre	1995 - 1998
Member Pacific Regional Biotech Team (Precursor to Team Biologics) incl. Plasma Fractionation	1995 - 1998
State of California Liaison for Biotech Team	1995 - 1998
Rank (0-4, Lieutenant Commander)	1995 - 1997
Rank (0-3, Lieutenant)	1994 - 1995
Drug Team Leader/ANDA Pre-Approval Manager	1994 - 1995

13) **State of California, Department of**
Health Services, Food and Drug Branch

Food and Drug Investigator	1988 - 1994

14) **State of California, Department of**
Health Services, Chronic Disease
Branch, Hypertension Control Program

Graduate Student Assistant/Data Analyst	1986 - 1988

15) **County of Los Angeles, Occupational Health**
and Safety Division, Los Angeles, CA

Student Professional Worker, Epidemiology	1985 - 1986

16) **Center for Health Sciences,**
University of California, at Los Angeles

Research Assistant, Jules Stein Eye Institute, Dr. M.O. Yoshizumi, Retina Division	1984 - 1986

SUMMARY OF EXPERIENCE - continued

Ophthalmic Assistant, Jules Stein Eye Institute, Dr. M.O. Yoshizumi, Retina Division — 1984 - 1986

Data Entry Operator, Jonsson Cancer Center — 1985 - 1986

17) **Medical Center, University of California, at Davis - Oncology Department**

Research Assistant — Summer 1983

18) **University of California, at Irvine**

Research Assistant, School of Medicine, Nephrology Department — 1982 - 1984

Research Assistant, School of Physics — 1982 - 1983

RESEARCH PROJECTS - Undergraduate Studies

- Use of Cyclosporin A in Kidney Transplantation in Rats
- Cancer research projects requiring skill in tissue culture techniques
- Plasma physics research projects

RESEARCH PROJECTS - Graduate Studies

- Design, implementation, reporting, and analysis of surveys on communicable diseases
- Development of data collection and reporting instruments
- Analysis of epidemiological factors in relation to larger social and demographic trends
- Effects of Cytochalsin B and D on Intravitreal Fibrosis and Tractional Retinal Detachment in Rabbits
- Low Back Injuries in Los Angeles County Firefighters - Graduate Studies/Student Professional Worker with County of Los Angeles, Occupational Health and Safety Division (*Masters Thesis*)

PAST LETTERS OF RECOGNITION

- Audrey F. Manley, Acting Surgeon General: Letter of Congratulations for Promotion to Commander, 0-5
- Ron Chesemore/Gary Dykstra, ORA/FDA: Letter of Congratulations for Promotion to Commander, 0-5
- Tom Hazlet, FDA Science Advisor: Letter of Recommendation for Promotion to Commander, 0-5
- Elaine Messa, District Director: Letter of Recommendation for Promotion to 0-5
- Letter of Appreciation from John Dolan, President, LC Resources, Inc.
- Letter of Appreciation from Rosetta Baird, Amphastar Pharmaceuticals, Inc.
- Letter of Appreciation from Michael Verlander, Polypeptide Laboratories
- Letter of Appreciation from Michael Akhavan, President Elect, ASHRAE
- Audrey F. Manley, Acting Surgeon General: Letter of Congratulations for Promotion to Lieutenant Commander, 0-4
- Gary Dykstra/Ron Chesemore, ORA: Letter of Congratulations for Promotion to Lieutenant Commander, 0-4
- Wendy Brough, Deputy District Attorney, County of Orange: Letter of Recommendation
- Ozzie Schmidt, Supervising Investigator, State of California, FDB: Letter of Recommendation
- Prosy Delacruz, Regional Administrator, State of California, Food and Drug Branch: CAFDI Commendation - Ray Wilson, Pharm.D., Food and Drug Scientist, State of California, FDB: AFDO Award Nomination
- Leslie Rodrigue, Supervising Investigator, FDA, Los Angeles District: Achievement Medal Nomination - Leslie Rodrigue, Supervising Investigator, FDA, Los Angeles District: Commendation Medal Nomination
- Leslie Rodrigue, SCSO, FDA, LA District: Investigator of the Year, 1995
- Jim Kozick, Director, Domestic Investigations, FDA, Los Angeles District: "Stanley J. Kissel, Jr. Award for Outstanding Health Services Professional of the Year, 1996
- Letter of appreciation from American Chemical Society for Drug Pre-Approval talk
- Letter of appreciation from Southern California Pharmaceutical Discussion Group for Clinical Trials and GMP talk
- Memo of appreciation from Jim Cosec, Director, Domestic Investigations, FDA, Los Angeles District for contributions to highly successful District Open House/Meeting (1995/1996) and Biotechnology Industry Conference (April 19, 1996)
- Letter of appreciation from xxxxx Pharmaceutical for facility review
- Letter of appreciation from xxxxx Pharmaceutical for facility review
- Letter of appreciation from Gary German re: Certification Focus Group in Denver, CO
- Letter of appreciation from Gary German re: Certification Focus Group in Rockville, MD
- Letter of appreciation from Landis & Gyr for HVAC validation talk
- Letter of congratulations from Ron Chesemore for being nominated for FDA Investigator of the Year

PAST LETTERS OF RECOGNITION - continued

- Letter of appreciation from xxxxx Pharmaceuticals, Inc. for facility review
- Letter of appreciation from xxxxx Laboratories, Inc. for facility review
- Letter of appreciation from Paul Kelley, Bayer Corp. re: ISPE talk in Burlingame, CA
- Letter of commendation from Elaine C. Messa, District Director for pre-approval work
- Letter of appreciation from Orange County Regulatory Affairs (OCRA) for participation in GMP & Validation Seminar
- Letter of appreciation from Mary Malarkey, Acting Chief Branch II, DEL, CBER for BLA work dated April 9, 1996
- Letter from Brian J. Donato of Hyman, Phelps & McNamara for my presentation at the 10/24/96 District Open House
- Letter of appreciation from xxxxx for non-regulatory site visit on May 29, 1996

PRESENTATIONS/INDUSTRY OUTREACH

- FDA AOAC USP Conference , FDA Los Angeles District Office, Irvine, CA, Dec. 2013
- ISPE Vendor Night – FDA Compliance Trends, San Diego, CA, August 2011
- OCRA / FDA Conference - Current Drug GMPs, Irvine, CA, June 2011
- Annual PDA Meeting – Pharmaceutical Manufacturing Science in the 21st Century – Innovation/Implementation – Preparing for FDA Inspections, Anaheim, CA, April 2006
- AOAC/SCPDG/FDA – Regulatory Compliance for the 21st Century, March 2006
- Annual PDA Meeting - Preparing for FDA Inspections with a Focus on Sterile Drug Manufacturers (Aseptic Processing), Chicago, IL, April 2005
- Pharmaceutical Sciences Group – Current Compliance Trends - Update Symposium, Toronto, Canada, May 2004
- So. California PDA Chapter – FDA Compliance Expectations, Irvine, CA, Nov. 2003
- PDA Course Series – Preparing for FDA Inspections with a Focus on Sterile Drug Manufacturers (Aseptic Processing), Las Vegas, NV, November 2002
- TIDES 2002 - Laboratory Controls and Stability, Las Vegas, NV, May 2002
- IBC's 3rd International Process Validation for Biologicals, San Diego, CA, February 2002
- So. California PDA Chapter – FDA Expectations: Cleanroom Compliance Trends, Irvine, CA, November 2001
- Korean PDA – FDA International Inspections, Seoul, Korea, May 2001
- IIR 2nd Annual Pharmaceutical GMP - Audits and Inspections - Strategies for Ensuring Continuous Quality and Compliance – Meeting FDA's Expectations in the Aseptic Processing Area, Miami, FL, October 2000
- PDA Baltimore Course Series - Course Instructor - Preparing for FDA PAI and cGMP Inspections, Baltimore, MD, June 2000
- FDA Compliance Issues Concerning Cleaning Validation, Institute for Validation Technology, Philadelphia, PA, April 2000

PRESENTATIONS/INDUSTRY OUTREACH - continued

- PDA Chicago Course Series - Course Instructor - Preparing for FDA PAI and cGMP Inspections, Chicago, IL, March 2000
- PDA European Course Series - Course Instructor - Preparing for FDA PAI and cGMP Inspections, Basel, Switzerland, February 2000
- 3rd Annual Microbiological Monitoring and Control Seminar - Preparing for FDA Inspections, Institute For International Research, Philadelphia, PA, January 2000
- Team Biologics: Meeting the Challenges of Applying Drug GMPs to Biological Products - AAI International, La Jolla, CA, October 1999
- PDA Irvine Course Series - Course Instructor - Preparing for FDA PAI and cGMP Inspections, Irvine, CA, November 1999
- ISPE/INTERPHEX*West* - FDA Program Co-Moderator, Long Beach, CA, Sept. 1999
- The FDA Review Process for New Product Applications: An Interactive Workshop, Irvine, CA, July 1999
- IBC's International Conference on Oligo-Therapeutics, Oligo-Technologies, and Peptide Technologies, Sheraton Torrey Pines, La Jolla, CA, May 1999
- Regulatory Compliance for Biologics and Drugs - Inspectional Findings, UCSD Extension, Rancho Bernardo, CA, March 1999
- Regulatory Concerns for Pharmaceutical Companies/Validation of Process Chromatography Seminar - Institute for International Research, Philadelphia, PA, February, 1999
- Preparing for PAIs, CGMPs and Post Market Inspections - PDA Boston Course Series, December 1998
- Clinical Trial Material Compliance Trends - Drug Information Association Spring Conference, Dana Point, CA, November 1998
- Vulnerabilities in Sterile Drug Processing - 3rd Annual GMP By The Sea Conference, Newport, Rhode Island, September 1998
- Critical Utilities Design Operation - ISPE/InterPhex, Long Beach, CA, September, 1998
- FDA Review Process For New Product Applications - An Interactive Workshop, Irvine, CA, July 1998
- ISPE Clinical Trials Workshop - San Diego Chapter, La Jolla, CA, July, 1998
- AOAC Sterilization Conference - Los Angeles District Office, Irvine, CA, June 1998
- FDA Perspectives on Biotechnology Product Development - Penn State University, Happy Valley, PA to be held in Philadelphia, PA (invited speaker), April, 1998
- Inspectional Trends in Manufacturing and in the Laboratory - PDA Spring Conference, San Francisco, CA, March 1998
- Inspectional Trends - PhRMA Spring Conference, Coronado, CA, March 1998
- Barrier Technology - An FDA Perspective - PDA Southern California Chapter, Irvine, CA, March 1998
- Role of Management/Laboratory GMPs/Key Elements of a Quality Assurance Program - FDA/ASQ Laboratory Symposium, San Diego, CA, February 1998

PRESENTATIONS/INDUSTRY OUTREACH - continued

- Basic Principles in Sterilization Validation for New Investigators - FDA, Los Angeles District, Irvine, CA, February, 1998
- FDA's Proposed Revisions to the Drug GMPs - ISPE, San Diego Chapter, La Jolla, CA, February 1998
- High Purity Water Systems - ISPE Bay Area Chapter, Santa Clara, CA, September 1997
- FDA's Industry Outreach Initiatives - Annual COA Meeting, Tucson, AZ, June 1997
- Validation of Aseptic Processes/Compliance Issues - Institute of Validation Technology, Validation West II, Anaheim, CA, May 1997
- Sterilization Validation - AAPS/SCPDG, Costa Mesa, CA, May 1997
- HVAC Systems - Design and Validation Course - UCSD, La Jolla, CA, February 1997
- Drug Compliance - ISPE, Greater Los Angeles Chapter, Cerritos, CA, February 1997
- Basic Principles of Validation - ASHRAE, San Diego, CA, January 1997
- Drug Pre-Approval Program - Annual AAPS Meeting, Seattle, WA, October 1996
- The FDA & Pacific Regional Biotech Team - Los Angeles District Open House, Irvine, CA, October 1996 and May 1997
- Inspection Trends/Tech. Transfer - Penn State University, Happy Valley, PA, April 1997
- FDA New Investigator Course - Los Angeles District Office, Irvine, CA, January, 1997
- Baxter Healthcare GMP Conference - Red Lion Inn, Glendale, CA, Dec. 1996\
- Introduction to the Pacific Regional Biotech Team/High Purity Water Systems and Passivation - Cal Chem, Irvine, CA, Sept. 1996
- Introduction to the Pacific Regional Biotech Team/Compliance Issues - LINC, University of California, Irvine, Sept. 1996
- Multi-Product Biopharmaceutical Facility Design, Validation, and Start-up - ISPE, Bay Area Chapter, Crowne Plaza Hotel, Burlingame, CA, September, 1996
- Environmental Monitoring - ASQC, Oakland, CA, May 1996
- Product Development Reports - McGaw, Irvine, CA, May 1996
- Introduction to the Pacific Regional Biotech Team - OCRA/FDA Biotech Conference, Irvine, CA, April 1996
- HVAC Design/Validation - Landis and Gyr Symposium, San Diego, CA, March 1996Drug Pre-Approval Program/Drug Inspections - GAO, Los Angeles, CA, Dec. 1995
- GMP's for Clinical Trials Suppliers/Intro. to Validation: - Southern California Pharmaceutical Discussion Group, Carlsbad, CA, December 1995
- The FDA Drug Pre-Approval Program and Process Validation - American Chemical Society, Anaheim, CA, October 1995
- The New FDA and the Team Concept - An Investigator's and Team Leader's Perspective - California Food and Drug Regional Meeting, Oxnard, CA, June 1995
- FDA and the Cosmetic Industry - International Cosmetic Manufacturers and Distributors Association, Beverly Hills, CA, September 1994
- The GMP Inspection for Medical Device Manufacturers - An Investigator's Perspective, North American Science Associates Seminar, Laguna Hills, CA, Spring 1993 & 1994

PRESENTATIONS/INDUSTRY OUTREACH - continued

- The Pre-Approval Inspection - An FDA Perspective, Southern California Pharmaceutical Discussion Group, Fall Meeting, Costa Mesa, CA, September 1994
- The Potential for a Computerized Data Collection System in California, State of California, Department of Health Services, Chronic Disease Branch, Hypertension Control Program Statewide Meeting, Santa Ana, CA, April 1987
- A Statewide Computerized Data Collection System for Hypertension Monitoring of Compliance - National Conference on High Blood Pressure Control: Consensus Amid Controversy, Las Vegas, NV, April 1987
- California's Need for a Statewide Data Collection System - Development, Implementation, and Future Uses - State of California, Department of Health Services, Hypertension Advisory Committee Meeting, Sacramento, CA, Sept. 1987
- Low Back Pain in Newly Hired Los Angeles County Firefighters Between 1971 and 1985, American Public Health Association Annual Meeting, Las Vegas, NV, Fall 1986

MISCELLANEOUS REGULATORY ACTIVITIES | HIGHLIGHTS

- Planning Committee member – Annual PDA Meeting – Anaheim, CA (2006)
- Current member of PQRI (Industry/FDA) charged with proposing industry's perspective on a current Guideline on Aseptic Processing (2001)
- International and Domestic Sterile Drugs Specialist (FDA)
- Expert witness (Industry)
- Involved as lead field investigator in numerous high profile regulatory and compliance cases: including numerous warning letter regulatory actions, product seizures, consent decrees and motions for permanent injunction.
- Participated in two official *non-regulatory site visits* for the Pacific Regional Biotech Team including inaugural non-regulatory site visits in the San Francisco Bay and Portland area
- Conducted *new facility blue print reviews* for over 30 pharmaceutical and biotechnology firms throughout the Pacific Region for the Pacific Regional Biotech Team and Los Angeles District Drug Team
- Published in Journal of Validation Technology: *Pre-Approval Inspections, Master Planning and BPCs*, November 1996, Volume 3, Number 1
- Selected to participate in *CSO Certification Focus Group Meeting* by FDA, DHRD, ORA in order to finalize draft training plan document for certification of investigators, October, 1995, Rockville, MD
- Invited to participate in *CSO Certification Focus Group Meeting* by FDA, DHRD, ORA in order to input into the development of a training plan for the certification of investigators in order to further promote the uniformity of inspections, September, 1995, Denver, CO

MISCELLANEOUS REGULATORY ACTIVITIES | HIGHLIGHTS

- Vice President and Moderator, California Association of Food and Drug Investigators (CAFDI), July 1, 1993 to May 31, 1994
- Moderator, Southern California Region 3, State of California, Food and Drug Branch Meetings - December 17, 1992 and May 4 & 5, 1993

PROFESSIONAL ORGANIZATIONS

- BIOCOM FDA Committee Member – 2008 to Present
- PDA Planning Committee – Annual Meeting – Anaheim, CA, April 2006
- Editorial Board Member - Journal of cGMP Compliance (Institute for Validation Technology) - 2000 to 2002
- Parenteral Drug Association - Southern California Chapter President - 1998 to 2001
- Faculty Member - PDA Training and Research Institute - 1998 to Present
- Parenteral Drug Association, Member
- Western Association of Food and Drug Officials (WAFDO), Member
- Orange County Regulatory Affairs Group (OCRA), Member
- Southern California Pharmaceutical Discussion Group (SCPDG), Member
- International Society for Professional Engineers (ISPE), Member
- International Who's Who of Professionals, Member
- University of California, at Irvine Alumni Association, Lifetime Member
- Reserve Officers Association (ROA), Lifetime Member
- Commissioned Officers Association (COA), Member
- American Society for U.S. Surgeons (AMSUS), Lifetime Member

MAILING ADDRESS

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Orange, CA 92863-6026

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E-mail: jyuen@jeffyuen.com

SUMMARY OF EXPERIENCE - State of California, Food and Drug Branch

- Protection of public health as a Food and Drug Investigator/Peace Officer for the State of California, Department of Health Services, Food and Drug Branch (February, 1988 to May, 1994)

- Enforcement of laws and regulations (California Health and Safety Code, Title 21 Code of Federal Regulations, and Business and Professions Code Sections) related to the licensure and manufacturing of foods, pharmaceuticals, medical devices, bottled water, health fraud, toys, and certain hazardous household products.

- Filing of civil and criminal cases with the local City of District Attorney's Office when appropriate in order to protect consumers from unsafe, dangerous, and otherwise unfair business practices within the food, pharmaceutical, medical device, bottled water, and health food industries.

CRIMINAL AND CIVIL CASE HISTORY: (Lead Investigator)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted the sale of an adulterated and misbranded food supplement (i.e. Mr. xxxx distributed a weight loss product with furosemide in capsule form [an unapproved prescription drug] without declaring the furosemide on the label). (Filed in December, 1994)

STATE OF CALIFORNIA vs. xxxx dba xxxx dba xxxx The case, filed through the Orange County District Attorney, noted a history of misbranding food supplements and unlawful advertisement of unapproved new drug products. (Filed in December, 1994)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted the sale of adulterated and misbranded snack foods (i.e. less expensive oils were substituted for expensive peanut oil). (Filed in December, 1993)

STATE OF CALIFORNIA vs. xxxx dba xxxx The case, filed through the Orange County District Attorney, noted the distribution of adulterated Over-The-Counter Drugs and a history of Drug GMP deficiencies. (Filed in December, 1993)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of insanitary food processing conditions and a violation of injunction. (Filed in December, 1994)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange District Attorney, noted a history of Food GMP deficiencies. The firm settled the case by signing a permanent injunction, press release, and $30,000 in civil penalties. (July, 1994)

CRIMINAL AND CIVIL CASE HISTORY: (Lead Investigator) - continued

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted sale of misbranded oysters (i.e. falsified shellfish tags re: freshness). Firm agreed to signing a permanent injunction, press release, and $33,000 in civil penalties.

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of GMP deficiencies and involvement in the sale a weight loss product with an unapproved and undeclared prescription drug: furosemide in capsule form (i.e. furosemide was undeclared on the product label). Firm stipulated to sign a permanent injunction, press release, and pay civil penalties in the amount of $75,000. (May 26, 1994)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of GMP deficiencies and involvement in the sale of sub-potent Over-The-Counter drugs. Firm agreed to a settlement which included signing to a permanent injunction, press release, and $44,000 in civil penalties. (May 24, 1993)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted history of gross Food GMP deficiencies. Firm agreed to a settlement that included a permanent injunction, press release, and $8,961 in civil penalties. (December 20, 1993)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted significant GMP deficiencies. A Temporary Restraining Order was issued by Judge Seymour. Firm stipulated to a permanent injunction, press release, and sum total of $45,0000 in civil penalties. (April 21, 1993)

STATE OF CALIFORNIA vs. xxxx dba xxxx dba xxxx The case, filed through the Orange County District Attorney, noted a history of significant Food GMP deficiencies and violation of criminal probation. (January 23, 1993)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of Food GMP and misbranding deficiencies. Firm agreed to settle the case by signing a permanent injunction, press release, and approximately $40,000 in civil penalties. (June, 1992)

STATE OF CALIFORNIA vs. xxxx dba xxxx dba xxxx The case, filed through the Orange County District Attorney, noted history of significant Food GMP deficiencies. Firm's owner pled guilty to violation of Health and Safety Codes which prohibit the manufacture and sale of adulterated and misbranded foods. The firm was ordered to pay a total of $15,000 in fines, $21,750 in penalty assessment, 10 days volunteer community service, and 3 years informal probation. (April 19, 1991)

CRIMINAL AND CIVIL CASE HISTORY: (Lead Investigator)

STATE OF CALIFORNIA vs. xxxx & xxxx The criminal case, filed through the Orange County District Attorney, noted a history of the sale of adulterated and misbranded oils. Each defendant pled guilty to the charges and agreed to pay $4,500 in fines/costs to investigation and 3 years informal probation. (November 4, 1992)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of poor compliance with Food and Bottled Water GMPs. The firm stipulated to signing a permanent injunction, press release, and $58,000 in civil penalties. (February 2, 1992)

STATE OF CALIFORNIA vs. xxxx, MD The case, filed through the Orange County District Attorney, noted the sale of an unapproved AIDS drug. Dr. xxxx pled nolo contendere to violating Drug GMPs, selling an unapproved new AIDS drug, and selling a misbranded AIDS drug. Dr. xxxx subsequently was involved in an Administrative Hearing with the State of California, Attorney General's Office. The Administrative Law Judge ruled that Dr. xxxx will not be allowed to practice medicine in the State of California (Medical License was revoked). (January 7, 1992)

STATE OF CALIFORNIA vs. xxxx The criminal case, filed with City of Anaheim City Attorney, noted a history of Food GMP deficiencies. The firm pled guilty to the charges and agreed to pay fines. (June 26, 1991)

KENNETH W. KIZER, MD, MPH, DIRECTOR OF THE DEPARTMENT OF HEALTH SERVICES vs. xxxx The case, filed with through the State of California Attorney General, noted the sale of adulterated surgical gloves. The firm stipulated to a preliminary injunction and agreed to rework the surgical gloves for industrial purposes only. (June 18, 1990)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted the sale of substandard fluoridated drinking water and numerous Food and Bottled Water GMP deficiencies. The firm stipulated to signing a permanent injunction, press release, and $12,760 in civil penalties. (April 13, 1990)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of Food GMP deficiencies. The firm's owner pled guilty of the charges and agreed to pay fines and serve a 3 year informal probation. (September 13, 1989)

STATE OF CALIFORNIA vs. xxxx The case, filed through the Orange County District Attorney, noted a history of Food GMP deficiencies. The firm stipulated to a permanent injunction, press release, and $40,000 in civil penalties. (September 5, 1989)