ALEX CHANG, MS, RAC

Founder of BioDesign Regulatory Services, LLC; Regulatory Professional and Principal Consultant

Email: a.chang@biodesign-rac.com
Phone: 408-839-5826

Websites:
www.biodesign-rac.com
www.linkedin.com/in/alexchang/

VALUE OFFER

Extensive experience in regulatory submissions in the pharmaceutical, medical device, diagnostics and biologics industry (510(k), PMA, IND, NDA, ANDA, and BLA) for the US and Design Dossier and Technical Files for the EU). Strong experience in managing multiple projects and providing regulatory strategies to project teams. Very versatile in handling various aspects of regulatory from development to post-marketing. Experience working in small start-ups to large corporation with great success. Results-driven and a great mentor. Trained in ISO 13485:2016 Lead Auditor. Extensive IVD experience and in QMS, Design Controls and Risk Management. MDSAP, EU MDR and EU IVDR experience.

BioDesign Regulatory Services, LLC
May 2018- present
Founder and Principal Consultant
Past and current projects include:

- Ongoing (current) Responsible for managing and drafting 510(k) submissions for a medical aesthetics company. (2019-present)
- Ongoing (current) Responsible for 510(k) submissions and Tech File self-certification for an IVD company; also responsible in helping the company transition from IVDD to IVDR. (2019-present)
- Ongoing (current) role as the US. Agent for a Taiwanese Contract Manufacturer of pharmaceutical products. (2018-present)
- Created Technical File for an IVD company against current IVDD (2019)
- Provided regulatory support for a large diagnostic company in registering their clinical (CLIA) laboratory in Texas (2018)

Allergan, Inc., Pleasanton, California
May 2018- May 2019
Medical device division of Allergan focused in the CoolSculpting product line, a cryolipolysis device for fat reduction
Sr. Manager, Regulatory Affairs

- Regulatory Affairs lead for the regulatory department with three direct reports
- Supervised direct reports on global regulatory, labeling/translations, MDR/Complaints and Marketing Review (Ad/Promo)
- Submitted a traditional 510(k) within 30 days of hire for a claim expansion and received clearance within 60 days.
- Provide regulatory impact assessment on reportability for Change Order Requests
- Assigned as the Individual Responsible for Regulatory Compliance for the upcoming EU MDR transition and is the regulatory lead for the Pleasanton facility in transitioning to the new EU MDR. Also received training for the EU MDR from Oriel-STAT.
- Represented Regulatory during audits including MDSAP and Notified Body surveillance inspections.

SINGULEX, INC., Alameda, California
April 2014- May 2018
Privately held company pioneering Next Generation Immunodiagnostics utilizing proprietary SMC technology to provide unprecedented ultra-sensitivity in the precision measurement of biomarkers.
Sr. Manager, Regulatory Affairs

- Regulatory representative in the Diagnostics, Clinical Lab, and Life Science business units of the company.
- Oversees and maintain state licenses for the Singulex Clinical Laboratory which includes being the regulatory representative in all team projects for the lab and ensuring that the laboratory is in compliance with all applicable laws pertaining to the lab in California and in all other states where Singulex operates.
- In collaboration with the Director of Customer Operations and Singulex Compliance Officer, responsible for creating a robust process to supervise over 50 phlebotomists across the US and to manage four Singulex Patient Service Centers for collecting patient's specimens.
- Collaborates with cross-functional team members in the development and commercialization of break-through diagnostics products. Responsibilities include submitting 510(k)s and creating Technical Files

ALEX CHANG, MS, RAC

EDUCATION

- SANTA CLARA UNIVERSITY
  Santa Clara, California
  Masters of Business Administration – (Currently pursuing. 2017-present.)

- NORTHEASTERN UNIVERSITY
  Boston, Massachusetts
  Masters of Science in Regulatory Affairs (2009-2011)

- FLORIDA INTERNATIONAL UNIVERSITY
  Miami, Florida
  Bachelor of Science in Biological Sciences, 1999

CERTIFICATIONS

- EU MDR Transition Training Certificate of Completion (ORIEL-STAT A MATRIX), Oct. 2018
- ISO 13485:2016 Certified Lead Auditor (ORIEL-STAT A MATRIX), Mar. 2018
- Regulatory Affairs Certification (RAPS), Spring 2007
- Advanced Certificate in Regulatory Affairs (San Diego State University), Aug. 2007

COMMUNITY ACTIVITIES

- RAPS SF Chapter Leader-Program Chair (term: 2015-2017)
- RAPS SF Chapter Leader-Education Chair (term: 2013-2015)
- Volunteered as a guest speaker for the RAPS US RAC Study Session to discuss IVD Regulations, August 2015
- Volunteered as a guest speaker hosted by Kathy Nusser of Varian Medical System to discuss about Generic Drugs, August 2007.

in order for the IVD products to be legally placed in the US and European markets.

- Key support to the Quality Department in creating processes for Complaint Handling, Adverse Events Reporting (MDRs) and Post Marketing Surveillance. Also instrumental in creating procedures for the Quality System in accordance to FDA 21 CFR 820 and ISO 13485 which led to our company's achieving the milestone of becoming ISO 13485 certified in 2016.
- Led the risk management activities for the Diagnostics Project Team and took on responsibilities of managing the risk meetings, and generating the risk plans, usability plans, and risk reports required for regulatory filings.
- Work closely with Marketing to approve all marketing materials (adverts, sales materials, slide presentations product labeling, brochures, website content, videos, etc.) to ensure that all claims are truthful, non-misleading, and are fully supported by study data and publication.
- Implemented UDI (Unique Device Identifiers) to comply with the compulsory FDA requirements to include the UDI barcode in all IVD labeling. Also responsible for coordinating with our contract manufacturers in assigning Global Trade Item Number (GTIN) and maintaining the UDI database with FDA.
- Provide semi-annual updates to executive management on new laws and regulations as well as the regulatory landscape for the following countries/regions: US, Europe, Canada, Brazil, China, and Australia, as part of the Dx Management Review.
- Also certified as a ISO 13485:2016 Lead auditor from Oriel-STAT.

GRIFOLS, INC. (Formerly NOVARTIS DIAGNOSTICS), Emeryville, California
August 2011- April 2014

Emeryville Division: focused in the development of preventive treatment and tools for infectious diseases. The division has two business units: the blood testing unit and the Nucleic Acid and Testing (NAT) unit.

Associate III, Regulatory Affairs

- Worked in both business units: blood testing unit and Nucleic Acid Testing (NAT) unit.
- Collaborated with joint-partner Hologic (formerly Gen-Probe) as the Grifols Regulatory Affairs representative and provided regulatory advice for the IND submission of the Dengue Virus Assay Test. Currently involved in three development projects with Hologic.
- Collaborated with joint-partner Ortho Clinical Diagnostics as the Novartis Regulatory representative in the development of the Ortho Clinical Diagnostic's HIV Combo assay.
- Involved with ROW registrations and renewals for blood testing and NAT products in APAC and EMEA regions. The product(s) and countries are listed below:
  - RIBA HCV 3.0 SIA and RIBA HIV-1/HIV-2 SIA: India, Indonesia, Singapore and Thailand.
  - Procleix Ultrio Elite Assay and Panther Instrument System: Indonesia, Russia, and Saudi Arabia.
  - Procleix Ultrio Plus Assay and Tigris Instrument System: Saudi Arabia.
- Regulatory representative to the Cell Banking Improvement Team in the effort to streamline the current manufacturing process of licensed and unlicensed seedstocks.
- Provided regulatory evaluations to CMC changes and submitted Annual Reports, CBE and CBE-30 to the FDA.
- Submitted changes made to the existing DMFs to the FDA.

ALEX CHANG, MS, RAC

CELERA, Alameda, California
April 2007- August 2011

A medical device company focused in the development of In Vitro Diagnostic Devices based on genetic detection platforms.

Manager, Regulatory Affairs (March 2011- August 2011)

- Successfully submitted Celera's first PMA application, which has been accepted for FDA regulatory filing, while meeting an aggressive project timeline.
- Regulatory liaison for the KIF6 Genotyping Assay PMA with the FDA.
- Member of the 510(k) Working Group and the Molecular Diagnostic Task Force, which consist of Industry leaders who meet regularly to share ideas and provide recommendations to FDA on policy decisions.
- Worked with senior management in providing regulatory strategies with a leading pharmaceutical company in the co-development of a companion diagnostics.
- Successfully submitted a Medical Device License Application for Health Canada.

Senior Regulatory Affairs Specialist (April 2007-March 2011)

- Developed submission strategies and prepared submissions for domestic and international filings according to established timelines.
- Prepared and submitted FDA 510(k) Pre-market Notification and prepared internal documentation for non-filing decisions for the following products: HIV-1 Genotyping System (ViroSeq) and Cystic Fibrosis Genotyping Assay
- Prepared and submitted Design Dossier to the Notified Body for CE Marking.
- Primary regulatory contact for Celera's corporate partner in Rest of the World (ROW) registration filings.
- Routinely provided Regulatory Intelligence and review current regulations, guidance, and external standards to ensure that the company is operating in compliance with the Quality Regulatory System.
- Ensured that Celera products meet regulatory labeling requirements for IVD, RUO and ASRs.
- Provided risk assessment and mitigation.
- Provided regulatory guidance in labeling and promotional materials.
- Submitted a Pre-market Approval (PMA) application KIF6 Genotyping Assay.
- Established contact with FDA project managers and attended meetings with the FDA via teleconference.

IMPAX LABORATORIES, INC., Hayward, California
April 2003- April 2007
A technology based pharmaceutical company specializing in the development of generic and branded drugs.

Senior Regulatory Affairs Associate

- Worked in both business units: Generic and Brand divisions.
- Involved with the preparation and submission of three (3) Investigational New Drug Applications and one (1) New Drug Application.
- Supported Global Clinical Trials by submitting an Investigational Medicinal Products Dossier (IMPD) for the Clinical Trials Authorization (CTA) application.
- Have experience in Common Technical Documents (CTD) and played a key role in transitioning our department to CTD-format and Structured Product Labeling.

- Reviewed Informed Consent Forms and Study Protocols for critical Brand Clinical Trials.
- Instrumental in training and mentoring several regulatory affairs associates.
- Acted as manager for several months and worked closely with the Vice President and Senior Director of Regulatory Affairs.
- Lead author for fifteen (15) Abbreviated New Drug applications
- Ensured regulatory compliance by maintaining and documenting adverse events and submitting annual reports for all 39 approved drug products
- Responded to numerous deficiency letters sent out by the FDA in a timely manner
- Have labeling and post-marketing experience.
- Function as primary regulatory contact in the Product Launch meetings.
- Experience in Drug Listing and submitting Promotional Materials to the agency.
- In charge of labeling for IMPAX and its third party marketing partners.
- Function as primary regulatory contact for product and adverse complaints.
- Provided support to the legal department on litigation issues
- Work closely with department heads in Clinical, Product Development, and Marketing Departments as part of the Brand Team
- Establish contact with FDA project managers and attend meetings with the FDA via teleconference.
- Have 4 years of CMC experience

MEDIMMUNE VACCINES, INC., Santa Clara, California
January 2001- April 2003

A biotech company focused in developing and marketing products that address medical needs in infectious disease, immune regulation, and cancer.

Research Associate II (Process Development)

- Drafted Standard Operation Procedures (SOPs) and Technical Reports for the Pilot Plant and Manufacturing departments
- Involved with improving the manufacturing process of the nasal vaccine (FluMist®) for the influenza virus
- Assisted lead scientists in genotyping the RNA segment of the influenza virus and performed numerous experiments to factor the best conditions in viral cultivation

Trained to work in a cGMP (current Good Manufacturing Process) environment