

Kenneth Yan

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PROFESSIONAL SUMMARY

- Extensive knowledge and exposure in all phases of clinical trials in different therapeutic areas such as Oncology, Central Nervous system and cardiology in accordance with the applicable ICH, GCP, FDA and local regulation with focus in monitoring and in In House and monitoring responsibilities.
- Remarkable Knowledge in all areas of research including budgeting, GCP, IRB protocol submissions, on-going regulatory and IRB phases and IND safety reporting.
- Demonstrated competencies in managing clinical trials data, formulating source documents and data collection charts and adverse event reporting.
- Developed, authored and reviewed Case report Forms (CRFs) and Protocol.
- Created and Reviewed Informed consent forms.
- Detailed knowledge of study specific regulatory documents and able to update, and maintain study specific trial master files and system.
- Extensive background in cell culture, assay, quantitative analysis, instrumentation and microscopy.
- Conversant in Chinese (Cantonese and Mandarin) and studied 5 years of Spanish.
- Experienced with Windows XP/Vista/7 and Mac OSX operating systems and MS Office programs.
- Self-motivated achiever with leadership qualities and good analytical, technical and interpersonal skills.

EDUCATION

Carnegie Mellon University Pittsburgh, PA
Master of Science in Biomedical Engineering, May 2012
Bachelor of Science in Chemical Engineering, May 2011
Studied Abroad at Shanghai International Studies University, Summer 2010
Overall GPA: 3.27/4.00

Bronx High School of Science Bronx, NY
High School Diploma, June 2007

EXPERIENCE

Qtech Solutions, Inc.

In-House Clinical Research Associate Intern, July 2013 – September 2013

- Assessed contents and included relevant information in sections of an Investigator Brochure and IND application.
- Addressed concerns in situational GCP priority case scenarios from investigational sites.
- Reviewed and provided missing information for regulatory requirement criteria for IRB protocol review standards and IRB application for human subject research.
- Provided a description and outline for each element covered in a Phase II double blind placebo controlled clinical trial protocol.
- Prepared a budget per patient upon reviewing a protocol for Phase II clinical trial.
- Identified and classified discrepancies upon performing manual review of CRFs and prepared quality control report.
- Reviewed artifacts from Trial Master Files and provided list and purpose of core/recommended documents pertaining to each zone of TMF.
- Examined monitoring visit report to identify correct order as per standard IRB format and determine any discrepancies.
- Prepared a presentation for an investigator meeting outlining important information covered in clinical trial protocol.
- Provided a brief outline for each section covered in the Site initiation checklist.
- Inspected adverse events case scenarios from clinical trials and identified severity and appropriate reporting timelines in accordance to regulations.

Center for Ultrasound Molecular Imaging and Therapeutics, University of Pittsburgh Medical Center

Clinical Research Assistant, February 2012 – May 2012

- Thesis: Optimization of Microvascular Perfusion
- Implemented several key design parameters into a prototype intravital microscopy rat stage to improve microcirculation studies.
- Studied cardiac catheterization procedures while shadowing interventional cardiologists at UMPC Presbyterian Hospital.

Bone Tissue Engineering Center, Carnegie Mellon University

Undergraduate Research Assistant, September 2010 – May 2011

- Thesis: Delivery of siRNAs Using Cationic Nanostructured Star Polymers to Prevent Cell Differentiation to Bone
- Participated in a project to determine the *in vitro* knockdown efficiency of anti-Runx-2, anti-OSx siRNAs delivered by cationic NSPs to prevent BMP-induced C2C12 cell differentiation.
- Maintained C2C12 cell cultures and assessed biocompatibility of polymers using fluorescence microscopy.

**ACTIVITIES
& HONORS**

American Institute of Chemical Engineers

Biomedical Engineering Society

Society of Asian Scientists and Engineers

Hong Kong Students Association

Intramural Sports Teams (Captain): Football, Soccer, Racquetball, Tennis