



CHICAGOLAND

Chapter Meeting – June 2019



Topic: System Engineering and the EU Medical Device Regulation

Presenter: Jamie Roman, Regulatory Consultant, Roman Engineering

Presentation Site: IBM – Schaumburg, IL

Date: Thursday, June 20, 2019

Agenda:
6:00 - 6:30 p.m. CT – Dinner & Networking
6:30 - 6:45 p.m. CT – Announcements & Introductions
6:45 - 7:00 p.m. CT – Mini-Presentation on the INCOSE System Safety Working Group
7:00 - 8:15 p.m. CT – Feature Presentation and Q&A

Abstract

The European Union has released a sweeping Medical Device Regulation (MDR) that goes into effect for all Medical Devices sold in Europe, next year. This presentation will discuss the unique role of systems engineering in the management of documentation required by the MDR Technical File. We will discuss how to plan a technical file transition to the MDR, “state of the art”, and some new requirements that have a large impact. The MDR expands on ISO 14971 with related requirements for benefit-risk analysis, clinical evaluation, and post market surveillance. Last and certainly not least, we will discuss the issues related to labeling requirements changes.

About Our Speaker

Jamie Roman provides regulatory consulting for various medical device companies with experience transitioning over 30 technical files to the MDR. Jamie has over 30 years experience in systems engineering for products with high reliability applications including aerospace, transportation, and medical devices. Jamie spent many years with GE as a Master Black Belt, corporate reliability council, and in various engineering leadership positions. Jamie has led the efforts to revamp Design Controls procedures, risk management, and perform quality remediation of electromechanical devices which were under regulatory scrutiny.

Questions? For more information, go to <http://www.incose.org/Chicagoland/>.



CHICAGOLAND

Chapter Meeting – June 2019



Topic: System Engineering and the EU Medical Device Regulation

Presenter: Jamie Roman, Regulatory Consultant, Roman Engineering

Presentation Site: IBM – Schaumburg, IL

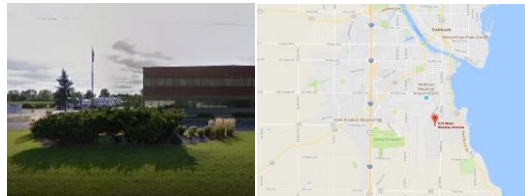
Attend / Network at a Physical Site, or attend at a Virtual Site or attend remotely



IBM, 10 N. Martingale Rd.
Schaumburg, IL 60173
3rd Floor Conference Room



BB7, 5407 Fen Oak Dr.
Madison, WI 53718
Mendota Conference Room



Oshkosh Corp (**Limited to Oshkosh Employees**)
370 W. Waukau Ave
Oshkosh, WI 54902

Attend Live, Online:
Meeting begins at 6:30 PM
<https://incose.pgimeet.com/GlobalmeetTwelve>
Access Number: [1-719-457-1414](tel:1-719-457-1414)
Guest Passcode: [944 440 9838](tel:944-440-9838)

Questions? For more information, go to <http://www.incose.org/Chicagoland/>.