

# DONNA HONGO, PHD, CLS

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CLINICAL OPERATIONS, REGULATORY AFFAIRS & COMPLIANCE, QUALITY ASSURANCE

## EDUCATION

Doctor of Philosophy (Ph.D.) – *Genetics and Molecular Cell Biology*  
Bachelor of Science (B.S.) – *Medical Technology*  
*Six Sigma for Managers Certificate*  
*Project Management/ PMP Certificate*

## WORK EXPERIENCE

**Hongo Consulting, LLC** – Vacaville, CA  
Owner/Principal

**Symbiotica, Inc.** – Vacaville, CA  
Co-Founder, Compliance Officer

**MyOme, Inc.** – San Francisco, CA  
Oct 2019 – present  
Head of Quality and Regulatory

**NephroSant, Inc.** – Brisbane, CA  
Aug 2019 – March 2020  
Sr. Dir. Clinical Operations

**HealthTell, Inc.** – San Ramon, CA  
Mar 2016 – Nov 2019  
Advisor, Regulatory and Quality

**uBiome, Inc.** – San Francisco, CA  
May 2016 – July 2019  
SVP Regulatory and Quality, Chief Compliance Officer

**MEDGENOME, Inc.** – Foster City, CA  
Feb 2016 – Feb 2018  
Advisor, Regulatory and Quality

**Lifecode, Inc.** – Foster City, CA  
Aug 2013 – Jan 2016  
Director, Laboratory Operations & Regulatory Affairs

**Aviir, Inc.** – Irvine, CA  
Nov 2012 – Dec 2013  
Consultant, Quality Assurance

**Life Technologies, Inc.** – West Sacramento, CA  
Jun 2012 – Nov 2012  
Quality Assurance Manager

**Navigenics, Inc.** – West Sacramento, CA  
Feb 2009 – Jun 2012  
Director, Clinical Operations

**Affymetrix Clinical Services Laboratory** – West Sacramento, CA  
Jul 2006 – Feb 2009  
General Supervisor

**Adventist Health's Redbud Community Hospital** – Clearlake, CA  
Mar 2006 – May 2008  
Lead, Clinical Laboratory Scientist

**Sutter Health** – Lakeport, CA  
Jan 2006 – Mar 2006  
Clinical Laboratory Scientist

## PROFILE

- Licensed Clinical Laboratory Scientist – experience includes hospital-based/emergency care facilities and molecular genetics laboratories
- College of American Pathologist (CAP) inspector for Molecular Genetics
- Experienced Executive with more than 15 years in the biotech & healthcare industry, including manufacturing and supply chain:
  - ✓ Regulatory Affairs & Compliance – laboratory, manufacturing, and corporate compliance (CLIA, CAP, NYSDOH-CLEP, ISO 15189, ISO 13485, various state DOH, OSHA, GxP - GLP, (c)GMP, GDP, GCP, EU Guidelines, EMA, ICH Guidelines, FDA Regulations and Guidelines (e.g. 21CFR820), etc.)
    - Privacy and Security – Program implementation and functioned as HIPAA security Officer, HIPAA Privacy Officer, GDPR Data Protection Officer
    - Safety - Laboratory and Corporate Safety Program, compliance to OSHA, and functioned as EH&S Officer
  - ✓ Quality - quality governance, including system setup and implementation- data quality and quality controls, quality assurance, quality monitoring and metrics; document control, continual improvement initiatives
  - ✓ Clinical operations – performed bench testing and also held supervisor and management responsibilities - testing personnel, general supervisor, technical supervisor; operational scale-up and stream-line using lean six-sigma
  - ✓ Risk Management – audit and inspection, investigation, corrective and preventive action planning and execution
  - ✓ Supply Chain – vendor relationship management, vendor setup and materials management system implementation, equipment management and maintenance
  - ✓ Research and Development – managed internal and external collaborations to transition testing and platforms to clinical validation and approval, led and coordinated IRB proposals and submissions for approval, served as Principal Investigator for IRB-approved R&D Projects
  - ✓ Project Management – consultant and advisor for various laboratories and healthcare facilities on project based goals, including preparation for regulatory inspection
  - ✓ Team Leader – mentorship programs, training programs, and continuing education programs
  - ✓ Finance - Developed annual budgets, revised forecasts to meet business needs and monitor/control expenditures to assure efficient use of company resources.
  - ✓ Executive – Involved in business strategy discussions and planning, created team/department-specific OKRs to meet established company goals, authored and initiated project specification and execution documents, led various mission teams, and managed the corporate business control program
    - Client Services – in addition to clinical responsibilities, led customer support teams and provided regulatory compliance support
    - Automation Engineering – in addition to clinical responsibilities, led team of engineers and technicians with equipment IQ, OQ, PQ, equipment validation, maintenance, calibration, and preventive maintenance

**LinkedIn:** <https://www.linkedin.com/in/donna-hongo-47707963/>

References available upon request