

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					
Appointment OR Reappoint	ment	Council Con Yes No	Council Confirmation required? Yes				
Appointing Authority: Council Mayor Other: Fill in appointing authority	Appointed: dd/yy.	Term of Position: * 5/15/2023 to 5/14/2026 □ Serving remaining term of a vacant position					
Residential Neighborhood: Leschi	ode: 4	Contact Phone No.:					
Background: The Services Industry representative on tentertainment, restaurants, nightclubs, or restaurant Taste of the Caribbean and the Quality and Regulatory Compliance for Pachemistry and a Masters of Business Additional Compliance, along with her role as a local good fit to continue as the Services Industry	and ho ne nigh hillips. ministr al resta	tels. Ms. Con t club Red Loo Ms. Comrie ation degree. aurant and nig	nrie is d unge. has a l Her fo ght clu	co-owner of the local Seattle She is also the Director of Global Bachelor of Science degree in amiliarity with Regulatory b owner, make her a particularly			
Authorizing Signature (original signature		Appointing Signatory: Bruce A. Harrell					
Druce W. Hanell		Mayor of	Mayor of Seattle				

^{*}Term begin and end date is fixed and tied to the position and not appointment date.

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 N

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 OA 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

Seattle Fire Code Advisory Board

15 Members: Pursuant to Ordinance 124707, all members subject to City Council confirmation, 3-year terms:

• 15 Mayor-appointed

Roster:

*D	**G	RD	Position No.	Position Title	Name	Term Begin Date	Term End Date	Term #	Appointed By
							3 years from Council		
2	М		1.	Architect	Loren Brandford	N/A	confirmation	1	Mayor
				Chemical					
6	F		2.	Engineer	Tara Henriksen	9/1/21	8/31/24	4	Mayor
				Mechanical					
			3.	Engineer	Vacant	4/1/21	3/31/24		Mayor
6	М		4.	ВОМА	Shawn Wood	6/1/22	5/31/25	1	Mayor
			5.	Insurance Industry	Vacant				Mayor
1	F		6.	Marine Industry	Amy Liu	9/24/21	9/23/24	2	Mayor
6	М		7.	Port of Seattle	Chris Todd	8/15/23	8/14/26	3	Mayor
6	М		8.	Manufacturing/ Warehouse	Fritz Chess	6/1/22	5/31/25	3	Mayor
6	М		9.	Research Labs	Kurt Lustig	6/1/22	5/31/25	3	Mayor
6	M		10.	Fire Protection Industry	Kevin Marr	8/15/23	8/14/26	3	Mayor
6	М		11.	Public	Scott Peterson	6/1/22	5/31/25	1	Mayor
6	M		12.	Public	Matt Trueblood	N/A	3 years from Council confirmation	1	Mayor
6	М		13.	Labor	Ricky Campbell	6/1/22	5/31/25	1	Mayor
			14.	Major Institutions	Vacant	6/1/22	5/31/25		Mayor
2	F		15.	Services Industry	Carlene M. Comrie	5/15/23	5/14/26	3	Mayor

SELF-IDENTIFIED DIVERSITY CHART					(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Male	Female	Transgender	NB/O/U	Asian	Black/ African American	Hispanic/ Latino	American Indian/ Alaska Native	Other	Caucasian/ Non- Hispanic	Pacific Islander	Middle Eastern	Multiracial
Mayor	9	3			1	2				9			
Council													
Other													
Total	9	3			1	2				9			

Key:

Diversity information is self-identified and is voluntary.

^{*}D List the corresponding *Diversity Chart* number (1 through 9)

^{**}G List gender, M= Male, F= Female, T= Transgender, NB= Non-Binary, O= Other, U= Unknown

RD Residential Council District number 1 through 7 or N/A