

# City of Seattle Boards & Commissions Notice of Appointment

Appointee Name: Carlene M. Comrie											
Board/Commission Name: Seattle Fire Code Advisory Board	Position Title: Service Industry Representative										
X Appointment OR Reappointme	Council Con X Yes No										
Appointing Authority:  Council  Mayor  Other: Fill in appointing authority	Council 4/13, Mayor			of Position: * /2017 /2020	CLERK	20 PM 4: 38	OF SEATLE				
Residential Neighborhood: Leschi					Contact Phone No.:						
Background: The Services Industry representative on the entertainment, restaurants, nightclubs, or restaurant Taste of the Caribbean and the Quality and Regulatory Compliance for Posteristry and a Masters of Business Address Compliance, along with her role as a local good fit for the Services Industry representation.	and ho ne nigh hillips. ministr al resta	tels. Ms. Con t club Red Lo Ms. Comrie ation degree. aurant and nig	nrie is d unge has a E Her fo ght clui	co-owner of the loo She is also the Dire Bachelor of Science amiliarity with Reg b owner, make her	cal Seatt ector of ( e degree ulatory	le Global in	117				
Authorizing Signature (original signature	Appo	ointing Signatory:									
Eld Bm		vard B. Murray yor of Seattle									

### CARLENE M COMRIE

#### **EDUCATION**

# BABSON COLLEGE, F.W. OLIN GRADUATE SCHOOL OF BUSINESS, Wellesley, MA Master of Business Administration, May 2010.

## UNIVERSITY OF WESTERN ONTARIO, London, Ontario Canada Bachelor of Science in Chemistry, June 1996.

#### EXPERIENCE

TASTE OF THE CARIBBEAN/ RED LOUNGE, Seattle, WA Co-Owner

2013 - Present

PHILIPS ELECTRONICS NA, Bothell, WA Director Global Compliance

2015 - Present

PHILIPS ELECTRONICS NA, Bothell, WA Director Regulatory Affairs (Emergency Care and Resuscitation)

2014 - 2015

## PHILIPS ELECTRONICS NA, Andover, MA

2010 - 2013

Director QA and Regulatory Compliance for Patient Care & Clinical Informatics (PCCI)

- Ensure strategic alignment of quality activities between global business units to create a common quality management system direction for the business group.
- Provide leadership to all business locations to ensure product quality and quality system compliance to ISO 13485 and FDA Quality System Regulation (21 CFR 820), Environmental compliance to ISO 14001, Canadian CMDCAS, Japan PAL regulation and all other worldwide medical device quality and environmental regulations.
- Provide leadership and oversight to business Q&R to ensure ongoing quality management system compliance, as measured by key performance indicators and audit (external and internal) results.
- Lead quality system improvement initiatives within business group including standardization of key processes.
- Provide operational support to business group supply chain, including support for manufacturing, supplier management, logistics and M&A integration.
- Interface with BU/BL Q&R management to address product quality and regulatory compliance issues and requirements.
- Identify and implement best practices between all locations to improve efficiency without risking compliance.
- Develop and implement a compliance strategy and Internal Audit program that ensures that PCCI businesses are compliant to regulatory requirement.
- Conduct due diligence inspections for potential mergers and acquisitions to ensure PCCI is fully aware of the regulatory compliance status of targeted company(s).
- Change and thought leader that champions quality management system and product quality improvement.
- Provide compliance expertise and guidance, including: information, opinion and interpretation to entire business
- Create a quality community within the business group.
- Analyze data for trends and recommend preventive actions as necessary.
- Lead quality system management reviews.

## Sr. Quality Systems Manager (2008 - Present)

- Responsible for managing a team of eleven with four direct reports.
- Provide leadership in quality assurance and regulatory compliance on departmental or cross-functional initiatives.
- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues.
- Provide direction, coaching, and mentoring on quality and regulatory compliance to departmental, functional, site and divisional personnel.
- Manage the implementation of process controls, and CAPA systems designed to meet or exceed internal and external requirements.
- Identify and manages the implementation of effective quality systems to support the development, qualification, and on-going manufacturing of products.

## Global Regulatory Compliance Auditor (2006 – 2008)

- Supported third-party audits, subject matter expert training and other initiatives which increased Boston Scientifics' corporate-wide FDA readiness.
- Performed as auditor and lead auditor for Corporate audits of manufacturing sites and focused Quality System topic audits for medical devices and combination products.
- Identified best practices and highlighted in audit reports systemic areas for improvement within the organization.
- Communicated FDA responses and associated commitments throughout Boston Scientific.
- Facilitated FDA re-inspection readiness and general audit preparedness.
- Provided assistance to sites during regulatory inspections as Field Corporate Audit Support Representative.
- Developed audit document templates for agendas and report formats utilizing FDA QSIT technique, international standards (e.g. EN ISO 13485:2003) and other applicable regulations.

## ABBOTT LABORATORIES, Abbott Park, IL

2004-2006

## **Corporate Inspection Administrator**

- Consulted and advised division on regulatory policies and quality related issues.
- Managed the inspection process, developed inspection strategy, delivered Audit Preparedness training.
- Conducted internal and supplier audits for the division.
- Served as point of contact during regulatory and non-regulatory inspections for the division.
- Creates and implements the inspection strategy for all regulatory and non-regulatory inspections.
- Facilitated and/or supported 40+ Regulatory and non-regulatory inspections on a yearly basis.
- Coordinated the organization response to all audit observations as well as facilitated the response process.

### AVENTIS BEHRING L.L.C, Kankakee, IL

1999-2004

## Quality Systems Engineer/Validation Specialist/ Auditor

- Responsible for reviewing change control documentation for compliance to cGMP regulations, federal guidelines and industry standards.
- Reviewed and executed validation protocols.
- · Conducted internal and supplier audits.
- Supervised and trained all contractors associated with projects.

## NOVEX PHARMA, Richmond Hill, ON, Canada

1997 - 1999

### Calibration Engineer

• Supported the laboratory, R&D and production by ensuring instrumentation/equipment were calibrated and maintained per schedule.

## SPECIAL INTEREST

• Tae Kwon Do • Traveling • Reading • Music • Nightlife Advocate

## **Fire Code Advisory Board**

As of March 2017

Fifteen members: Per Ordinance 124707, all subject to City Council confirmation, three year terms, no term limits

■ 15 Mayor-appointed

## Roster:

				Taura Chave Taura Fred Taura Av						
*D	**G	Position No.	Position Title	Name	Term Start Date	Term End Date	Term #	Appointed By		
	Ν	1.	Architects	James R. Fair	03/30/2015	03/30/2018	3	Mayor		
	F	2.	Chemical Engineers	Tara Henriksen	8/31/2015	8/31/2018	2	Mayor		
	F	3.	Mechanical Engineers	Rae Anne Rushing, PE	03/30/2015	03/30/2018	4	Mayor		
	Μ	4.	вома	Brad Middleton	06/01/2016	05/31/2019	1	Mayor		
		5.	Insurance Industry	Vacant				Mayor		
	Μ	6.	Marine Industry	Allen Rainsberger	03/30/2015	03/30/2018	4	Mayor		
	М	7.	Port of Seattle	Jason Johanson	5/27/2014	5/27/2017	1	Mayor		
	М	8.	Manufacturing/ Warehouse	Fritz Chess	05/31/2016	05/31/2019	1	Mayor		
	М	9.	Research/ Labs	Kurt Lusting	05/31/2016	05/31/2019	1	Mayor		
	М	10.	Fire Protection Industry	James Moren	10/31/2015	10/31/2018	3	Mayor		
	Ν	11.	Public	Lucas Grothkopp	03/30/2015	03/30/2018	3	Mayor		
	Μ	12.	Public	Steven Potokar	5/27/2014	5/27/2017	1	Mayor		
	Μ	13.	Labor	Scott Peterson	5/27/2014	5/27/2017	1	Mayor		
(3)	М	14.	Major Institutions	Hugo Sotelo	05/31/2016	05/31/2019	1	Mayor		
(2)	F	15.	Services Industry	Carlene M. Comrie	05/15/2017	05/14/2020	1	Mayor		

Diversity Chart:				(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
	Men	Women	Vacant	Minority	Asian- American	Black/ African American	Hispanic/ Latino	American Indian/ Alaska Native	***Other	Caucasian/ Non- Hispanic	Pacific Islander	Middle Eastern	Multiracial
Mayor	11	3	1	2		1	1			12			
Council													
Other													
Total													

Key:

<sup>\*</sup>D List the corresponding *Diversity Chart* number (1 through 9)

<sup>\*\*</sup>G List gender, M or F

<sup>\*\*\*</sup>Other Includes diversity in any of the following: race, gender and/or ability