Tuesday, 13 November 2018

FDA Quality Systems Regulations (QSR) for Medical Devices
Naren Patel

Program (0.5 RUs)	
Overview:	**In this presentation attendees will clearly understand elements of the quality system regulations for the medical device and assist them to develop a plan to comply with the requirements.**
Speaker:	Naren is an ASQ Fellow; he is a performance-driven trained Six Sigma Black Belt Senior Executive with an extensive background of comprehensive achievements in developing, executing, managing, and improving operations for International Corporations, as well as medical and aerospace industries; leveraging business acumen across diverse cultures and economies. He is recognized for developing and implementing sound quality-assurance and reliability principles; decreasing cycle time and reducing costs. He has presented numerous papers including ASQ World Conference. He made significant contribution in developing a Web based course for "Supplier Quality Engineer in Biomedical industry, the course is offered by ASQ National. He holds ASQ certifications: CQE, CRE, and CQA.

Tutorial (0.5 RUs)	
Overview:	**The title of the tutorial is "An overview of QSIT", tools and techniques used by FDA to inspect and evaluate quality system of an establishment. In these tutorial attendees will get an insight of how FDA conduct an inspection and carryout quality audit.**

SCHEDULE		
Location:		**Fazzini's Taverna**, 9811 York Road, Cockeysville MD 21030 (410-667-6104; www.fazzinis.com)
TIME:	**5:00 p.m. - on**	Registration, networking and dinner
	6:30 - 8:30 p.m.	Tutorial (0.5RUs) and Program (0.5 RUs)

COST and REGISTRATION	
Cost:	**Advance registration is required**. No charge for program only. Cost $25 (members) / $30 (non-members) -- Cash or checks written to ASQ Baltimore accepted. No credit/debit cards accepted.
Registration:	Go to ASQBaltimore.org. Click on Event >> Reservations, select the meeting date and complete the form. If you need to CANCEL, please let us know otherwise you may be billed. Go to the reservations page that you used to register and select Cancel a reservation under the meeting date. Please add the meeting date in the comment section. In the event of **inclement weather**, the website will be updated with the status by 2pm on the day of the meeting.

DIRECTIONS
83 North to Exit 17 (Padonia Road) East. Left on York Road. Restaurant on right after Gibbons Blvd. Across from Valley Motors. We will be in the room behind the hostess station.

	2018 Nov	Dec	2019 JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT
Dinner Mtg												
Date	13	4		12	12	9	14	11			10	
Location	Faz	MT		MT	Faz	MT	MT	MT			MT	
Board Mtg												
Date	20		15	19	19	16	21			20	17	

ASQ DINNER MEETINGS	ASQ BOARD MEETINGS
• Second Tuesday of the Month • December Mtg: 1st Tuesday of the Month • No meeting: January, July or August • Location subject to change • March/ November Mtg: North of the city	• Third Tuesday of the Month • Earn RUs for volunteering (large and small projects) • Interested contact a Board member or info@asqbaltimore.org