

Jiaqi (Zoey) Cheng

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Education

University of Southern California | Los Angeles, California

- Doctor of Philosophy, Pharmaceutical and Translational Science 08/2020-05/2025
- Master of Science, Regulatory Science 08/2020-08/2024
- Master of Science, Biochemistry and Molecular Medicine 09/2018-05/2020

Northeastern University | Shenyang, China

- Bachelor of Science in Biomedical Engineering, GPA:3.86 (Top 10%) 08/2014-08/2018

Work Experience

Clinical and Regulatory Consulting Service Associate | USC Consulting Center, Los Angeles, CA

09/2024-Present

- Observed and supported clinical site monitoring and documentation to ensure compliance with regulatory requirements, protocol adherence, and high-quality data collection.
- Compiled a 510(k) submission for a single-lead EEG device and reviewed and responded to FDA requests for information.
- Developed and reviewed core labeling documents (Instructions for Use, package insert) for a single-lead EEG device.

Regulatory Affairs Intern | Hologic, San Diego, CA

05/2024-09/2024

- Conducted international registration for 15+ IVD products, communicate and provide documents to APAC and EMEA regional team.
- Improved and automated international registration processes to streamline information collection for greater efficiency.
- Generated a product database from the Agile document management system, covering molecular and cytology product lines.
- Assessed the regulatory impact of proposed changes to existing market products from other departments, communicate to marketing and research team.
- Reviewed labeling, and promotional materials to ensure compliance with labeling regulations.

Regulatory Affairs Intern | Yuyu Pharma Inc, Remote

01/2024-05/2024

- Conducted regulatory and market research on treatments for obesity and diabetes for strategic insight in product development.
- Performed comprehensive analyses of US and EU regulatory pathways, including market assessments for comparable drug classes.
- Reported directly to the CEO, managed company communications, and organized activities for the regulatory affairs team.

Formulation and Regulatory Consultant | Cizar Inc, Los Angeles, CA

01/2023-Present

- Test and optimize the formulation for anti-virus zinc eye drop product, PBPK modeling of the peptide-zinc formulation.
- Develop regulatory strategy for the US market, including the preparation of patent applications and request for designation.

Quality Compliance Student Intern | USC Team-Based Regulatory and Quality Solutions (TRAQS)

08/2022-01/2023

- Developed comprehensive cGMP training materials for a client plasmid DNA manufacturing company for all employee's annual refresher
- Delivered training content, including PowerPoint presentations, case studies, and quizzes, ensuring alignment with 21 CFR Part 210 & 211 600-680, ICH Q7 ICH Q5A requirements.
- Conducted in-depth research on FDA cGMP guidelines, identifying common compliance gaps and improving quality control processes.

Clinical Affairs Intern | Beijing Institute of Genomics, Chinese Academy of Sciences, Beijing, China

05/2017-05/2018

- Contributed to a clinical study designed to analyze HBV genotypes and drug resistance among chronic hepatitis B patients.
- Shadowed clinical study protocol development, including patient selection criteria, data collection methods, and laboratory testing strategies.
- Helped formulate strategic recommendations for clinical decision-making, optimizing antiviral drug regimens based on HBV genotype and resistance profiles.

Research & Project Experience

Infection Targeting Drug Delivery Research | USC Alfred E Mann School of Pharmacy | PI: Dr. Jennica Zaro

08/2020-Present

- Designed and constructed a pH sensitive cell penetrating peptide drug delivery complex.
- Developed local abscess infection mice model, tested the complex *in vitro* and *in vivo*.
- Utilized computational modeling to predict the secondary structure and self-interaction properties of antimicrobial peptides.

Immunology and Infectious Disease Research | USC Keck School of Medicine | PI: Dr. Brad Spellberg

10/2018-05/2020

- Build mice model for pre-clinical test of pan drug resistant *Acinetobacter baumannii* and adjuvant vaccine
- Collaborated with Howard Xu's Lab in Cal State LA test *In vitro* capsule ability by macrophage assay base on cell culture
- Conducted drug screening for extensively drug-resistant *Acinetobacter baumannii* in nutrient-limited media
- Studied the synergetic effect of current clinical used antibiotics and antimicrobial peptide.

Tumor Targeting Probe Research | NEU Molecular Institute | PI: Dr. Hongguang Liu

3/2018-07/2018

- Designed and constructed molecular probes for targeted cancer cell imaging
- Performed E. coli transformation, followed by protein expression, extraction, and purification
- Utilized fluorescent microscopy and immunohistochemistry for imaging, including image processing and analysis
- Investigated probe interactions in both cell cultures and tissue sections

Microbial Fermentation Research | PI: Dr. Yang Shu

3/2018-07/2018

- Cultivate actinomycete, extract and separate secondary metabolites to produce curcumin.

Undergraduate Innovation Project | PI: Dr. Chen Ding

3/2016-02/2017

- Design protocol to produce Garbage Enzyme
- Analyze physiological and biochemical influence of garbage enzyme on model plants

Quality and Regulatory Coursework Project

01/2021-08/2024

- Conducted root cause analysis, designed and implemented Corrective and Preventive Action (CAPA) plans and created process control charts as part of a group project focused on quality management systems.
- Prepared simulated 510(k), IND, and NDA submissions.
- Designed a comprehensive business plan for a hypothetical new drug launch.

Honors Mentorship and Leadership Experience

Student Ambassador, Regulatory Affairs Professionals Society Convergence (RAPS) 2024

- Assisted in organizing the event and provided support to speakers.

John Burt Leadership development program | USC 2024-2025

- Completed the John Burt Leadership Development Program, enhancing skills in strategic decision-making, effective communication, and fostering collaboration to empower teams and achieve impactful outcomes.

American Association of Pharmaceutical Science USC student chapter president | USC 2022-2023

- Served as president of American Association of Pharmaceutical Scientist USC student chapter, plan and host 10+ professional events, secured industry sponsorships through strategic negotiation, mentored team members, and fostered collaboration between academia and industry.

SHINE summer program PhD student mentor | USC Viterbi 2022

BUGS summer research Jr mentor | USC Dornsife 2021

ISA Graduate Student mentor | USC 2020

- Served as high school / international student, fostering students' interest in science, and providing support in developing technical skills, critical thinking, and academic confidence.

BMM Retreat Poster Award | USC 2020

Outstanding Graduate, National undergraduate Scholarship | NEU 2014-2018

Student peer leader | NEU Fall 2015 – Fall 2016

Activities and Involvement

Gilead case competition | Oct – Dec 2023

Deloitte Future of Work Bootcamp | March-April 2023

Poster presentation in Moving Target 2022 | August 2022

Poster presentation in USC school of Pharmacy PhD interview campus visit day | 2021-2024

Volunteer | Liaoning Science and Technology Museum May 2016 - June 2018

Shenyang College Student Scientific Creativity and Innovation competition | April 2016

License Certificate

CITI certificate: Information Privacy Security (IPS): Research HIPAA; Human Research: Biomedical Human Subjects; CITI Good Clinical Practice: GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus); GCP for Clinical Trials with Investigational Medical Devices.

Publications

Jiaqi Cheng, Samantha Marcotte and Jennica Zaro. “pH sensitive Antimicrobial Peptide with Targeted Activity in a Mildly Acidic Microenvironment” J. Drug Deliv. Sci. Technol. 93, 105420 (2024).

Jiaqi Cheng, Jun Yan, Zeferino Reyna, Matt Slarve, Peggy Lu, Brad Spellberg, and Brian Luna. 2021. “Synergistic Rifabutin and Colistin Reduce Emergence of Resistance When Treating Acinetobacter Baumannii.” Antimicrobial Agents and Chemotherapy, January.

Rubio, Jennifer, Jun Yan, Sarah Miller, **Jiaqi Cheng**, Rachel Li, Zac Builta, Kari Aoyagi, et al. 2024. “Polymyxins Retain Activity and Efficacy against ‘Resistant’ Strains When Tested in Physiological Conditions.” Antimicrobial Agents and Chemotherapy 68 (10): e0072524.

Vogelaar, Alicia, Samantha Marcotte, **Jiaqi Cheng**, Benazir Oluoch, and Jennica Zaro. 2023. “Use of Microfluidics to Prepare Lipid-Based Nanocarriers.” Pharmaceutics 15 (4): 1053.

Luna, Brian, Vincent Trebosc, Bosul Lee, Malina Bakowski, Amber Ulhaq, Jun Yan, Peggy Lu, **Jiaqi Cheng** et al. 2020. “A Nutrient-Limited Screen Unmasks Rifabutin Hyperactivity for Extensively Drug-Resistant Acinetobacter Baumannii.” Nature Microbiology 5 (9): 1134–43.

Peer Review Reviewer for Spectrum Journal

Skills

Computer: Microsoft office, R Language, Image J, Prism, SPSS, GastroPlus, Simulation Plus, Snapgene, Minitab, Biorender, Flowjo, Smartsheet, Agile document management.

Language: Mandarin, Japanese, scientific writing, scientific speaking.

Medical/ Regulatory Skill: Regulatory Pathway Knowledge: IND, NDA, 510K, PMA, OTC monograph; Quality and Compliance: CAPA plan, SOP development, pharmacovigilance and drug safety monitoring; Process Control: control chart; Risk Management: risk mitigation plan, root cause analysis; Business Strategy: business plan development and analysis, cost-effectiveness analysis; Market Access and Reimbursement: market analysis and access strategy, pricing and reimbursement strategy; Medical Law: medical law compliance, case brief, intellectual property management; Clinical Trail Management: clinical trial design, consent form design, clinical data collection, clinical data analysis, clinical monitoring; Medical Affair: medical information, scientific communication, medical review, medical strategy, cross-functional collaboration.

Lab Technique: Flow Cytometry, ELISA, Mice model handling (injection, blood collection, tissue harvest), Immunofluorescence, Immunohistochemistry, MIC assay, hemolysis assay, cell culture, qRT-PCR, plasmid design, gene Transformation, Western Blot, Protein purification, AKTA, HPLC, microfluidics, Electrophoresis.