



# 2019

Annual **INCOSE**  
international workshop

**Torrance, CA, USA**

January 26 - 29, 2019

# Healthcare

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[www.incose.org/iw2019](http://www.incose.org/iw2019)

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## CHAIR

Chris Unger (Christopher.Unger@med.ge.com)

## MEMBERS

132

## CO-CHAIR

Bob Malins (rjmalins@eaglesummittech.com)

## INCOSE CONNECT ADDRESS



<https://connect.incose.org/WorkingGroups/Healthcare/Pages/Home.aspx>

## INCOSE WEB PAGE



<https://www.incose.org/incose-member-resources/working-groups/Application/healthcare>

# Charter Summary



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## WG PURPOSE/MISSION

To improve Healthcare delivery, medical devices and services development, and Healthcare SE education by bringing together systems engineers and systems thinkers to identify, develop, and tailor best practices for the Healthcare industry. We will achieve that by

- Articulating the value and application of systems engineering to Healthcare through simple examples and easily deployable guidelines, and
- Providing a forum for developing and sharing best practices, meeting world class experts in Systems Engineering and Healthcare (and across other industries).

*The creation of our group was driven by the fact that many if not most of the organizations in the biomedical and Healthcare industries do not necessary recognize or understand the value of systems engineering and could thus benefit from the application of INCOSE principles.*

## WG GOAL(S)

Our five-year strategic objectives are to:

- Increase the systems engineering and systems thinking capabilities of the Healthcare delivery, medical devices manufacturers, and HCIT suppliers and users to enable improved Healthcare outcomes and value
- Increase individual & corporate INCOSE membership from the Healthcare industry
- Engage leaders in the Healthcare industry seek to raise the use of systems engineering practices by engaging INCOSE support and services
- Publish impactful information on systems engineering in the Healthcare industry and serve as the clearinghouse of Healthcare needs and systems engineering best practices
- Accelerate the transformation of Healthcare systems engineering to a model based discipline

### 5-year Vision

**Systems Engineering for Medical Device Technology:** HWG is the recognized 'clearinghouse' best practices for systems

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engineering for Healthcare device and services development

- Capturing and documenting systems engineering theory customized to the Healthcare industry, as well as critical best practices (as captured in a Healthcare domain extension to SEBoK, among other places)
- Capturing and documenting 'state of the art' Agile, Lean Startup, and Iterative Development practices in Healthcare
- Healthcare specific guidance to ISO/IEC 29110 Systems and Software Engineering — Lifecycle Profiles for Very Small Entities (VSEs)

**Systems Engineering for Healthcare Delivery:** Build on the UK RAE/RCS systems thinking process and develop a strategy for broader deployment.

**Systems Engineering Education for the Healthcare Industry:** HWG is the recognized source for the definition of systems engineering competencies and methods in Healthcare and the source for a suite of Healthcare-related systems engineering education products for use by the community.

## WG SCOPE

The scope of our working group covers

- Manufacturers of devices and providers of services (Clinical and Research use only devices, in-vitro and in-vivo products, pharmaceuticals, and biologics),
- All points-of-care through the entire Healthcare delivery life-cycle,
- Academic Medical Centers (AMCs),
- Regulatory agencies,
- Healthcare insurance providers, and
- Healthcare advocacy groups.

While these organizations may be served by other INCOSE working groups, it is believed that our working group will uniquely

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address the breadth of their needs.



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# IW Outcomes



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## IW Outcomes

There were no specific accomplishments planned for IW other than outreach to INCOSE membership in general and to other working groups addressing healthcare relevant topics. The working group's focus is on making progress at the HWG's Healthcare Systems Engineering Conference, May 1-2, 2019 in Minneapolis.

# Planned Work past IW



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## PLANNED ACTIVITIES

Execute the HWG's 5th Annual Systems Engineering in Healthcare Conference (HWGSEC 2019) on May 1-2, 2019, in Minneapolis, MN (<https://www.incose.org/hwg-conference-2019/home>). The conference will have tracks addressing

- Agile systems engineering methods for medical devices
- Cybersecurity in healthcare
- Modeling for healthcare applications
- System engineering methods in healthcare delivery

## PLANNED WORK PRODUCTS

- Publish the proceedings of the Systems Engineering in Healthcare Conference through the working group and through INCOSE TechOps.
- Complete the white paper tailoring the FDA's model V&V methodology for application to V&V of control loop models and software in medical devices.