

Application Form

Profile

Siavash

First Name

Ghaffari

Last Name

Email Address

Blackrock Microsystems

Employer

QMS Manager

Job Title

Home Address

Suite or Apt

City

State

Postal Code

Primary Phone

Which Boards would you like to apply for?

Sugar House Park Authority Board of Trustees: Submitted

Referred by:

Qualifications

Please tell us about yourself.

I am applying for a second term and I am the President-Elect of the SHPA board, starting in January 2025.

Why are you interested in serving on a board or commission?

I have the same interests as in my initial application. I am applying for a second term and have been with the SHPA for the last four years.

What education, work experience, or volunteer experience do you have that applies to the board you are applying for?

I am applying for a second term, and I have been with the SHPA for the last four years.

What unique perspectives could you bring to the board?

Experience. I am the second most senior serving member of the SHPA.

Upload a Resume

Demographics

Some boards and commissions require membership to be racially, politically or geographically proportionate to the general public. The following information helps track our recruitment and diversity efforts.

Are you a Salt Lake County employee?

Yes No

Are you a current member of another Salt Lake County board or commission?

Yes No

Race/Ethnicity *

District *

District 4

Gender Pronouns *

Age Range *

Summary

- Over 25 years of laboratory experience in biotech and pharma settings
- Over 9 years of quality management experience in the medical device industry
- Experience in meeting regulatory requirements (domestic and international) and obtaining/managing international certifications

Certifications

- Certified Manager of Quality/Operational Excellence (CMQ/OE)
- Project Management Professional (PMP)
- Regulatory Affairs Certification (RAC) for medical devices
- Certified Medical Device Lead Auditor

Competencies

- Maximizing compliance with policies and procedures
- Promoting process efficiency and accuracy
- Ensuring product safety and efficacy

Skillsets

- Establishing and maintaining a Quality Management System (QMS) for Class II/III medical devices
- Leading management reviews of QMS effectiveness
- Hosting audits
- Managing postmarket surveillance activities
- Quality event management activities

PROFESSIONAL EXPERIENCE

Blackrock Microsystems Inc. dba Blackrock Neurotech, July 2020-June 2023

Director of Quality

Management Representative

Directed the Quality team's efforts for a Class II medical device company

- Building a culture to promote a QMS that is effective, efficient, and compliant to meet regulatory requirements throughout the organization.
- Supporting product development throughout the lifecycle of the product.
- Managing postmarket surveillance activities (i.e., customer feedback, complaint management, CAPA, medical device reporting, etc.) and quality event management activities (i.e., nonconformances, suppliers, deviations, RMAs, etc.).
- Managing the relationship with our notified body (EC Certification) and auditing organizations (MDSAP 13485:2016).
- Overseeing the management of ISO Class 7 cleanrooms and environmental monitoring activities for sterilized, implantable products.
- Transitioned from paper-based to an electronic QMS (MasterControl Inc.) and built the electronic learning management system (LMS).
- Implemented validation master plan (VMP) and requalified all company assets.
- Aligned Risk Management process with ISO 14971:2019 and EU MDR requirements.

University of Utah, October 2021- December 2021

Associate Instructor

- MST 6963-002 *Fundamentals of Quality Management Systems for a Medical Device Company*

Vela Operations USA (formerly Great Basin Scientific), July 2018-July 2020

Director of Reagent QC

- Relunched Great Basin Scientific's quality management system and five (5) FDA-cleared and CE marking of molecular *in-vitro* diagnostic (IVD) tests.

LoD-Max Biotech LLC, May 2017- Present

Quality Management System Consulting (March 2018 - Present)

- Founded a consulting firm to bring medical device companies and laboratories into compliance with regulatory and certification requirements using QMS.

Great Basin Scientific, Inc., 2014-2017

Associate Director, Quality Control (Aug. 2016 - Feb. 2017)

- Managed the QC department to support manufacturing of molecular diagnostic reagents and medical device manufacturing
 - Transferred R&D technology to manufacturing
 - Assisted the Director of Regulatory Affairs for FDA compliance and submissions
- QC Scientist (Oct. 2015 - Aug. 2016)*
R&D Scientist (Sept. 2014 - Oct. 2015)
R&D Senior Associate Scientist (Jan. 2014 - Sept. 2014)

University of Utah School of Medicine, 2012-2013

Research Associate

AvanSci Bio LLC, 2011-2012

Consultant

Myriad Genetics Inc. dba Myriad Pharmaceuticals/Myrexix Inc., 2001-2011

Scientist I (2008-2011)

- Helped transition to EU medical device regulation (MDR) (2017/745)

Research Associate IV (2003-2008)

Research Associate III (2001-2003)

Intermountain Healthcare (IHC), 1999-2001

Myriad Genetics, Inc., 1997-1999

Arizona State University, 1995-1996

EDUCATION

Master of Science and Technology, Biotechnology Track

- University of Utah, Salt Lake City, Utah, 2016

Bachelor of Science in Biology

- Arizona State University, Tempe, Arizona, 1995

PROFESSIONAL DEVELOPMENT AND TRAINING

Certified Medical Device Lead Auditor for ISO 13485:2016 and 21 CFR 820, since 2019

- Certification through Exemplar Global and Axion Corporation

Certified Manager of Quality/Organizational Excellence (CMQ/OE), issued 2019

- Active member of American Society for Quality (ASQ), Salt Lake Section 0615

Regulatory Affairs Certification (RAC) for Medical Devices, issued 2020

- Active member of Regulatory Affairs Professionals Society (RAPS), RAPS Utah Chapter

Certified Project Management Professional (PMP), issued 2020

- Active member of Project Management Institute (PMI), Utah chapter.

Six Sigma for Managers, completed in 2014

- University of Utah, Salt Lake City UT, completed Green Belt Project

Analytical & Quantitative Light Microscopy Course, completed in 2009

- Marine Biological Laboratory, Woods Hole MA

Howard Hughes Medical Institute Internship for Biology Research Experience for Undergraduates (B-REU) completed in 1994

- Arizona State University, Tempe Az