Application of Systems Engineering to Regulatory Compliance Activities for Medical Devices

Presented by Apoorv Maheshwari

INCOSE Healthcare MBSE Challenge Team: Modeling for a Healthy Future

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Outline

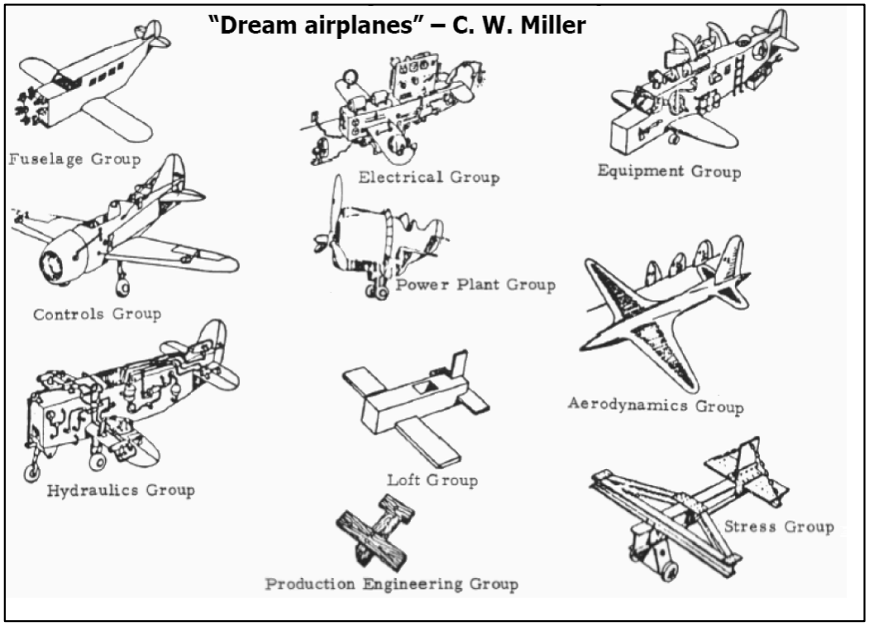
- About the Challenge Team
- Why MBSE?
- Objectives
- Approach
- Demonstration
- Lessons Learned
- Future Work

About the Challenge Team

- **Mission**
  - Demonstrate value and utility of MBSE in biomedical programs
  - Provide INCOSE members reference design to adopt for specific drug, device, and/or biological product development efforts.
- In 2014, finalized reference architecture using MagicDraw to develop SysML-compliant model drug delivery system
  - Requirements, structure, behavior, interfaces, parametrics
  - Emphasis on assurance of safety, reliability, usability, interoperability, and compliance with standards and regulations
- In 2015, added product development process model described in this presentation

Why do we need MBSE?

- Improved communication
  - *Think about language barrier in a global team*
- Improved understanding through logical models
  - *Provide high level of abstraction*
  - *Reuse or design sharing*
- Improved design of test cases
  - *Weakness exposed in the model*
- Easier verification
  - *Model testing vs. just reviews*
  - *Leveling of requirements*



Objectives

- High-level
  - Demonstrate value and utility of MBSE in the biomedical-healthcare applications
  - Develop clear roadmap for biomedical device developers to integrate systems engineering activities with regulatory compliance activities
- Project-specific
  - **Break the mold:** Medical device industry is conservative, risk averse and continues to use well-established document-based processes
  - **Safety Assurance:** Demonstrate safety, addressing safety and addressing risk (pump recalls)
  - **Guidance Manual:** Assist user on key processes along with the reference pump model

Approach

- Follow Appendix B of Buede's 2009 textbook, *The Engineering Design of Systems*
- Harmonize with
  - ISO 15288: Systems and software engineering - System life cycle processes
  - ISO 14971: Application of Risk Management to Medical Devices
  - IEC 62366-1: Application of Usability Engineering to Medical Devices
- Build on approach in 2015 INCOSE IS best paper *"SysML Activity Models for Applying ISO 14971 Medical Device Risk and Safety Management Across the System Lifecycle"*

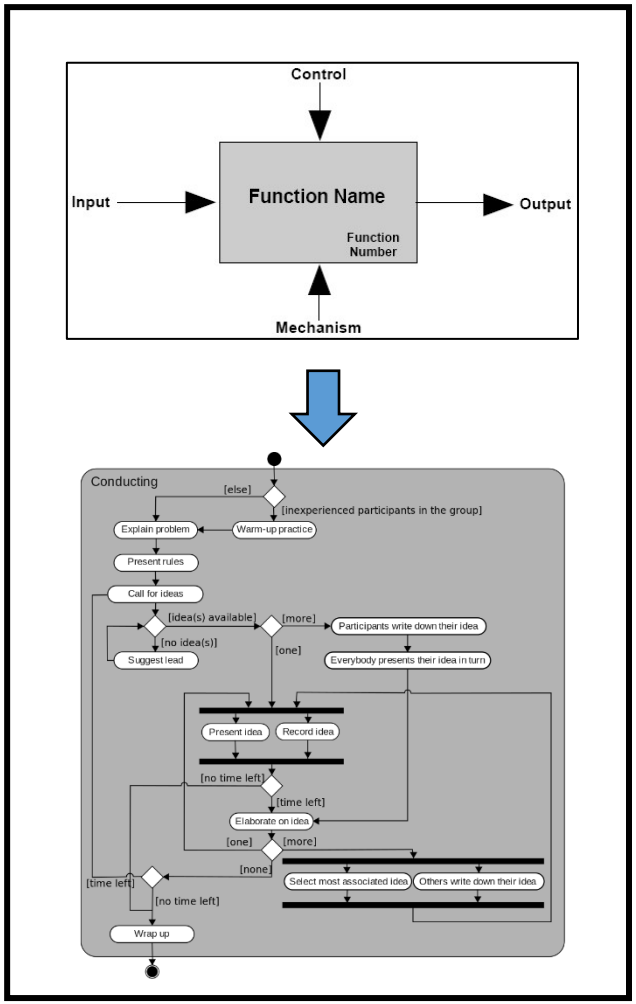
Reference Model for Infusion Pump

- Existing model completed in 2014 represents a generic infusion pump (drug delivery system) depicting:
  - Drug Delivery Requirements
  - Drug Delivery Structure
  - Behavioral Use Cases

An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts.

Added Engineering Design of Systems

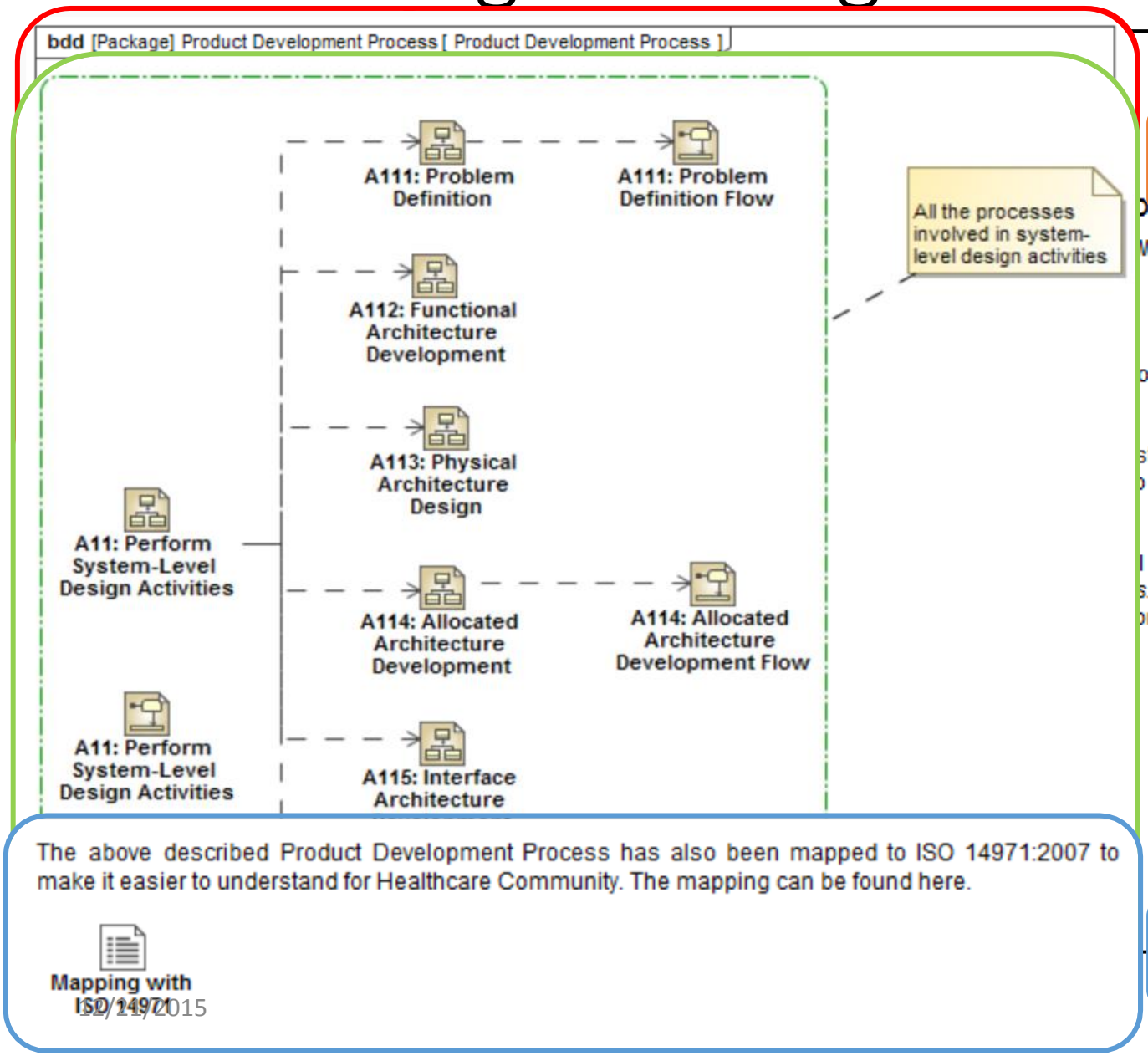
- Buede's textbook model for engineering design of a system converted from IDEF0 to SysML activity diagrams and linked to existing model
- Model can be accessed anywhere with an internet connection *(read-only)*



Demonstration

Can be accessed at:
http://web.ics.purdue.edu/~amaheshw/Infusion%20Pump/Model_May20.html

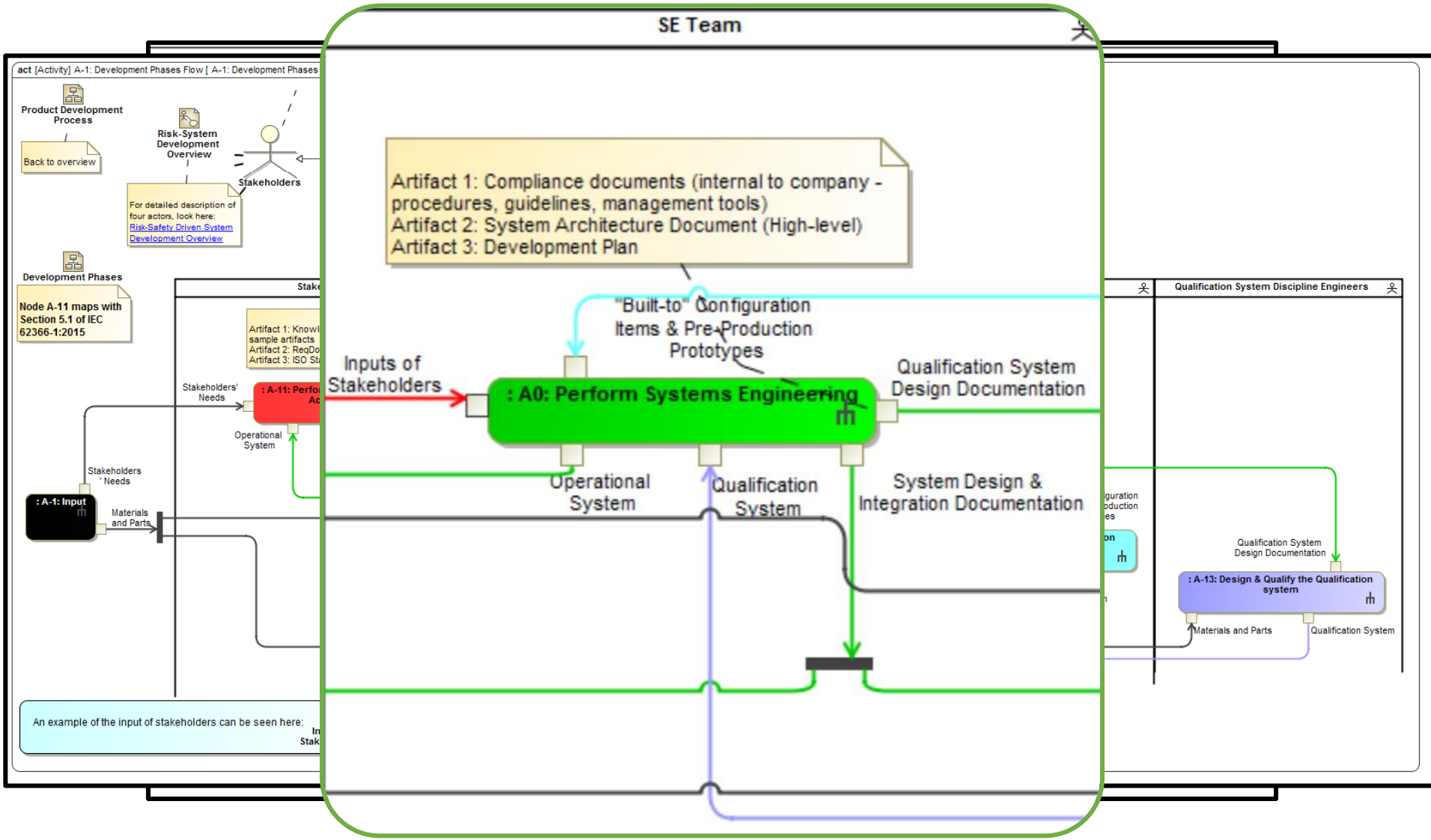
Main Navigation Page



Pre-Systems Engineering Processes

System-level Design Activities

Mapping Information


act [Activity] A-1: Development Phases Flow [A-1: Development Phases
Product Development Process
Back to overview
Risk-System Development Overview
Stakeholders
For detailed description of four actors, look here:
Risk-Safety Driven System Development Overview
Development Phases
Node A-11 maps with Section 5.1 of IEC 62366-1:2015
Stakeholders' Needs
Operational System
Stakeholders' Needs
: A-1: Input
Materials and Parts
An example of the input of stakeholders can be seen here:
SE Team
Artifact 1: Compliance documents (internal to company - procedures, guidelines, management tools)
Artifact 2: System Architecture Document (High-level)
Artifact 3: Development Plan
"Built-to" Configuration Items & Pre-Production Prototypes
Inputs of Stakeholders
: A0: Perform Systems Engineering
Qualification System Design Documentation
Operational System
Qualification System
System Design & Integration Documentation
Qualification System Discipline Engineers
Qualification System Design Documentation
: A-13: Design & Qualify the Qualification system
Materials and Parts
Qualification System

Example: Mapping ISO 14971

14971	Buede's Diagrams		
Risk Analysis Step	**Produced by**	**Part of Artefact**	**Feeds to**
Intended Use	A1111 Develop Operational Concept	System-level Operational Concept	
Identify characteristics related to safety	A1111 Develop Operational Concept	Preliminary Hazard Identification	System-level Operational Concept (using FDA guidance document, etc.)
	A112 Develop System Functional Architecture	Functional Hazards (from use cases)	System-level Final Architecture
	A113 Design System Physical Architecture	Physical Hazards (from use cases)	Physical Architecture
	A1142 Define & Analyze Functional Activation & Control Structure	Emergent Hazards from Activation & Internal Structure	Alternative-level Allocated Architecture
Risk estimation	A1143 Conduct Performance & Risk Analyses	Estimated Risks	Analysis Results
Risk Control	A1143 Conduct Performance & Risk Analyses	Risk Controls, Option Analysis	Architecture Changes
Risk Management Report	A1144 Document Architectures and Obtain Approval	Risk Evaluation in Risk Management Report	Risk Analysis

Lessons Learned

- Differences in the vernacular terminology
- Pick the right problem
- Define the problem right

Future Work

- Parametric Modeling
  - Connect the SysML model with MATLAB
- Emergency Department
  - Focus: Diabetes Problem
  - Integrate infusion pump model to deliver insulin

Questions?

Abstract

- The INCOSE Biomedical-Healthcare Model-Based Systems Engineering (MBSE) Challenge Team has developed a reference model that uses SysML to represent a generic infusion pump and a systems engineering process for planning, developing, and obtaining regulatory approval of a medical device. This presentation describes recent updates to the model that incorporates Buede's textbook model for the engineering design of a system and harmonizes it with ISO 15288 and applicable medical device industry standards such as ISO 14971 Application of Risk Management to Medical Devices and IEC 62366-1 Application of Usability Engineering to Medical Devices. The model provides a clear roadmap that biomedical device developers can follow to integrate systems engineering activities with regulatory compliance activities to provide a more cohesive approach to developing effective and safe medical devices.