

STELLA CHEN

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PROFILE

Regulatory affairs professional specializing in EU regulations, including EU IVDR 2017/746, with a strong interest in medicine and healthcare. Committed to following all regulations and SOPs to ensure compliance and good documentation practices for traceability. Motivated individual looking to leverage current experience in leadership and regulatory compliance and experience working in regulated and ISO certified workplaces for a dynamic career in quality management.

TECHNICAL TRAINING & PROFESSIONAL SKILLS

- Regulatory Affairs
 - Compliance
 - Experience with regulating agencies and guidelines
 - Standard Operating Procedures
 - Communication
 - Data Management
 - Quality Management Systems
 - ISO Standards
 - Leadership
 - Bilingual – Cantonese Speaking
 - Time Management
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EDUCATION

- **Biomanufacturing Training Program** – BioConnect DE, Newark, DE Feb. 2026
 - **M.S., Biotechnology (Molecular Targets and Drug Discovery Technologies)** – Zanvyl Krieger Incomplete
School of Arts & Science, Johns Hopkins University, Baltimore, MD
 - **B.A., Biochemistry and Minor in Psychology** – Hunter College, CUNY, New York, NY May 2018
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WORK EXPERIENCE

- **Owner and Operator, Mango Mango, Middletown, DE** Feb. 2022 – Jan. 2026
 - Worked with contractors, local governing bodies, and corporate advisors to open Delaware's second Mango Mango
 - Oversaw daily operations and managed 15+ employees, two social media accounts, store finances, inventory, staff training, and resolves customer issues
 - Ensured the store followed all local, state, and federal regulations and food safety guidelines

- **Regulatory Affairs Professional II, Siemens Healthineers, Newark, DE** May 2020 – Sep. 2023
 - Reviewed and approved technical documentation for *in vitro* products (reagents, calibrators, controls) to ensure compliance with European *In Vitro* Diagnostic Regulations (2017/746)
 - Compiled and evaluated regulatory documents and data to support the creation and approval of IVDR technical documents
 - Created, reviewed, and routed IVDR technical files for submission to the Notified Body, ensuring accuracy and regulatory completeness
 - Prepared technical documents and audit responses to support product certification and regulatory inspections

- **Regulatory Affairs Associate, Jos. H. Lowenstein & Sons, Brooklyn, NY** Oct. 2018 – May 2020
 - Authored Safety Data Sheets (SDS) and toxicological summaries for products using the Scientific Community of Consumer Safety (SCCS), Cosmetics Ingredients Review (CIR), and National Institute of Health (NIH)
 - Analyzed regulatory guidance from U.S. and international agencies to ensure the hair and fur dye products complied with domestic and international regulations
 - Generated Globally Harmonized System (GHS) compliant labels, responded to customer requests, and supported updates to standard operating procedures
 - Served as a contact person for European Union (EU) Regulations, Evaluations, Authorization and Restriction of Chemicals (REACH) compliance, assisting with certificate management, and EU REACH dossier submissions

- **Student Observer, Weill Cornell Medical College – New York Presbyterian, NY** Aug. 2015 – May 2016
 - Observed daily hospital rounds alongside a hospitalist and infectious disease specialist, evaluating 10-15 patients per round
 - Reviewed patient medical histories and presenting symptoms prior to rounds to assess potential diagnoses and reasons for hospitalization
 - Participated in post – evaluation discussions regarding medication plans, treatment options, and discharge decisions

- Gained foundational clinical exposure to infectious diseases, including HIV/AIDS and MRSA, and developed familiarity with medical terminology and disease progression
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ADDITIONAL EXPERIENCE

Internship

Summer Medical and Dental Education Program, Yale School of Medicine – New Haven, CT Summer 2015

- Attended literature, organic chemistry, and advanced biology lectures by Yale School of Medicine professors and seminars by Yale New Haven Hospital physicians
- Engaged in hands – on activities such as suturing and ultrasound scans
- Observed emergency and pediatric physicians during morning rounds to review patient histories, discuss presenting symptoms and possible diagnoses, and learned charting protocols