Curriculum Vitae

Name: Charissa Man Yee WONG
Language: Fluent English, Fluent Mandarin, Fluent Cantonese, Basic Japanese, Basic German

Professional Qualifications:

- Registered Doctor, The Medical Council of Hong Kong, since July 2010
- Project Management Professional (PMP) Certificate
- Regulatory Affairs Certification (Devices), RAPS
- Regulatory Affairs Certification (Drugs), RAPS
- Regulatory Affairs Certificate Program (RAPS), Medical Devices and Pharmaceuticals (Dual)
- Member, Project Management Institute (PMI)
- Member, Regulatory Affairs Professional Society (RAPS)

Qualifications/Certificates obtained:

- **Master of Public Health in Epidemiology**, *Harvard T.H. Chan School of Public Health, Harvard University*, 2015 – 2017
- **Bachelor of Medicine and Bachelor of Surgery (MBBS)**, *The University of Hong Kong*, 2004-2009
- **Master of Journalism with Distinction**, *The University of Hong Kong*, 1999-2001
- **Bioinformatics MicroMasters, Bioinformatics** (Computer Science, Biology & Life Sciences), *University of Maryland University College*, 2019
- **Bachelor of Arts in Architectural Studies**, *The University of Hong Kong*, 1995-1998
- **Early Childhood Education**, Basic Core Certificate with Distinction, *UCLA Extension*, 2014
- Certificates of Attendance, **Infectious Diseases Courses and Postgraduate Diploma**, Centre of Infection, *The University of Hong Kong*, 2005-2009
- Certificate of Attendance, **Medical Journalism Course**, *Hong Kong Press Council, Hong Kong Journalists Association, Federation of Hong Kong Journalists and Hong Kong Tuberculosis, Chest and Heart Diseases Association*, July 2003

Work / Academic Experience:

- **Staff Scientist, Clinical Applications and Marketing Support,** Genetic Sciences Division, *Thermo Fisher Scientific*, *South San Francisco,* November 2021 to present
    - Be the liaison between R&D and Marketing to effectively support our customers.
    - Prepare and present technical documents and presentations to internal and external partners.
    - Closely interact with Clinical, Scientific and Medical Affairs, Regulatory and Business Development.
    - Be the point of contact for inquiries requiring in-depth technical and scientific knowledge of our clinical applications.
    - Be knowledgeable about regulatory implications.
    - Assist with education and support of customers.
    - Support collaborations with partners and with Key Opinion Leaders ("KOLs").
    - Support product launch activities with a strong "customer-first" attitude.
- **Senior Technical Writer (with Regulatory and Clinical Development Involvement),** *GRAIL Inc., Menlo Park*, August 2019 to October 2021
- **Technical Writer (with Regulatory and Clinical Development Involvement)**, *GRAIL Inc., Menlo Park*, January 2018 to August 2019
    - Duties as Senior Technical Writer / Technical Writer with Regulatory and Clinical Development Involvement at GRAIL:
        - Actively participated in various regulatory affairs and clinical development meetings.
        - Actively involved in development of clinical trial protocols and clinical summary reports of large-scale Multi-Cancer Early Detection clinical studies, including writing, reviewing, amending, and cross-functional facilitation with R&D, biostatistics, regulatory, quality, clinical development, medical affairs and medical writing, manufacturing, and marketing.
        - As a medical doctor (MD) with Master of Public Health in Epidemiology from Harvard University, I have contributed clinical expertise and content to clinical development and regulatory documents for submissions to FDA and EU.
            - The regulatory filings include three IDEs, PMA, IVDD, IVDR submissions regarding the Multi-Cancer Early Detection Test (Class III IVD device in US; Class C IVD device in Europe).

        - I worked on the IDE Annual Report for the PATHFINDER Project, IVDR submission, and IVDD updates.

    - Collaborated with quality, scientists, and engineers in creating, reviewing, and updating, formatting, and submitting controlled documents, including design plans, product lifecycle plans, protocols, SOPs, work instructions, guidance documents, reports (feasibility, end-to-end, analytical validation), batch records, experiment workbooks, risk management documents, materials specifications, verification and validation documents for reagents, assays, equipment, automation equipment, and bioinformatics pipelines.

    - Departments served include R&D, Product Development, Regulatory, Clinical Development, Equipment, Engineering, Bioinformatics, Biostatistics, Regulatory, Quality, Manufacturing, and Clinical Lab

    - Managed and tracked more than 1,000 controlled documents annually and work with project managers, study leads, regulatory, quality, and document control departments to ensure its timely completion

    - Collaborated with Quality / Doc Control and key stakeholders to create GRAIL style guides, documentation guidelines, and templates for regulatory submission documents, clinical development documents, technical documents, SOPs, protocols, reports, work instructions, validation and verification plans and reports

    - Software / Platform used for documentation, statistical analysis, presentation, photo-editing, drawing, and calculations: Smartsheet, EndNote, JMP, Python, STATA, G Suite, Microsoft Word, Excel, PowerPoint, AODocs, Veeva, Jira, Confluence, Phabricator, Pilgrim, Photoshop, Procreate, Adobe InDesign, AutoCAD etc.

- **Visiting Scholar in Pediatrics**, *UCSF Osher Center for Integrative Medicine*, August 2017

- **Family Medicine Doctor**, *Human Health Medical Centre*, Hong Kong, May 2012 to May 2016

- **Resident, Family Medicine**, *Prince of Wales Hospital*, *The Hong Kong Hospital Authority*, July 2013 to December 2013

- **Resident, Anatomical Pathology**, *Queen Elizabeth Hospital,* The Hong Kong Hospital Authority, July 2010 to April 2012

- **Medical Intern**, *The Hong Kong Hospital Authority*, July 2009 to June 2010 (Orthopedics and Traumatology in Queen Mary Hospital, Medicine in Princess Margaret Hospital and Prince of Wales Hospital, Surgery in Queen Mary Hospital)

- **Reporter and Acting News Editor**, *The Associated Press*, Hong Kong Bureau, May

2000 to August 2004

- Wrote all types of breaking news and features in English related to Hong Kong, Macau, and southern China for all U.S. and international media organizations that The Associated Press served. Covered assignments in other parts of Asia, e.g. Taiwan and Malaysia. From August 2003 onwards, in charge of the editorial team in Hong Kong bureau whenever the news editor was out of town for assignments or holidays.

- **Features Editor,** *Hinge Marketing Ltd.,* September 1999 to April 2000

  - Wrote stories, profiles, and commentaries in English about worldwide architecture, art and design for Hinge, a Hong Kong-based monthly architectural magazine.

- **Architectural Assistant,** *Michael Ng Architects & Consultants Ltd.,* July1998 to August 1999

  - Involved in architectural and interior design, drafting, and presentations using AutoCAD, 3D Studio etc. Conducted meetings and maintained correspondence with clients, engineers, contractors and suppliers. Monitored architectural work on site from start to finish.

- **Customer Services Agent,** *Northwest Airlines*, Summer 1995

  - Responsible for serving and helping customers, checking-in and ticketing services