Submission #	1220970
IP Address	76.14.105.104
Submission Recorded On	10/05/2021 9:14 AM
Time to Take Survey	46 minutes, 26 seconds

Page 1

City of South San Francisco Boards and Commissions

This form may be used to apply for one or more Board/Commission positions.

Board/Commission of interest (select all that apply)

San Mateo County Mosquito & Vector Control District (SMC MVCD)*(City Representative on County Committee)

Are you interested in participating in the Citizen's Academy?

Yes

Full Name

Michael Yoshida

Street Address

[redacted]

City, State Zip

CA South San francisco 94080

Preferred Phone Number

[redacted]

Cell phone/alternative contact number

SKIPPED

***Email**

[redacted]

***If you selected more than one Board/Commission of interest, please rank your preferences here, starting with your first choice.**

n/a

***How many years have you been a resident of South San Francisco?**

22

***Have you attended any meetings of the commission/board for which you are applying? If so, which one(s)?**

no

BPAC

Are you a resident of South San Francisco?

Yes

If no, are you employed in South San Francisco?

Number of hours employed in South San Francisco:

SKIPPED

Housing Authority Tenant Commission

Are you a resident of the Housing Authority?

Youth Commission - (Ages 14 to 22)

If not a resident of South San Francisco, are you a student of SSFUSD?

Current School:

SKIPPED

Conference Center Authority Hotel Representative

Which hotel within the City of South San Francisco are you representing?

South San francisco

South San Francisco General Plan 2040 Community Advisory Committee

What is your District of Residency?

SKIPPED

Click here to locate your District.

***Why do you want to be a member of a Board or Commission? What do you feel you could contribute to the Board or Commission?**

I want to be more involved in my local services and government. I feel that the best way to contribute is to volunteer and be actively involved in groups that are in place for the people. Being able to represent the city would instill a person that is willing to learn the needs of the city while also having the scientific and business background to challenge and develop the Mosquito & Vector Control District to grow in areas that may be potential growth areas.

*__What qualifies you for this appointment?__

I have a degree in Aquatic Biology from UC Santa Barbara with from that an obvious interest in ecology and natural balance. I also applied that background to have a 28+ year career in Biotech. Being able to apply this fundamental science and business background will hopefully serve as an asset to the San Mateo County Mosquito & Vector Control District. Also being a active member within the community of SSF, I hope that others feel that I am there to represent the city and al the parts of the city that may otherwise take this service for granted and not know what allow the District to keep the community safe and prosperous.

*__What is your vision for growth in South San Francisco?__

My vision for SSF is to see it grow in a manner that allows both a broader financial base from business revenue, such as biotech and high tech companies while supporting a growing population with better planned housing growth. I would love to see better managed housing development and land use that does not continue to remove green space from the map. I see a future SSF where people want to live because of that balance not just because we create lots of housing units.

*__Are you currently receiving any form of compensation from the City of South San Francisco for work performed? If yes, please explain.__

no

*__Do you have any relatives serving on Council, Commissions, Boards, and Committees or otherwise employed by the City of South San Francisco? If yes, include name, position and relationship.__

no

*__EDUCATION - Please include name and location of college/university/technical or trade school with dates attended and major.__

BS from University of California at Santa Barbara. Aquatic Biology. 1986-1990

*__What community activities are you presently involved in, or have been in the past?__

El Camino High School- PTSA Board of Directors. San Francisco Aquarium Society ((current President). AYSO Region 249- Board of Directors. Scouts BSA (formally Boy Scouts of America)- current Asst. Scout Master Troop 72

__MILITARY SERVICE - Please include dates and branch.__

n/a

*__WORK EXPERIENCE - Please include dates employed, employer and position.__

please see attached

Attachment Resume

Michael Yoshida CV 2021.pdf

__Please list any other background information (business, education, personal) that might be useful in determining your eligibility.__

SKIPPED

*__By typing my name, I certify that, to the best of my knowledge, all statements in this application are complete and true. I agree and understand that any misstatement of material fact will cause me to forfeit all rights to the appointment to a Commission, Board, or Committee.__

Michael Yoshida

The interest of the City is served best by actual and regular participation by Board and Commission members. Thus, upon the second absence from a regular meeting within any rolling twelve-month period, a member shall receive a written communication from the Mayor requesting that the member respond to the Mayor with an explanation for said absences within one week of the member's receipt of the written communication. The Mayor shall report to the City Council the reasons provided for the member's absences. If the City Council determines that the absences occurred for legitimate reasons, the City Council may excuse both or one of the absences. Members are also encouraged to give advanced notice of their absence from meetings.

Applications are accepted on a continuous basis and will remain valid 1 year from the date of submission. If you are selected to serve on a Board or Commission, you may be required to file an Annual Statement of Economic Interest (FPPC Form 700) and bi-annual Ethics Training (AB1234).

Once this form is submitted, you will receive a response from the Office of the City Clerk within three business days to provide you with information regarding the next steps. Please keep an eye out for this email. If you do not receive an email, please call us at (650) 877-8518.

THIS FORM IS A PUBLIC RECORD, DISCLOSABLE PURSUANT TO GOVT. CODE 6250 ET SEQ.

MICHAEL D. YOSHIDA

[redacted]

PROFESSIONAL EXPERIENCE:

Ultragenyx, Novato, California
January 2019- Present

Senior Director, Manufacturing Management, Biologics and mRNA
Technical Operations

- In charge of late stage development, launch and commercial phase of Ultragenyx mRNA products within the Biologics and mRNA Manufacturing Management organization
- Provides strategic direction and technical expertise for product manufacturability over the life cycle of the products and builds the manufacturing team for the company's mRNA portfolio.
- Ensures supply of clinical studies, launch and commercial phase Plasmid, Drug Substance and Drug Product through interactions with Technical Development, Translational Science, Quality, Supply Chain Management (SCM), Regulatory, Commercial and Business Development organizations within the company and a variety of CMOs.
- This includes roles such as CMC project lead, CMO relationship manager, and leader or team member of various projects in the CMC area, as well as, supporting strategic projects in the Ultragenyx Gene Therapy organization.
- Drive and support mRNA CMC strategy, milestones and goals with input from the key stakeholders, like the CMC Review Forum and gaining approval from the Program Core Team and the respective functional management
- Support and maintain CMC Project Plan, QTPP (Quality Target Product Profile), Product Design History File and Quality Risk Management Plan
- Ensure fulfillment of agreed manufacturing service for clinical and commercial supply
- Support global CMC filings in accordance with applicable regulations and guidance
- Identify and select Plasmid, mRNA (API) and DP CMOs, ensure CMO compliance to cGMPs and strategic fit
- Lead relationship with CMOs and foster collaborative partnership
- Drive contract negotiation with CMOs to ensure sustainable supply and partnership
- Manage process optimization, troubleshooting, tech transfer and change control
- Direct business agreements, manage budget & cost control and improve COGs development
- Represent Manufacturing Management in the OPEX initiative within Tech Ops and CMC
- Drive performance management and continuous improvement
- Develop and nurture high performance teams
- Provide strong representation on global projects, CMC initiatives and Product Core Teams
- Support the UGT projects and support synergy between mRNA and Gene Therapy programs

Novartis, San Carlos, California
March 2017- December 2018

Associate Director, External Quality Assurance
Quality Assurance Manager, External Supply Operations BTDM

- Responsible for managing quality aspects at external suppliers and to ensure that the operational business remained in compliance.
- Responsible for managing quality interface for outbound relationships for Biopharmaceutical manufactured within internal BPO manufacturing sites. Work with all marketed regions to address registration requests and maintain global licenses.
- Global Quality manager for collaboration product that launched in 25 countries in 4 months.
- Supported launches of products in close collaboration with external partners and internal teams. Established quality systems needs to meet launch timelines.
- Assessed and ensured External Supplier readiness for HA inspections (PAI, directed, other)
- Lead External Suppliers Qualification process and act as Single Point of Contact / SPOC for all quality related activities at the External Supplier

- Responsible for coordinating and ensuring that Quality auditing of External suppliers was carried out - maintained an annual auditing program, participated in and/or lead audits, managed action plans and follow up on agreed upon CAPAs.
- Managed/Approved critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc) and ensured that Change requests were managed from receipt, through to the implementation and closure.
- Acted as SPOC for regional Quality groups for multiple biological products.

Allergan, Campbell, California
November 2007 – March 2017

Director of Operations- Site Head
Biologics Manufacturing- BSL (Bioscience Laboratories, Campbell)
May 2014 – March 2017

- Site Head (General Manager) for the commercial API manufacturing plant for Botox®
- Oversight of operations at the Bioscience Laboratories (BSL) facility, including Manufacturing, Facilities and Engineering, Quality Assurance, Quality Control, Validation, Technical Operations, Logistics, Continuous Improvement and Compliance.
- Responsible for the execution of all site activities and allocation of resources.
- Responsible for implementation of safety, Quality and production systems to ensure ongoing compliance for a licensed biologics manufacturing facility.
- Improved quality throughout the site and ensured strict adherence to GMP standards in order to meet all regulatory, cGMP and environmental regulatory agency requirements.
- Responsible for operations related to safety policy and procedures, including development of training programs, MSDS management and interfacing with corporate, local, state and federal regulatory agencies especially related to work with a CDC Tier 1 Select Agent.
- Responsible for annual expense budget and capital expenditures associated with operation of the Campbell site.
- Responsible for launch and support of Lean Reliability improvement program for Actavis/ Allergan Biologics Manufacturing site.
- Responsible for documenting and improving business process and product reliability for Botox DS supply chain
- Drove 5% annual operational cost reduction through extensive Value Stream Mapping of existing process at an already extremely Lean site.
- Responsible for the deployment of Operational Excellence within the Biologics manufacturing group.
- Developed consistent use of Lean knowledge and tools across site

Senior Manager
Biologics Technical Operations (BTO)
November 2007 – May 2014

- Technical Transfer between multiple sites, including Ireland Westport, Irvine/ BPS, and Irvine BLI
- Develop effective Virtual Teams to manage project development tasks and technical transfers.
- Provided leadership for process development and technology transfer to ensure successful commercialization of new processes and molecules.
- Represent Drug Substance Operations (DSO) on CMC Teams and BD projects to generate /oversee GMP material production; including contract manufacturing.
- Organize and lead technical and project teams to prepare for New Product Introductions (NPI) for DSO sites. This includes facility or systems modification / design, as well as specifying equipment, creating systems , procedures and practices while ensuring alignment with CMC needs
- Provided management and leadership to ensure that facilities, systems, procedures and production plans were in place to produce commercial and clinical product that meets all current and future schedule, compliance and cost of goods requirements
- Manufacturing Compliance for the DSO organization.
- Lead complex deviation investigations
- Provided direct support in the generation of documents used in regulatory filings

- Develop and implement novel approaches to solving non-routine technical problems and resolve recurring technical or processing issues and deviations
- Implement CAPAs and lead improvement opportunity projects
- Implement improvements to the equipment, procedures and systems used in Manufacturing
- Capital expenditure projects and function as a project manager.
- Key contributor for the initial Strategic Deployment (SD) initiative across Allegan Biologics organization.
- Led Development and Implementation of New Process Introduction (NPI) process as part of SD initiative.
- Managed a staff of Project Manager Professionals responsible for all clinical and commercial technical operation and leading CI projects
- Routinely Facilitated CI projects across Manufacturing, QC, QA, Facilities services, and Logistics.
- Provided training for staff on the use of Kaisens, A3 Countermeasures, Visualization Boards, Pareto Analysis, and Value Stream Mapping
- Coached, managed and reviewed CI projects with CI Manager across Biologics manufacturing organization.

Amgen Inc., *formerly Abgenix, Inc*. Fremont, California
September 2001 – November 2007

Senior Manager/ Sr. Project Manager
MFG Project Management-Amgen
October 2006- November 2007

- Manufacturing Project Manager for multiple departmental and site goals.
- Led multiple hiring "Blitz" activities to meet site expansion needs. This included staffing both Manufacturing and Quality Assurance.
- Member of PAI audit response team. Responsible for Manufacturing response and audit commitments.
- Core Team member for Bulk Manufacturing Expansion (BMX) project. A $100M+ expansion of the manufacturing facility.
- Managed New Product Introduction (NPI) for facility.
- Developed on-site training facility/ lab in conjunction with the corporate training group. This lab was outfitted to accommodate a 4 week intensive training program for the manufacturing group and other support groups.
- Responsible for Internal and External audit responses for the manufacturing group. Managed the departments activities and teams to ensure compliance commitments are addressed.
- Lead cross functional group to improve plant procedures and standardize development of SOPs and records.

Senior Manager
Manufacturing- Purification Operations- Abgenix
September 2001- October 2006

- One of the 5 original Abgenix Manufacturing staff members that oversaw the design and construction of a multi-product GMP manufacturing facility from Basis of Design through the successful completion and licensure/ market launch of Vectibix/Panitumumab. Facility included 2 X 12K bioreactor and associated seed train, as well as multi-train series of large scale purification suites. Additionally, the facility was fitted with a filling suite, inoculum prep room, cell banking, weigh dispense rooms, all operational utilities, and all support labs and areas.
- Responsible for equipment specification and ordering of Purification equipment as well as a number of utility and common area equipment. Oversaw RFQ, FAT, and SAT of items such as Fixed and Portable tanks (up to 3000L), Chromatography columns and skids, TFF skids, glassware washers, material handling system, and facility utilities. Managed ordering of original capital and expense items to fit out the facility.
- Key presenter and functional area lead during PAI with FDA, EMEA, and Health Canada.
- Extensive experience with aligning facility with cGMP practices through use of CFR, ICH, CDER guidelines as applicable with the manufacturing of drug product.

- Oversaw staffs management of Deviation/ CAPA system, Change Control, Technical Investigations, Process Modifications, Tech Transfers, and Document revisions.
- Worked with multiple companies to ensure technology transfer and implementation of processes into clinical manufacturing environment.
- Oversaw and prioritized the creation of SOPs, Batch Records, protocols, and technical reports.
- Extensive experience with Domestic and International vendors, partners and contractors.
- Hired and developed an organization of direct and indirect reports to commission, validate, operate, and later run routine production for the purification operation group during GMP, Conformance and Marketed Campaigns.
- Extensive process and cleaning validation experience. Manufacturing approver for validation protocol generation, technical review, and protocol summaries. Managed staff responsible for developing and executing I/OQ, EQ, and PQ for multiple systems.

Genentech Inc., South San Francisco, California
February 1994 – September 2001

Senior Supervisor / Quality Assurance Lot Release
Quality Assurance
July 2001- September 2001

- Provided QA oversight for manufacturing operations; Fermentation, Cell Culture, Purification, and Filling.
- Managed review of both Marketed and Clinical Documentation across Biochemical and Pharmaceutical divisions. Lead resolutions in production Discrepancy System. Provides Line Clearance for Pharmaceutical department.
- Supervised a staff of QA reviewers and provided leadership and technical expertise for other QA supervisors.

Senior Supervisor / Process Coordination Group
Biochemical Recovery Operations
February 1994- *July 2001*

- Managed team responsible for introduction of both Marketed and Clinical Processes to the Recovery Operations area.
- Worked with cross-functional teams to implement operational and technical improvements.
- Provided direction and support for Process Coordinators, Shift Supervisors and associates.
- Manufacturing leadership for Program Management I-Teams, MS&T, Quality and Validation to coordinate and implement processes into a GMP environment.
- Initiated New Protein Registrations, Automated Recipe creation, QA/ QACD documents.
- Responsible for critical product investigations, process improvements, and scheduling adjustments.
- Supervised a staff ranging from 8 to 19 technicians and associates.
- Coordinated and supervised Marketed and Clinical activities in a GMP environment.
- Duties included hiring, training, and developing staff. Key recruiter during company hiring campaign of approximately 0.5 employees per day for a year.
- Worked on key projects related to quality, compliance, logistics, and technical systems e.g. implementation of LIMS, and POMS.
- Participated in the designing, construction, and startup of the Large Scale Final Purification area

EDUCATION:

University of California at Santa Barbara.
B.A., Aquatic Biology, 1991.

PROFESSIONAL AFFILIATIONS:

ISPE, *International Society of Pharmaceutical Engineering*
AIChE, *American Institute of Chemical Engineers*
PDA, *Parental Drug Association*
Ohlone College, *Biotechnology Advisor Board*
San Mateo County Biotech Blue Ribbon Task Force, Advisory Board

BETA, *Biotechnology Education and Training Alliance*, Advisory Group