



**INCOSE**  
CHICAGOLAND

**CHAPTER MEETING - JUNE - 25 , 2026**

# Risk Management for Medical Devices

**Mike Gut**  
Past Chapter President

## Abstract

Risk Management considers safety as the primary stakeholder need - a system must function as intended, in its intended environment, safely.

ISO 14971 serves as the de facto standard for the application of risk management to medical devices. Join INCOSE Chicagoland and SME, Mike Gut to learn about the requirements for risk management and how they determine the safety of a medical device by the manufacturer during a product's life cycle.

## EVENT DETAILS

### LOCATION

1501 E. Woodfield Rd.  
Suite 300E  
Schaumburg, IL 60173  
3<sup>rd</sup> Floor Conference Room  
and  
Online through **Zoom**

### AGENDA

6:00 - 6:30 CT  
Networking  
6:30 - 7:00 PM CT  
Announcements  
7:00 - 8:15 PM CT  
Feature Presentation and Q&A



**Actalent**



For more information, go to <https://incosechicagoland-2026-06.eventbrite.com>





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## About Mike Gut

Mike Gut is a member of INCOSE Chicagoland and a Mechanical and Systems Engineer with more than nineteen years of experience in the medical device industry. Mike will be speaking from the Actalent offices in Schaumburg, sharing tips, tricks and lessons learned.

Mike has also served the chapter for more than a decade in multiple leadership roles including secretary and president, consistently supporting chapter activities, operations and events.