Chiaoyun (Benson) Kuo, PhD. RAC, Patent Agent

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2005	M.S.	Regulatory Science	University of Southern California, Los Angeles, CA
2000	Postdoctoral Fellow	Medicine	Stanford University, Stanford, CA
1999	Ph.D.	Biomedical Sciences	University of California, Riverside, CA
1987	B.S.	Biology	Tunghai University, Taiwan

Professional Experience

2021-present	Director
2010-2021	Associate Director, Consulting Service International Center for Regulatory Science, University of Southern California, Los Angeles, CA
2017-present	Faculty Member Department of Regulatory and Quality Science
2014-2017	Department of Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics & Policy School of Pharmacy, University of Southern California, Los Angeles, CA
2014-present	Member, Clinical Research Support Southern California CTSI, Los Angeles, CA
2018-2021	Member, Science and Technology Council, Institute of Regulatory Science, School of Pharmacy, Tsinghua University, Beijing, China
2012-2015	Adjunct Professor Tianjin International Joint Academy of Biomedicine Binhai New Area, Tianjin, China
2010-2014	Member, Preclinical Translation and Regulatory Support Southern California Clinical and Translational Science Institute (SC CTSI), Los Angeles, CA
2010-2012	Co-chair, Regulatory & Q.A. Committee Southern California Clinical and Translational Science Institute (SC CTSI), Los Angeles, CA
2008-2014	Adjunct Assistant Professor School of Pharmacy, University of Southern California, Los Angeles, CA
2008-2010	Manager, Consulting Service Regulatory Science Program, University of Southern California, Los Angeles, CA

2004-2008	Manager, Regulatory Affairs Alfred E. Mann Institute, University of Southern California, Los Angeles, CA
2003-2008	Partner Bayshore Patent Group, Fremont, CA
2002-2003	Research Liaison / Patent Scientist Hyseq Pharmaceuticals, Sunnyvale, CA
2001-2002 2000-2001	Group Leader, Intellectual Property Informatics Scientist, Protein Bioinformatics. Hyseq Inc., Sunnyvale, CA
1999-2000	Postdoctoral Fellow, Department of Medicine Stanford University, Stanford, CA
1994-1999	Graduate Research Assistant (Dr. Ameae Walker) Division of Biomedical Sciences, University of California, Riverside, CA

Awards

First Prize Winner, Poster Presentation, The 6th DIA China Annual Meeting, 2014
Faculty Development Grant Award, Chinese-American Faculty Association, 2014
Exemplary Employee, Gene Discovery Department, Hyseq, 2001
Dean's Fellowship, School of Medicine, Stanford University, 2000
National Institute of Health Postdoctoral Fellowship, 1999
Distinguished Graduate Student, Joy K. Tilton Cancer Research Foundation, 1996-1997
Distinguished Graduate Student Award, Cancer Federation, 1995-1996

Scholarly and Professional Activities

2021 Co-organizer, Summer Program for International Scholars, School of Pharmacy, USC

2021 Member, Steering Committee, Medical Devices 2021: Regulatory Harmonization of Non-Clinical and Clinical Development, APEC Center of Excellence at USC

2021 Co-organizer, Joint Efforts on the Medical Device Forum: From the Regulatory Perspectives, Ministry of Science and Technology, Taiwan

2020 Co-organizer, Tsinghua-USC Combination Products Online Workshop, Beijing, and Los Angeles

2020 Co-organizer, Medical Device Development and Commercialization: FDA Perspective, National Chung Kung University, Tainan, Taiwan

2019 Co-organizer, PKU-USC Day at Peking University, Beijing, China

2019 Co-organizer, NTU-USC Conference at National Taiwan University, Taipei, Taiwan

2019 Co-organizer, Keio-USC Conference at Keio University, Tokyo, Japan

2018 Co-organizer, US FDA Regulations Workshop for Zhejiang Province FDA Delegation, Cal State University Long Beach, Long Beach, CA

2018 Co-organizer, Regulatory Science Summer Program for International Scholars, USC, Los Angeles, CA

2018 Co-organizer, International Pharmaceutical Regulatory Science Forum, Frist Educators Summit, China Pharmaceutical University, Nanjing, China

2017 Co-organizer, Shanghai FDA CDEI – USC Conference on "Marketing Authorization Holder Related Drug Regulations and Practice in USA", USC, Los Angeles, CA

2017 Co-organizer, PKU-USC Day at Peking University, Beijing, China
2017 Co-organizer, Innovation and Market Access, Sino-US Professional Academic Forum of Drug Policy at China Pharmaceutical University, Nanjing, China

2017 Co-organizer, Shanghai FDA-USC Workshops at Shanghai FDA, Shanghai, China

2017 Co-organizer, Keio-USC Conference at Keio University, Tokyo, Japan

2017 Co-organizer, Regulatory Science Summer Program for International Scholars, USC, Los Angeles, CA

2016 Co-organizer, Regulatory Science Summer Program for International Scholars, USC, Los Angeles, CA

2015 Co-organizer, CPU-USC Day at China Pharmaceutical University, Nanjing, China

2015 Co-organizer, PKU-USC Day at Peking University, Beijing, China

2015 Co-organizer, Regulatory Science Summer Program for International Scholars, USC, Los Angeles, CA

2015 Co-organizer, US FDA Regulations Workshop for Jiangsu Province FDA Delegation, Cal State University Long Beach, Long Beach, CA

2014 Co-organizer, USC Workshop on Quality System Requirements and Auditing, Binhai New Area, Tianjin, China

2014 Co-organizer, Regulatory Science Summer Program for International Scholars, USC, Los Angeles, CA

2013 Co-organizer, CPU-USC Day at China Pharmaceutical University, Nanjing, China

2013 Co-organizer, PKU-USC Day at Peking University, Beijing, China

2013 Co-organizer, SKKU-USC Day at Sungkyunkwan University. Suwon, Korea

2011 Short-course co-organizer, Training Course of USC for the Development of Sino-American Collaboration, Shanghai, China

2010 Co-organizer, Regulatory Education Summit, Los Angeles, CA

2008 – 2010 Co-organizer, FDA-USC Certificate Program, Silver Spring, MD

Invited Presentations and Lectures

2021 Speaker, "US Reimbursement System" International Conference on Future Healthcare and Economic Development: Smart healthcare and Medical Innovation for the New Normal, Tainan, Taiwan

2021 Lecturer, "Reimbursement Strategies and Market Access in the U.S." Market Assessment of Biomedical Technology, National Chung Kung University, Tainan, Taiwan

2021 Speaker, Joint Efforts on the Medical Device Forum: From the Regulatory Perspectives, Ministry of Science and Technology, Taiwan

2020 Lecturer, Medical Device Development and Commercialization: FDA Perspective, National Chung Kung University, Tainan, Taiwan

2019 Lecturer, NCKU

2019 Speaker, "Patent Exclusivity Data Reveal the Challenge to Develop First-in-Class Drugs is Escalating"
Post-graduate Forum, National Medical Products Administration
Tsinghua University, Beijing, China

2019 Speaker, "Herbal Supplement Regulations in the United States"
Sichuan Traditional Chinese Medicine Academy of Sciences, Chengdu, China

2019 Speaker, "Patent Exclusivity Data Reveal the Challenge to Develop First-in-Class Drugs is Escalating"
School of Pharmacy, National Taiwan University, Taipei, Taiwan

2018 Speaker, "Innovation and Reimbursement—Specialty Pharmacy Supply Model"
Innovative Pharmaceuticals International Conference
China Pharmaceutical University, Nanjing, China

2017 Speaker, "New Medical Devices and FDA Regulations"
Taipei Medical University, Taipei, Taiwan

2017 Speaker, "Drug Master Files and FDA Regulation of Marketing Authorization Holders"
Shanghai FDA CDEI – USC Conference on "Marketing Authorization Holder Related Drug Regulations and Practice in USA", USC, Los Angeles, CA

2017 Lecturer, "International Health Care System"
School of International Pharmaceutical Business, China Pharmaceutical University, Nanjing, China

2017 Speaker, "FDA and Big Data: The Mandate of Real-World Data Use for the FDA and Its Efforts on Evidence Generation"
Innovation and Market Access, Sino-US Professional Academic Forum of Drug Policy
Pharmaceutical University, Nanjing, China

2017 Speaker, "Robotic Surgical Devices Regulations"
Shanghai FDA-USC Workshops, Shanghai Testing & Inspection Institute for Medical Devices (CmTC), Pudong, Shanghai, China

2017 Speaker, "Introducing IMEDS: A Public-Private Resource for Evidence Generation"
Keio-USC Conference, Keio University, Tokyo, Japan

2016 Lecturer, "The Health Care System in the U.S."
School of International Pharmaceutical Business, China Pharmaceutical University, Nanjing, China

2016 Speaker, "FDA Regulations on Marine Dietary Supplements and New Drug Development"
High value of Fisheries Resources to the Use of Innovative Development Summit
China Aquatic Products Processing and Marketing Alliance (CAPPMA), Beijing, China

2016 Speaker, "Regulatory Perspectives for Herbal Supplement in the United States"
Zhangzhou 2nd International Innovation and Entrepreneur Conference and Global Crowdfunding Summit
Zhengzhou, Henan, China

2016 Speaker, "HTA Implementation for Disruptive Medical Devices in Clinical Development"
Health Technology Assessment: Current Issues in Research and Policy Making
Taipei Medical University, Taipei, Taiwan

2016 Speaker, "Working with the FDA for Targeted Therapeutics in the Era of Precision Medicine – Medical Devices"
Biomedical Engineering Ecosystem Symposium
National Chungkung University, Tainan, Taiwan

2016 Speaker, "Working with the FDA for Targeted Therapeutics in the Era of Precision Medicine - Drugs"
International Conference on Regulatory Approaches for Fostering innovation in Drugs and Medical Devices, Taiwan CDE, National Taiwan University, Taipei, Taiwan

2014 Lecturer, "US FDA and Medical Product Regulations"
Tianjin University, Tianjin, China

2014 Speaker, "Eyeing on Quicker Regulatory Approvals: Recent Developments in FDA and CFDA"
Conference on "Biomedical Innovation: Current status and Challenges"
Chinese American Professional Society (CAPS), City of Industry, CA

2014 Speaker, "Regulatory Affairs Profession for Pharmacy Students"
School of Pharmacy, Taipei Medical University, Taipei, Taiwan

2013 Lecturer, "US FDA and Medical Product Regulations"
Tianjin University, Tianjin, China

2013 Speaker, "Regulation of Medical Devices: A Quick Primer"
USC Coulter Translational Partnership, USC, Los Angeles, CA

2013 Speaker, "FDA's Clinical Translational Research Rules and Regulations"
SC CTSI KL2 and TL1 Training Programs, Los Angeles, CA

2009 Speaker, "How to Prepare for GMP Audit"
Beijing International Healthcare Industry Forum, Beijing, China

2008 Speaker, "FDA GMP Regulations"
Fourth Annual China International Life Science Summit, Hangzhou, China

Past and Present Members

Regulatory Affairs Professionals Society
Orange County Regulatory Affairs Professionals Society
The Association of Graduate Regulatory Educators
The American Association for the Advancement of Science
Drug Information Association
American Pharmacists Association
American Association of Colleges of Pharmacy
American Association of Pharmaceutical Scientists

Regulatory Affairs Experience

- Prepared Pre-IND meeting packages
- Participated in FDA meetings (Pre-pre IND, Pre-IND, Q-sub)
- Compiled "Designation Request for Breakthrough Device" Q-Submission
- Compiled Orphan Drug Designation application and successfully received the designation
- Developed GMP components for drugs and medical devices
- Participated in GLP lab set-up and gap analysis
- Clinical trials monitoring
- Conducted GCP audits
- Responded to FDA audits
- Drafted and filed IDE applications and annual reports
- Drafted and filed IND applications and annual reports
- Prepared correspondences and annual reports to FDA and IRBs
- SOP drafting for drugs and devices
- Developed QA plan for software development
- Established and maintained the quality system in compliance with QSR
- Served as an internal auditor for MDSAP stage 2 audit
- Served as an internal auditor for ISO 13485 audit
- Consulted faculty and community members on regulatory affairs issues
- Developed regulatory strategies for innovative products, including drugs, biologics, devices and dietary supplements

Regulatory Affairs Education Experience

Teaching Activities

As an integral part of the Regulatory Science program, I have participated in at least a lecturing capacity in the following courses:

MPTX 511 - Introduction to Regulation
MPTX 512 - Regulation of Drugs and Biologics
MPTX 513 - Regulation of Medical Devices and Diagnostics
MPTX 515 - Quality Systems and Standards

MPTX 517 - Structure and Management of Clinical Trials
MPTX 518 - Writing Regulatory Drug Submissions
MPTX 519 - Global Regulation of Medical Products
MPTX 521 - Seminars in Regulatory and Quality Sciences (also as course coordinator)
MPTX 602 - Science, Research and Ethics
RSCI 520 - Risk Management Theory
RSCI 527 - Medical Product Safety
RSCI 529 - Risk Management Tools
RSCI 541 - Medical Product Development, Reimbursement, and Marketing (also as course coordinator)
RSCI 603 - Managing Complex Projects
RSCI 604 - Regulation in Asia (also as course coordinator)
RSCI 607 - Theory, Methods and Practice of Medical Products Research

Mentorship

Regulatory Research (Undergraduate and PharmD program)

2019 Analysis on Clinical Drug Development Times, FDA Review Time, and Patent Term Extension.
Isaac Gelman, Ruoying Sheng, and Chiaoyun Kuo, PhD

Intellectual Property Experience

Registered Patent Agent

USPTO Registration Number: P-53,164

Intellectual Property Experience

- Coordinated the joint meetings of the legal and bioinformatics departments
- Prepared patent disclosures
- Maintained the database of the patented sequences
- Composed update report for replying to office actions
- Acted as liaison for legal, bioinformatics, cloning, and screening departments regarding updates of existing inventions and the discovery of new genes

Patent Drafting and Prosecution

- Drafted provisional and nonprovisional biotechnology patent applications including claims
- Drafted responses to office actions
- Responded to restriction requirements
- Prepared IDS and replies to notices of missing parts
- Conducted prior art searches and patentability analysis
- Filed PCT applications
- Advised litigation attorneys on technical matters

Patents

7,981,413 Methods and compositions concerning antibodies that bind CD84-like polypeptides

7,425,610 Methods and materials relating to CD84-like polypeptides and polynucleotides

7,379,294 Quick plug/eject concept SATA hard disk drive rack (as patent agent)

Published Patent Applications

20110268724	METHODS AND MATERIALS RELATING TO CD84-LIKE POLYPEPTIDES AND POLYNUCLEOTIDES
20090069278	Hormonally-timed dermatological preparations (as patent agent)
20090042199	Methods and Materials Relating to CD84-like Polypeptides and Polynucleotides
20090023659	Methods and Materials Relating to CD84-like Polypeptides and Polynucelotides
20080260747	Methods and Materials Relating to CD84-like Polypeptides and Polynucleotides
20080080130	Quick plug/eject concept SATA hard disk drive rack (as patent agent)
20060052591	Methods and materials relating to carcinoembryonic antigen-like (cea-like) polypeptides and polynucleotides
20050204243	Method and testing system for storage devices under test (as patent agent)
20050175994	Methods and materials relating to prothrombinase-like polypeptides and polynucleotides
20050027114	Methods and materials relating to cd84-like polypeptides and polynucleotides
20050007345	Power saving device
20040122220	Methods and materials relating to preadipocyte factor-1-like (pref-1-like) polypeptides and polynucleotides
20030144491	Methods and materials relating to cadherin-like polypeptides and polynucleotides

Grants

2015 R34 grant for the Center for Dental, Oral and Craniofacial Tissue and Organ Regeneration (C-DOCTOR); PI: Dr. Yang Chai

2016 Lentiviral Gene Therapy for Bone Repair with Transduced Adipose Derived Stem Cells; PI: Dr. Jay R. Lieberman

2017 cGMP-grade placental stem cell production and characterization for treatment of congenital metabolic disorders; PI: Dr. Toshio Miki

2019 "Optimized Regulatory Strategy to Develop Theranostic Agent NMI for Glioblastoma Multiforme
Co-PI in 2019 School of Pharmacy Interdisciplinary Research Award
School of Pharmacy, University of Southern California

2019 R41 grant of A Novel Two-in-one Approach to Administer Surfactant and Provide Airway Support to VLBW Infants; PI: Dr. Virender K. Rehan

2020 NIAMS SBIR Phase II project on "Recovery of neuromuscular control following ACL injury"; PI: Dr. Francisco Valero

Scientific Publications

1. **Kuo C.** Regulatory Pathways and Barriers to Implementation of Tissue Engineering and Regenerative Medicine. 2019. Encyclopedia of Tissue Engineering and Regenerative Medicine.
2. Xu W, Xu ZY, Cai GJ, **Kuo CY**, Li J, Huang YS. 2016. Estimated Financing Amount Needed for Essential Medicines in China, 2014. Chin Med J (Engl). 129(6):716-22.
3. Sinha, UK, Villegas B, **Kuo C**, Richmond, FJ, Masood, R, Nelson, NI, and Loeb, GE. 2014. Safety of microstimulator during radiation therapy – a preliminary study on head and neck cancer patients. J Nucl Med Radiat Ther. (5):4-8.
4. Zhang J. and **Kuo CB.** 2014. The Global Landscape of Natural Drugs in Clinical Development. 1st Poster Prize. Shanghai. The 6th DIA China Annual Meeting.
5. Wu W, Coss D, Lorenson MY, **Kuo CB,** Xu X, Walker AM. 2003. Different biological effects of unmodified prolactin and a molecular mimic of phosphorylated prolactin involve different signaling pathways. Biochemistry. 42(24):7561-70.
6. Yang, L., Lii, S., **Kuo, B.,** Buckley, A., Buckley, D., Chen, C., Xu, X., Coss, D. and Walker, A.M. 2002. Maternal prolactin composition can permanently affect epidermal gamma/deltaT cell function in the offspring. Dev Comp Immunol. 26(9):849-60.
7. **Kuo, C.B.,** Wu, W., Xu, X., Yang, L., Chen, C., Coss, D., Birdsall, B., Nasseri, D. and Walker, A.M. 2002. Pseudophosphorylated prolactin (S179D PRL) inhibits growth and promotes beta-casein gene expression in the rat mammary gland. Cell Tissue Res. 309(3):429-37.
8. Xu, X., Kreye, E., **Kuo, C.B.** and Walker, A.M. 2001. A molecular mimic of phosphorylated prolactin markedly reduced tumor incidence and size when DU145 human prostate cancer cells were grown in nude mice. Cancer Res. 61(16):6098-104.
9. Yang, L., **Kuo, C.B.,** Liu, Y., Coss, D., Xu, X., Chen, C., Oster-Granite, M.L. and Walker, A.M. 2001. Administration of unmodified prolactin (U-PRL) and a molecular mimic of phosphorylated prolactin (PP-PRL) during rat pregnancy provides evidence that the U-PRL:PP-PRL ratio is crucial to the normal development of pup tissues. J Endocrinol 168(2):227-38.
10. Coss, D., Yang, L., **Kuo, C.B.,** Xu, X., Luben, R.A. and Walker, A.M. 2000. Effects of prolactin on osteoblast alkaline phosphatase and bone formation in the developing rat. Am J Physiol Endocrinol Metab. 279(6):E1216-25.
11. Coss, D., **Kuo, C.B.**, Yang, L., Ingleton, P., Luben, R. and Walker, A.M. 1999. Dissociation of Jak2 and STAT 5 activation after treatment of Nb2 cells with a molecular mimic of phosphorylated prolactin. Endocrinology 140(11):5087-5094.
12. Chen, T.J., **Kuo, C.B.**, Tsai, K.F., Liu, J.W., Chen, D.Y. and Walker, A.M. 1998. Development of recombinant human prolactin receptor antagonists by molecular mimicry of the phosphorylated hormone. Endocrinology 139(2):609-16. **(co-first author)**
13. **Kuo, C.B.,** Coss, D. and Walker, A.M. 1998. Prolactin receptor antagonist. Endocrine 9(2):121-131.
14. Bui, T., **Kuo C.B.,** Rotwein, P. and Straus, D.S. 1997. Prostaglandin A2 specifically represses insulin-like growth factor-I gene expression in C6 rat glioma cells. Endocrinology138(3):985-93.