



CHICAGOLAND

October 2018 Chapter Meeting

Risk Management for Medical Devices

Mike Gut

Principal Mechanical Engineer
ICU Medical
Lake Forest, IL

Thursday, October 18

6:00 – 6:30 pm – Dinner & Networking
6:30 – 6:45 pm – Intros & Announcements
6:45 – 8:00 pm – Presentation and Q&A

Abstract

Systems Engineering is about ensuring the System delivers all stakeholder needs.

Risk Management is an approach from a particular direction. Risk Management considers that a primary stakeholder need is safety. Therefore, the objective of Risk Management is to ensure the System delivers safety.

ISO 14971 governs Risk Management for Medical Devices worldwide. It is a recognized consensus standard for the US FDA, and following it is required for obtaining the CE mark for Medical Devices.

Attend this month's INCOSE meeting for an overview of Risk Management per ISO 14971. Learn the principles of Risk Management per ISO 14971, and how it is integrated into the lifecycle of the system.

About Our Speaker

Mike Gut is a member of the INCOSE Chicagoland Chapter and a degreed Mechanical Engineer with over 10 years' experience in the Medical Device industry.

Mike has led Risk Management activities (including plans, hazard analyses, post-production reviews, and reports) for two complex FDA Class II in vitro diagnostic systems. The resulting Risk Management Files enabled multiple regulatory clearances, and continue to deliver value in the lifecycle of these product lines.

Mike will give this presentation live from IBM in Schaumburg, sharing Risk Management lessons learned, tips, and tricks.

For more information, visit incose.org/chicagoland



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Attend & Network Onsite or Online

IBM

10 N Martindale Rd
Schaumburg, IL 60173
3rd Floor Conference Room

Design Integrity

1155 W Fulton Market
Chicago, IL 60607

BB7

5407 Fen Oak Dr
Madison, WI 53718
Mendota Conference Room

AbbVie Inc.

1 N Waukegan Rd
North Chicago, IL 60064
Building AP31
(Limited to AbbVie Employees)

Oshkosh Corp.

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

Online

Meeting begins at 6:30 pm CDT

<https://incose.pgimeet.com/GlobalmeetTwelve>

Phone: (719) 457-1414

Passcode: 944 440 9838

Presenter Location: Schaumburg

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