INCOSE International Symposium
Las Vegas, NV
June 30 - July 3, 2014

Parametric Analysis through a Model-based Reference architecture for Medical Device Development

Model-Based Systems Engineering (MBSE) Challenge Team Meeting

Tuesday, July 1, 2014

Steven Corns
Ajay Thukral
Jack Stein

BIOMEDICAL AND HEALTHCARE SYSTEM CHALLENGES

Biomedical-Healthcare Engineering and Application Environment

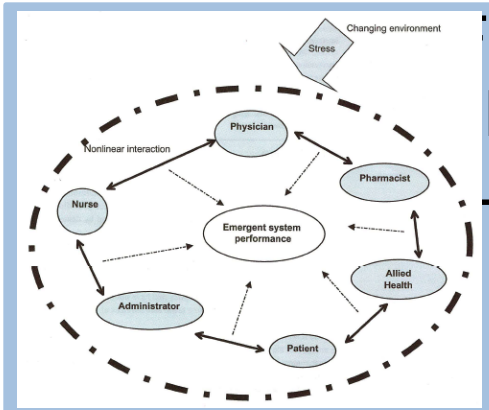
Las Vegas, NV
June 30 - July 3, 2014

Medical Devices

Pharmaceuticals

Healthcare Facilities and Equipment

Translation of T Systems / Elements of Medical Clinical Care Records



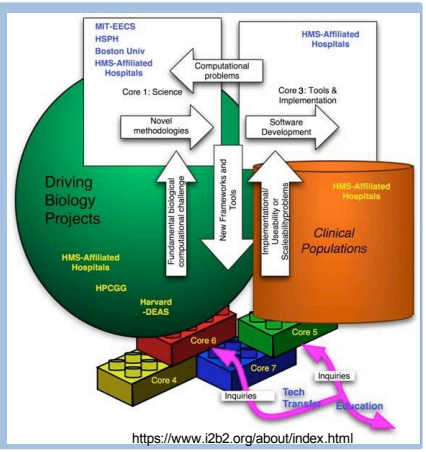
Collaborative Care System

Models, Analysis, & Simulations

Standards & Regulations

Techno

Health Systems



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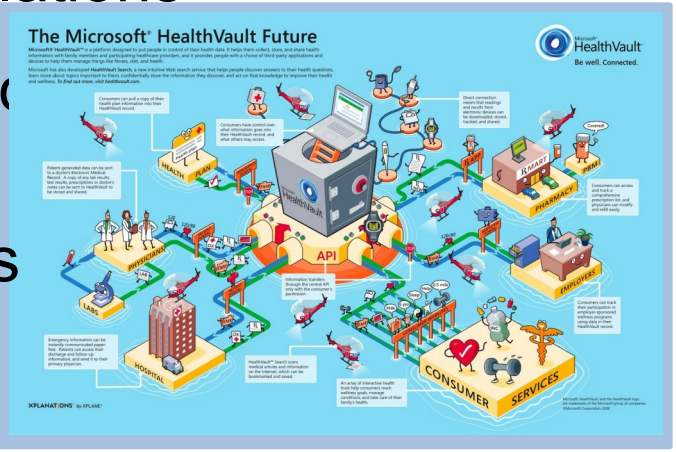

Biomedical-Healthcare System Solutions

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…are we there?

Vision that guides Biomedical-Healthcare Systems

Each Biomedical-Healthcare System strives to be a preeminent leader in clinical care, education, research and service. These are measured by objective evidence and established best practices….."

PROCESS OPTIMIZATION

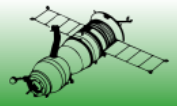
"For full effectiveness, all the work needs to be integrated into a unified program for performance."
Peter Drucker

"If it can be measured, it can be managed [and improved]"
Jack Welch

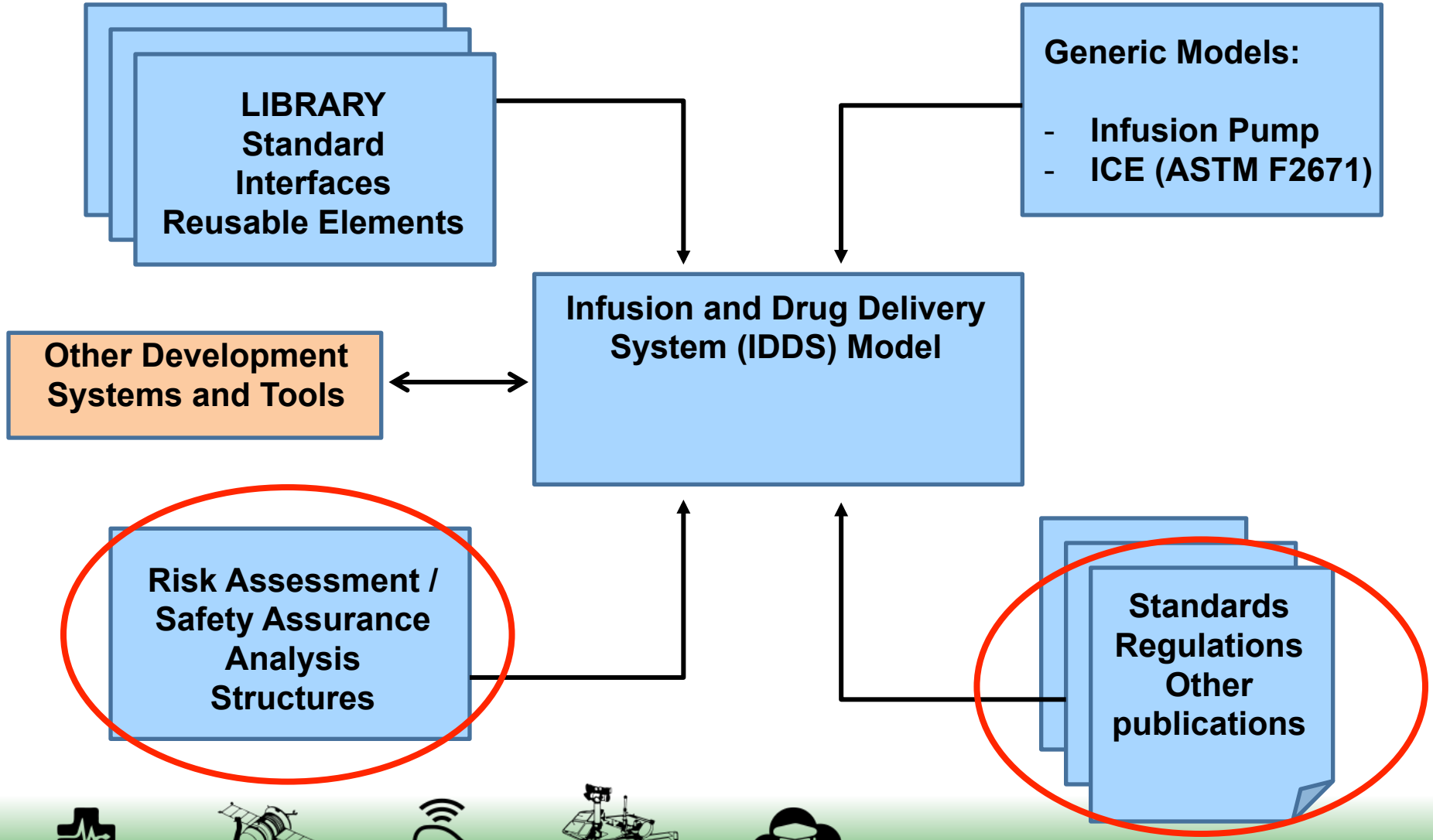
- *KPI's Metrics*
- *Balance Scorecard*
- *Hoshin Kanri*
- *Lean & Six Sigma*

Issues to be Addressed

- Time to adoption
- Ensure regulatory, compliance, and risk management requirements are met
- Cost reduction
- Consistency across device design
- Others?

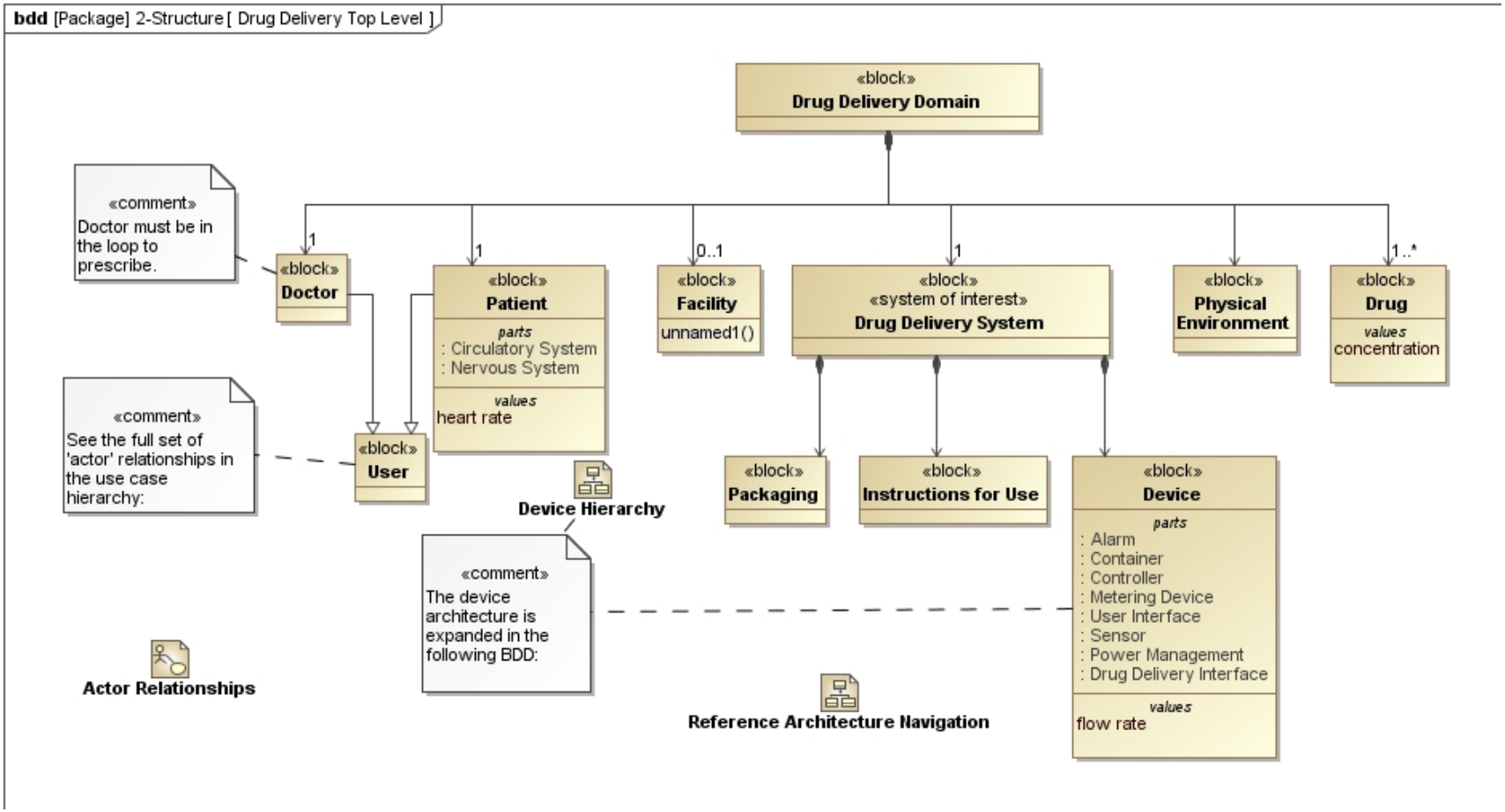




Vision – Enabling Excellence in Biomedical Healthcare System Engineering



MODELING EFFORTS

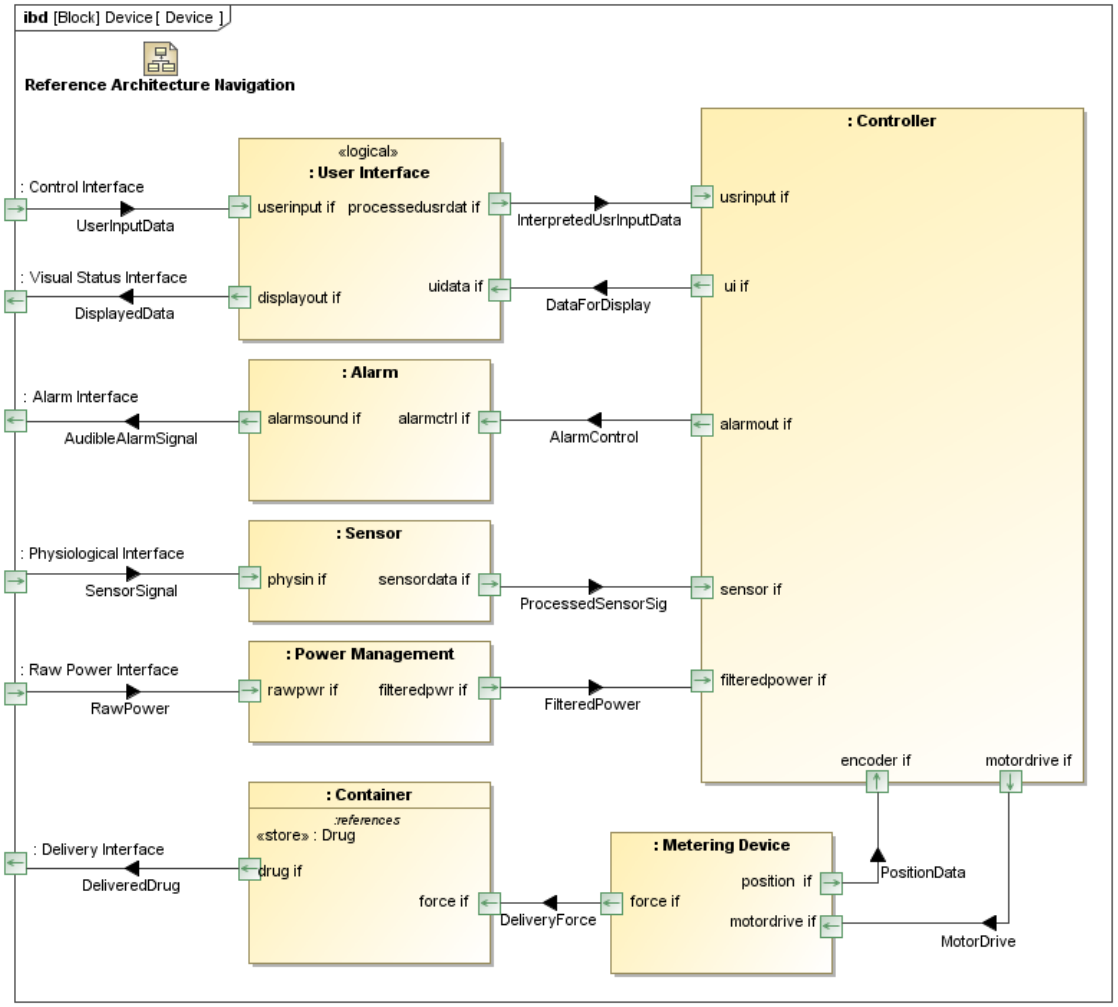
Domain


bdd [Package] 2-Structure [Drug Delivery Top Level]
«block»
Drug Delivery Domain
«comment»
Doctor must be in the loop to prescribe.
1
«block»
Doctor
1
«block»
Patient
parts
: Circulatory System
: Nervous System
values
heart rate
0..1
«block»
Facility
unnamed1()
1
«block»
«system of interest»
Drug Delivery System
«block»
Physical Environment
1..*
«block»
Drug
values
concentration
«comment»
See the full set of 'actor' relationships in the use case hierarchy:
«block»
User
Device Hierarchy
«block»
Packaging
«block»
Instructions for Use
«block»
Device
parts
: Alarm
: Container
: Controller
: Metering Device
: User Interface
: Sensor
: Power Management
: Drug Delivery Interface
values
flow rate
«comment»
The device architecture is expanded in the following BDD:
Actor Relationships
Reference Architecture Navigation

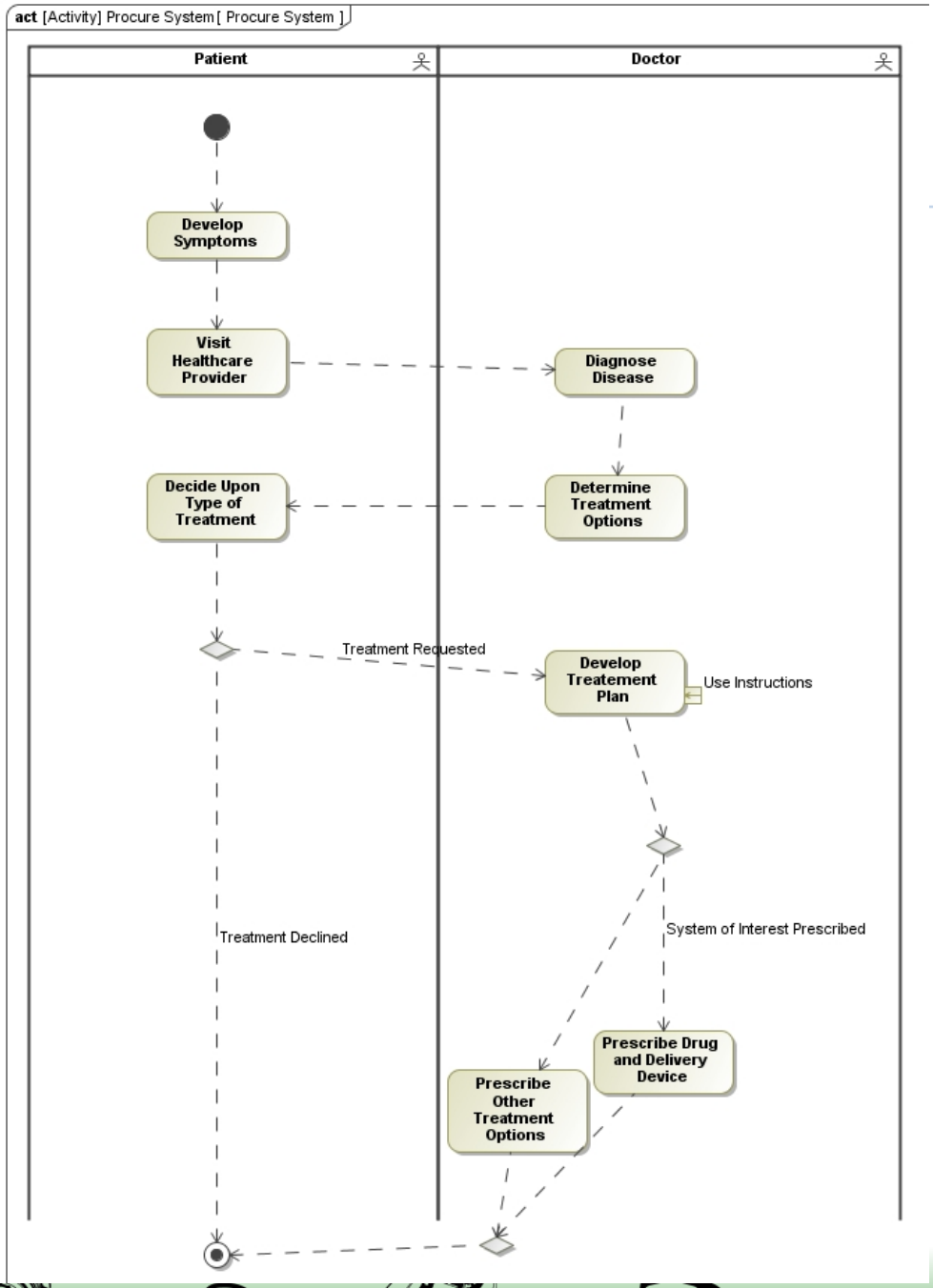
Requirements

#	ID	Name	Text
1	STK1	Stakeholder Requirements	
2	STK1.1	Business Requirements	
3	STK1.1.1	Target Markets	
4	STK1.1.1.1	Countries and Regions	
5	STK1.1.1.2	Distribution Methods	
6	STK1.1.2	Intended Use	
7	STK1.1.3	Indications for Use	
8	STK1.1.4	Marketing / Branding Requir...	
9	STK1.1.4.1	Financial/Business	
10	STK1.1.4.2	Physical	
11	STK1.1.4.3	Functional	
12	STK1.2	User Requirements	
13	STK1.2.1	Care Provider	
14	STK1.2.2	Patient	
15	STK1.2.2.1	User Demographics	
16	STK1.2.2.1.1	Health / Disease States	
17	STK1.2.2.1.1.1	Visual	
18	STK1.2.2.1.1.2	Dexterity	
19	STK1.2.2.1.1.2.1	Range of Motion	
20	STK1.2.2.1.1.2.2	Intricate Operation	
21	STK1.2.2.1.1.3	Audible	
22	STK1.2.2.1.1.4	Tactile	
23	STK1.2.2.1.2	Physical Attributes	
24	STK1.2.2.1.2.1	Age	
25	STK1.2.2.1.2.2	Weight	
26	STK1.2.2.1.2.3	Height	
27	STK1.2.2.1.2.4	Sex	
28	STK1.2.2.1.3	Level of Education	
29	STK1.2.2.1.3.1	Labeling Comprehension	
30	STK1.2.3	Service Professional	
31	STK1.3	Use Environment	The system shall be intended to be used exclusively in a hospital radiology department.
32	STK1.4	Drug Delivery Parameters	
33	STK1.4.1	Patient Delivery Body Location	
34	STK1.4.2	Flow Rate	
35	STK1.4.3	Patient Delivery Method	
36	STK1.4.3.1	Intravenous	
37	STK1.4.3.2	Oral	
38	STK1.4.3.3	Transdermal	
39	STK1.4.4	Volume	
40	STK1.4.5	Physiological Monitors	
41	STK1.4.6	Physiological Dose Adjustmen..	
42	STK1.4.7	Drug	
43	STK1.4.7.1	Formulation	
44	STK1.4.7.2	Container	
45	STK1.5	Regulatory and Compliance	
46	STK1.5.1	ISO 14971	
47	STK1.5.2	IEC 60601-1	
48	STK1.5.3	IEC 62366	
49	STK1.5.4	93/42/EEC	

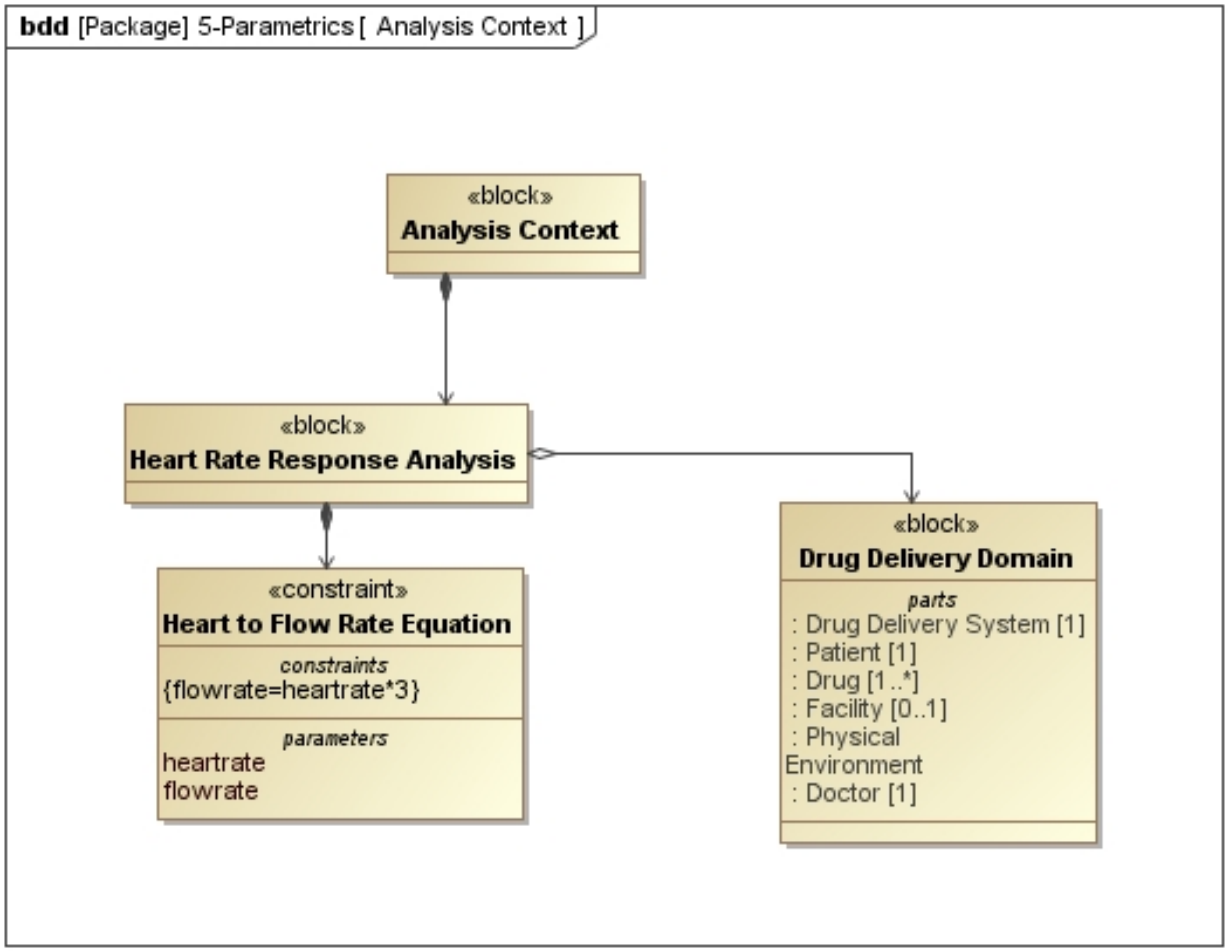
Device Description



System Procurement

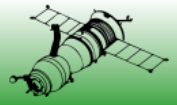


Method for Addition of Parametrics

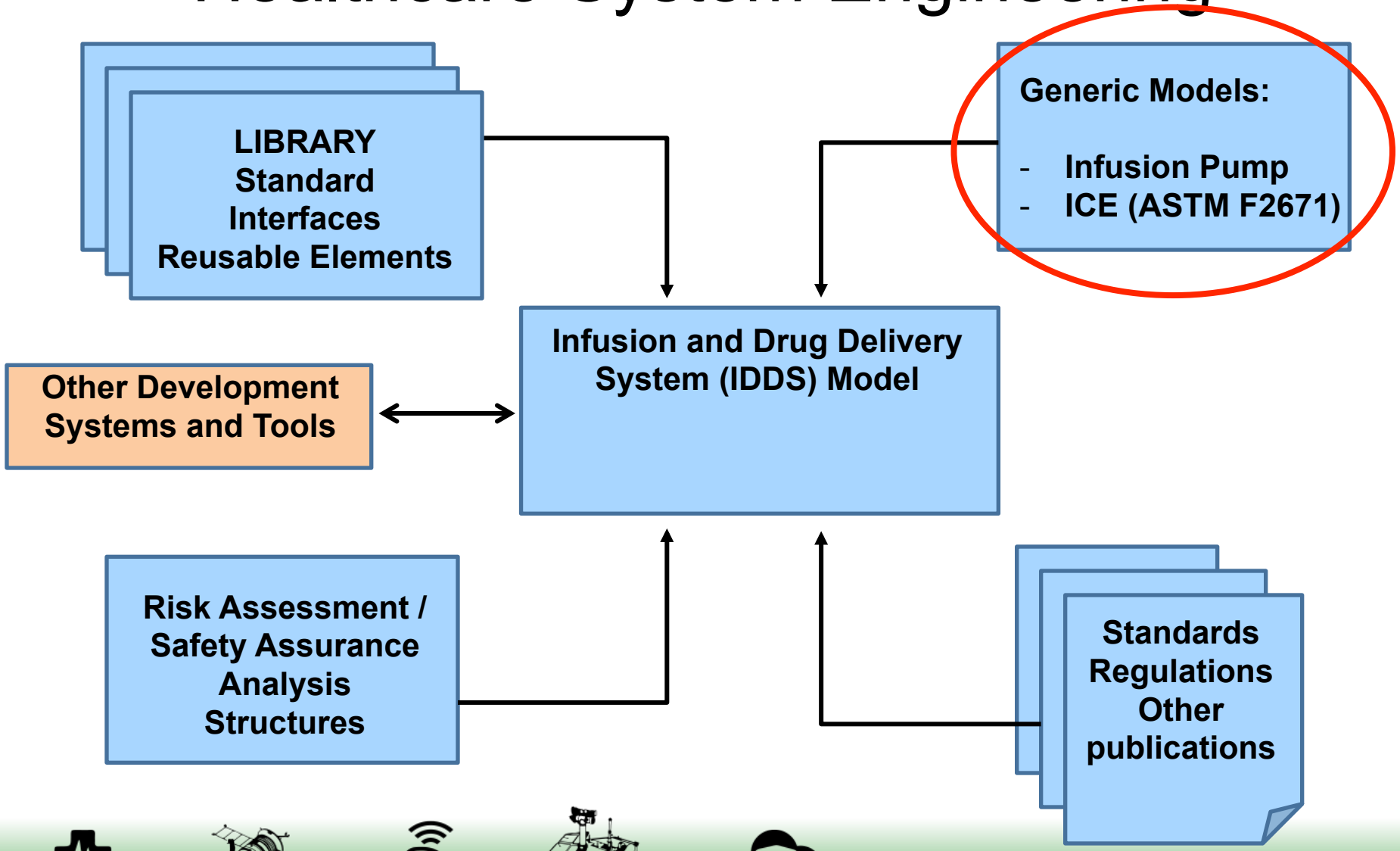


Addressing Risk Up Front

- Risk tolerance typically lower in medical devices
- Risk management a key element in device clearance/approval. New Safety Assurance practices and documentation likely (Infusion Pumps).
- Device clearance/approval is tightly linked to compliance with standards and regulations
  - ISO 14971 (Risk Management)
  - IEC 62366 (Usability Engineering)
  - ISO 62304 (Software Life Cycle)
  - IEC 60601 (Electrical Safety)
  - FDA Design Controls (Needs, Requirements, V&V, etc.)


Vision – Enabling Excellence in Biomedical Healthcare System Engineering

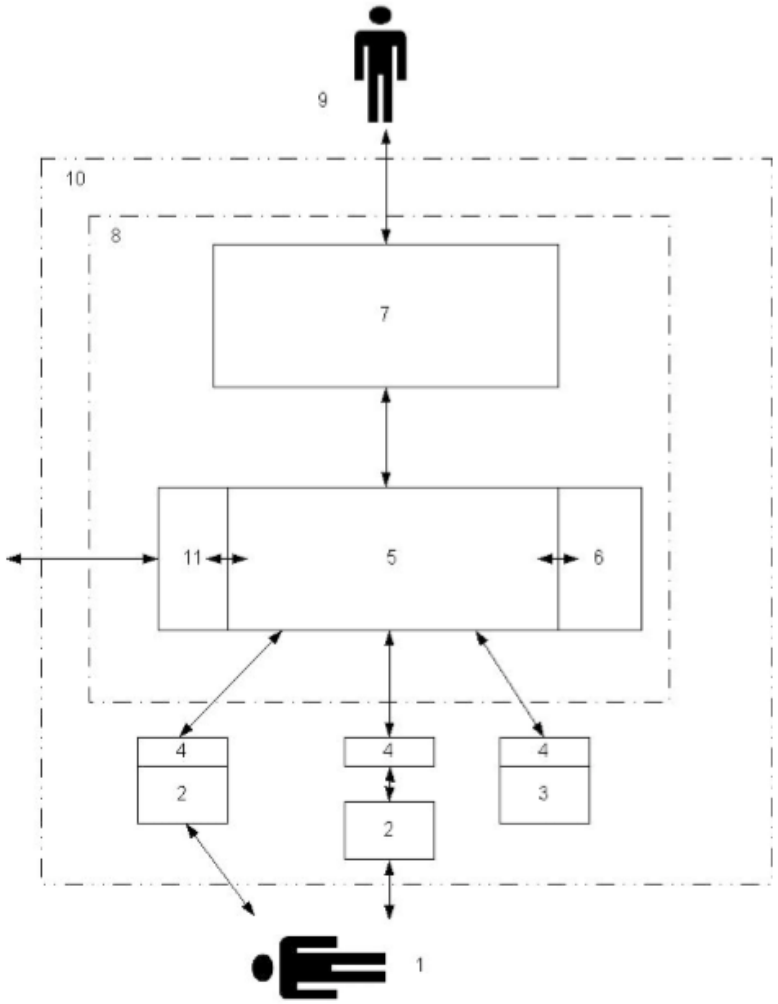


Integrated Clinical Environment (ICE)

Medical Device Plug-and-Play Interoperability

"Getting Connected for Safety"

ASTM F2671 Integrated Clinical Environment (ICE)

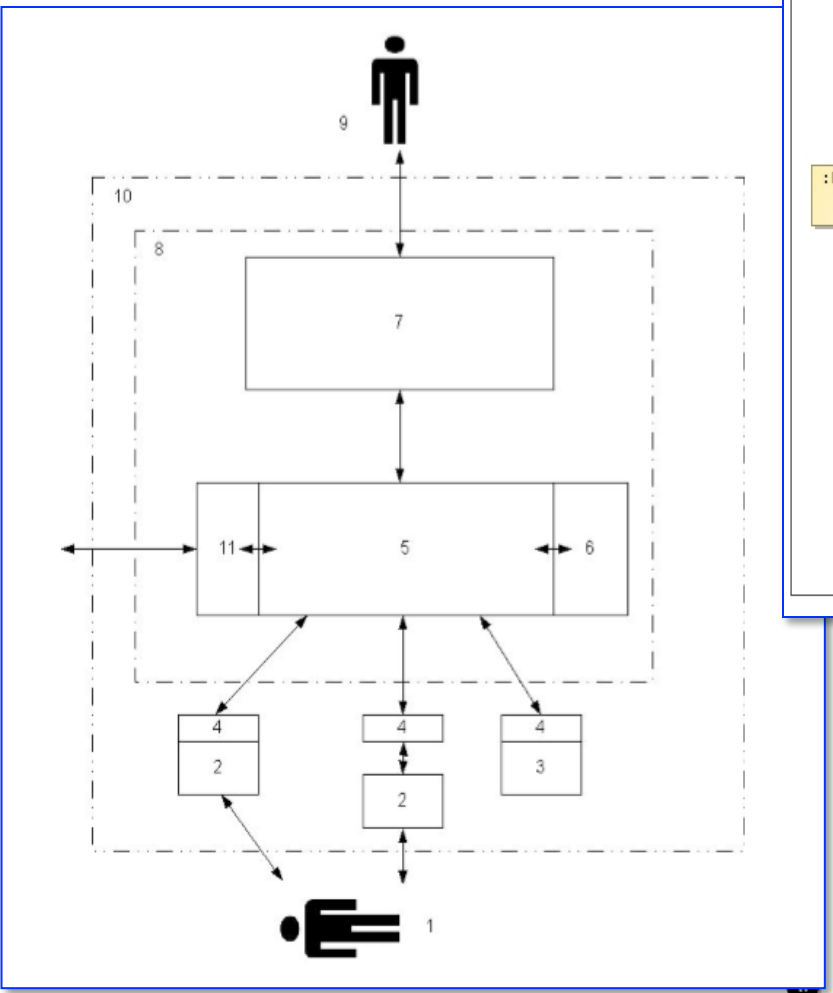


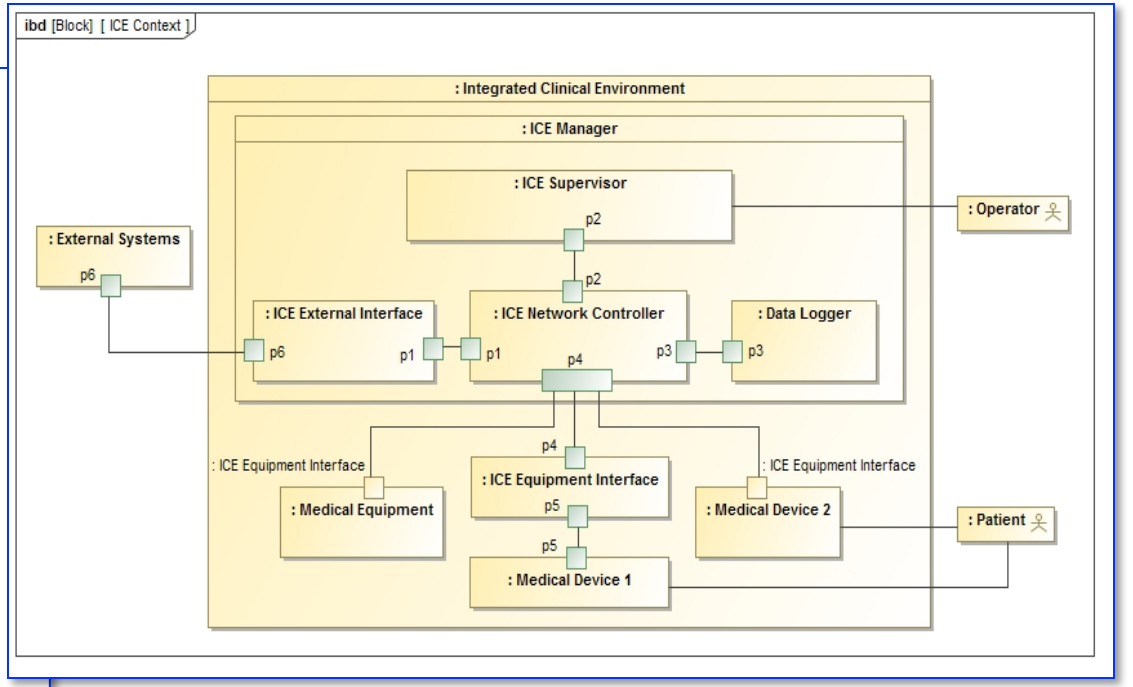
Key

1	PATIENT	7	ICE SUPERVISOR
2	MEDICAL DEVICE	8	ICE manager
3	equipment	9	OPERATOR
4	ICE EQUIPMENT INTERFACE	10	ICE
5	ICE NETWORK CONTROLLER	11	external interface
6	data logger		

Figure 1 from ASTM F2671 – Conceptual functional model showing the elements of ICE

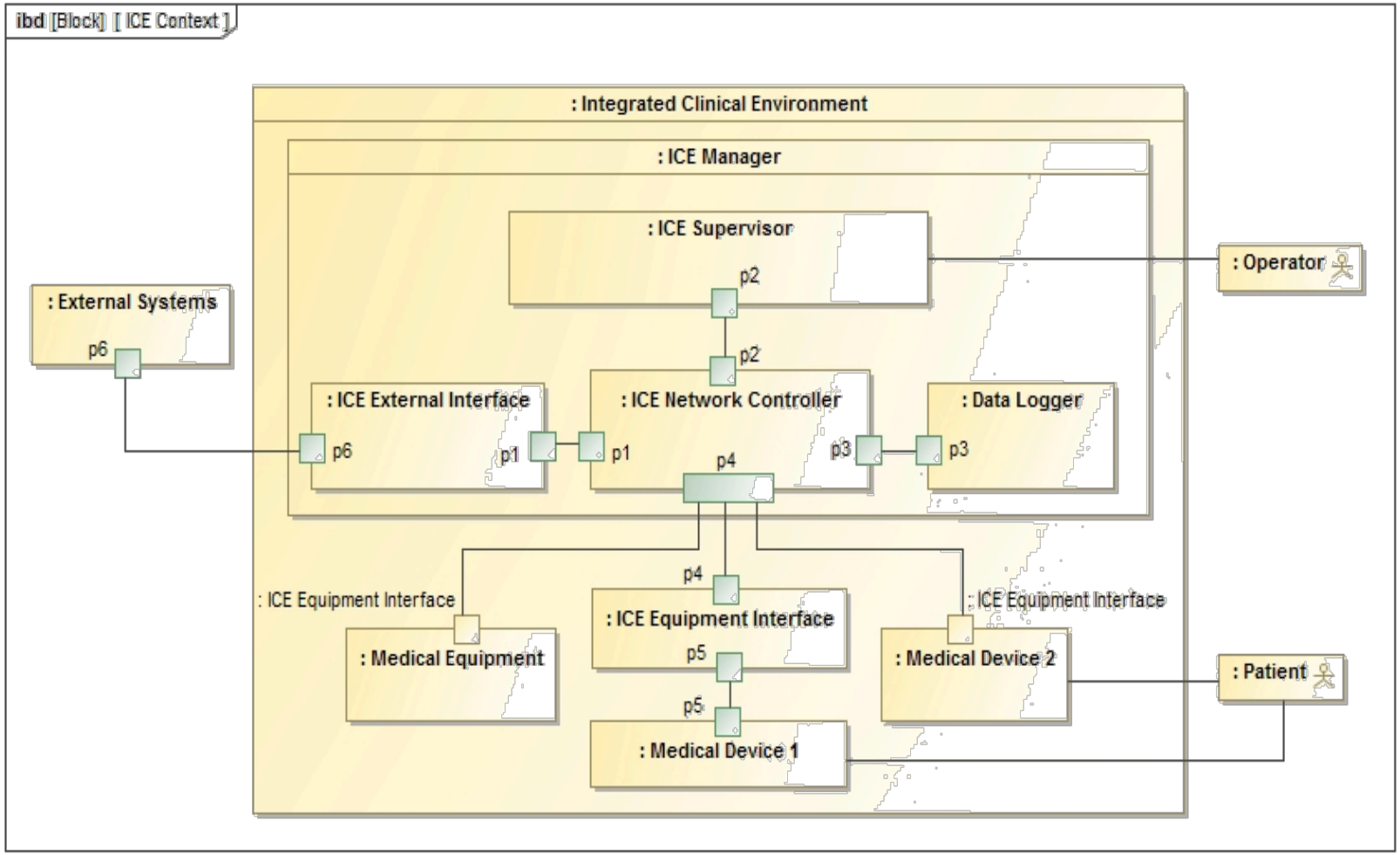
Bring Standards Directly Into the Design/Development Environment: Example – ASTM F2671 ICE (Interoperability)





Transform information in standards into integrated model elements, configurations, and views which are directly traceable to use scenarios, requirements, architecture, verification, validation, risk management, safety assurance, and other information.

SysML Representation of the ASTM F2671 Integrated Clinical Environment (ICE) Model



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Model-Driven Safety Analysis of Closed-Loop Medical Systems

Overview

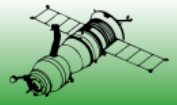
- Model of a patient controlled analgesia (PCA) pump
- Allows for model with a patient in the loop
- Create a model that incorporates this devices with higher level system

Patient Model

- Captures the patient nervous system and circulatory system response to the drug
- Mathematically modeled in python
- Linked to SysML parametric diagram using XMI

Patient Model

- $[\blacksquare C\downarrow 1\ @C\downarrow 2\ @C\downarrow 3\ ]=[\blacksquare -(k\downarrow 12+k\downarrow 13+k\downarrow 10\ )\&k\downarrow 21\ \&k\downarrow 31\ @k\downarrow 12\ \&-k\downarrow 12\ \&0@k\downarrow 13\ \&0\&-k\downarrow 31\ ][\blacksquare C\downarrow 1\ @C\downarrow 2\ @C\downarrow 3\ ]+[\blacksquare 1/V\downarrow 1\ @0@0\ ]I$
- $dl=[\blacksquare 1\&0\&0\ ][\blacksquare C\downarrow 1\ @C\downarrow 2\ @C\downarrow 3\ ]$

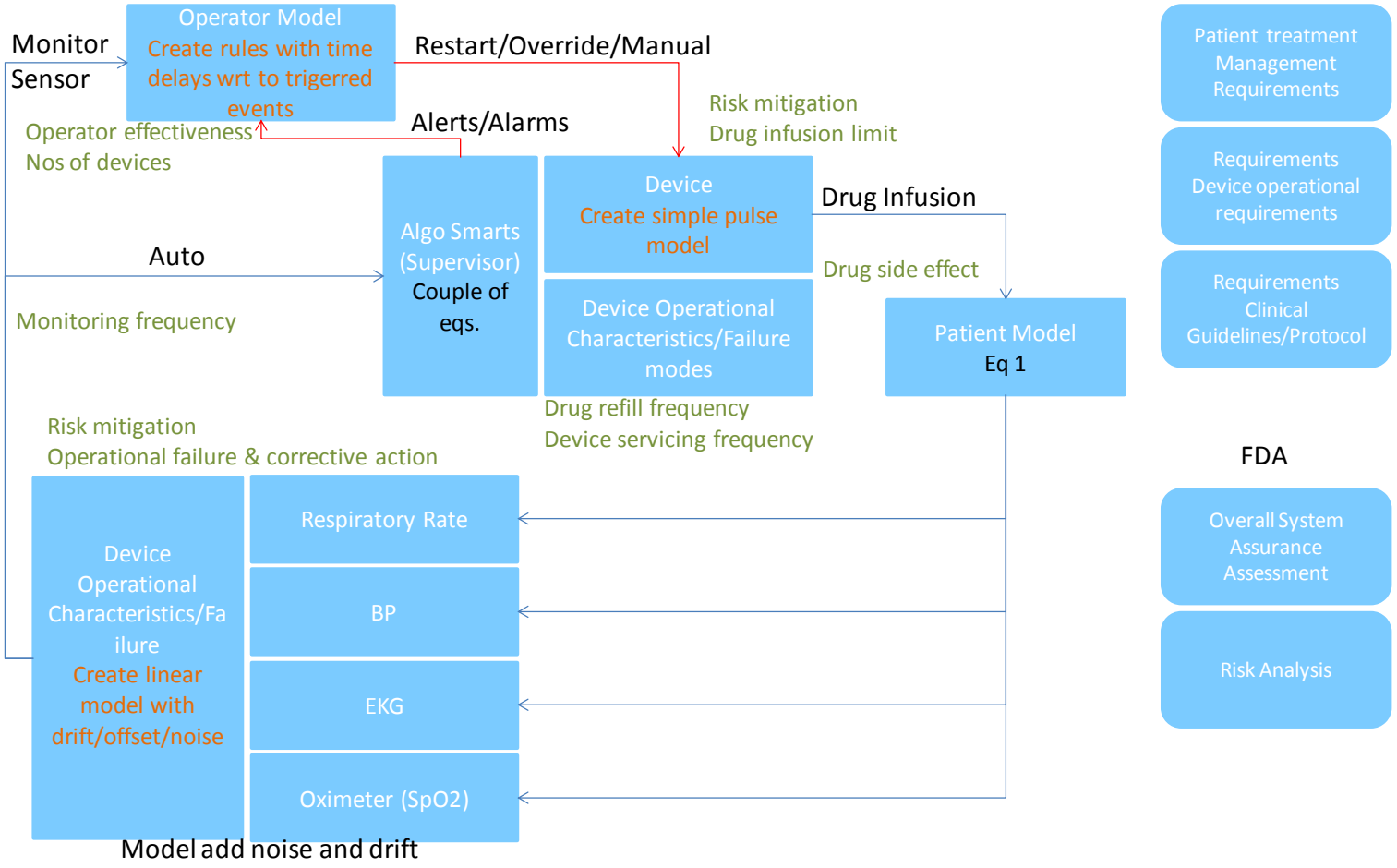

DrugModel

- Represents the effects of the human system on the drug
- Mathematically modeled in python
- Linked to SysML parametric diagram using XMI

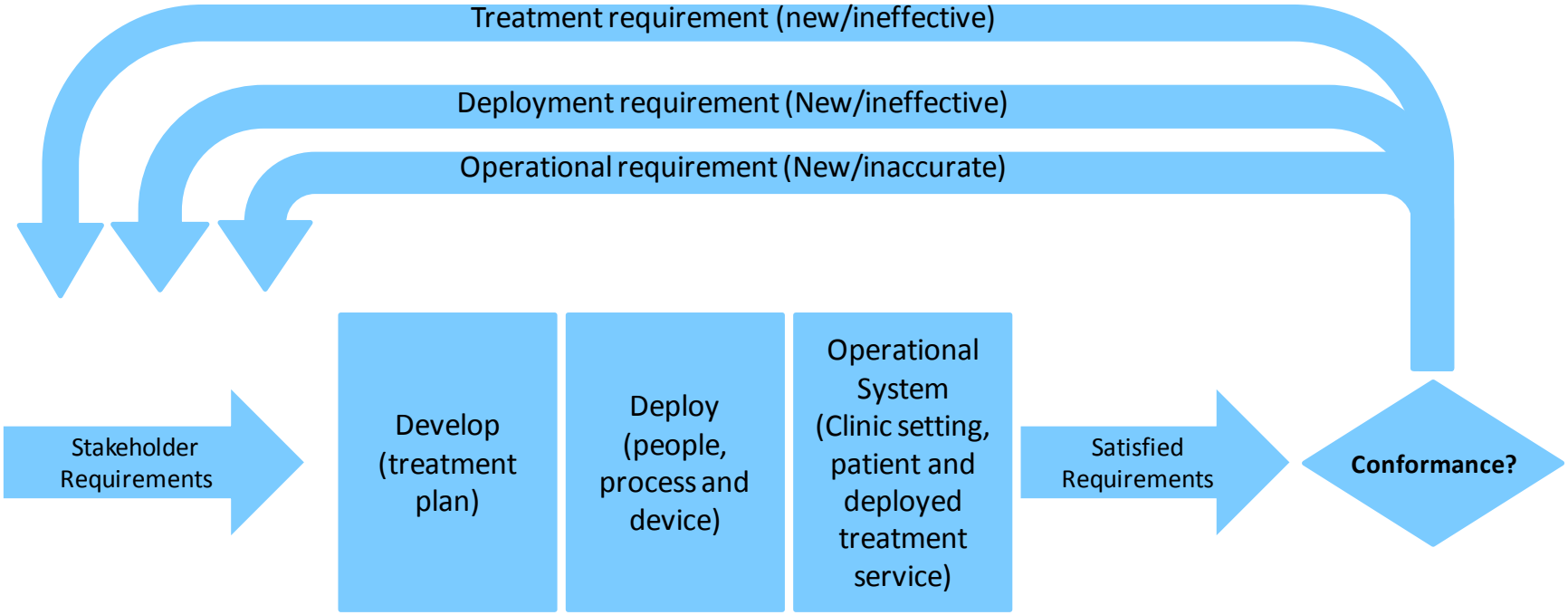
Drug Model

- $k\downarrow 10 = 0.152 min\uparrow -1$, $k\downarrow 12 = 0.207 min\uparrow -1$, $k\downarrow 13 = 0.040 min\uparrow -1$
- $k\downarrow 21 = 0.092 min\uparrow -1$, $k\downarrow 31 = 0.048 min\uparrow -1$, $V\downarrow 1 = 12\ liters$

Model and Environment



PCA Pump verification



Moving Forward

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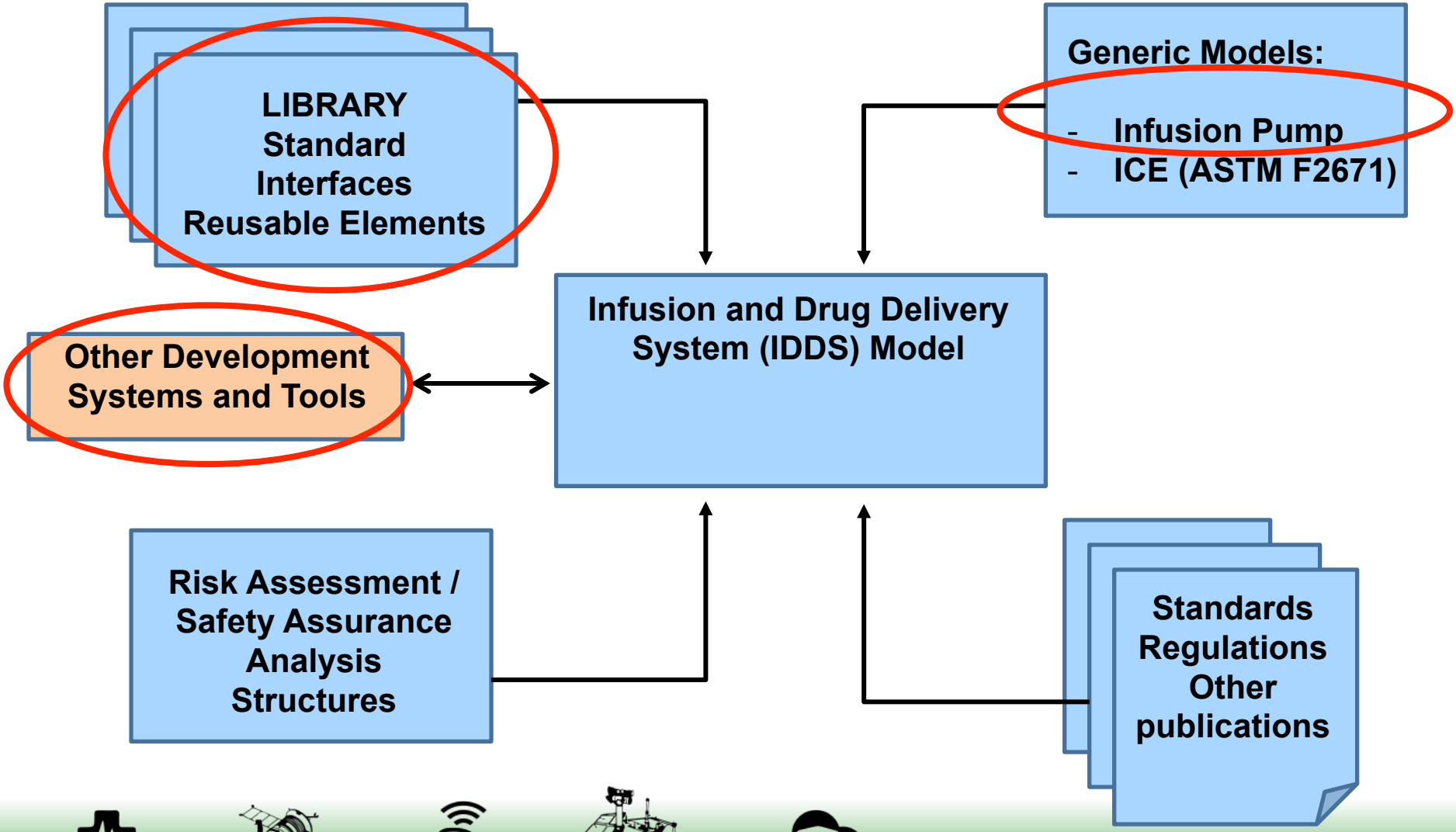
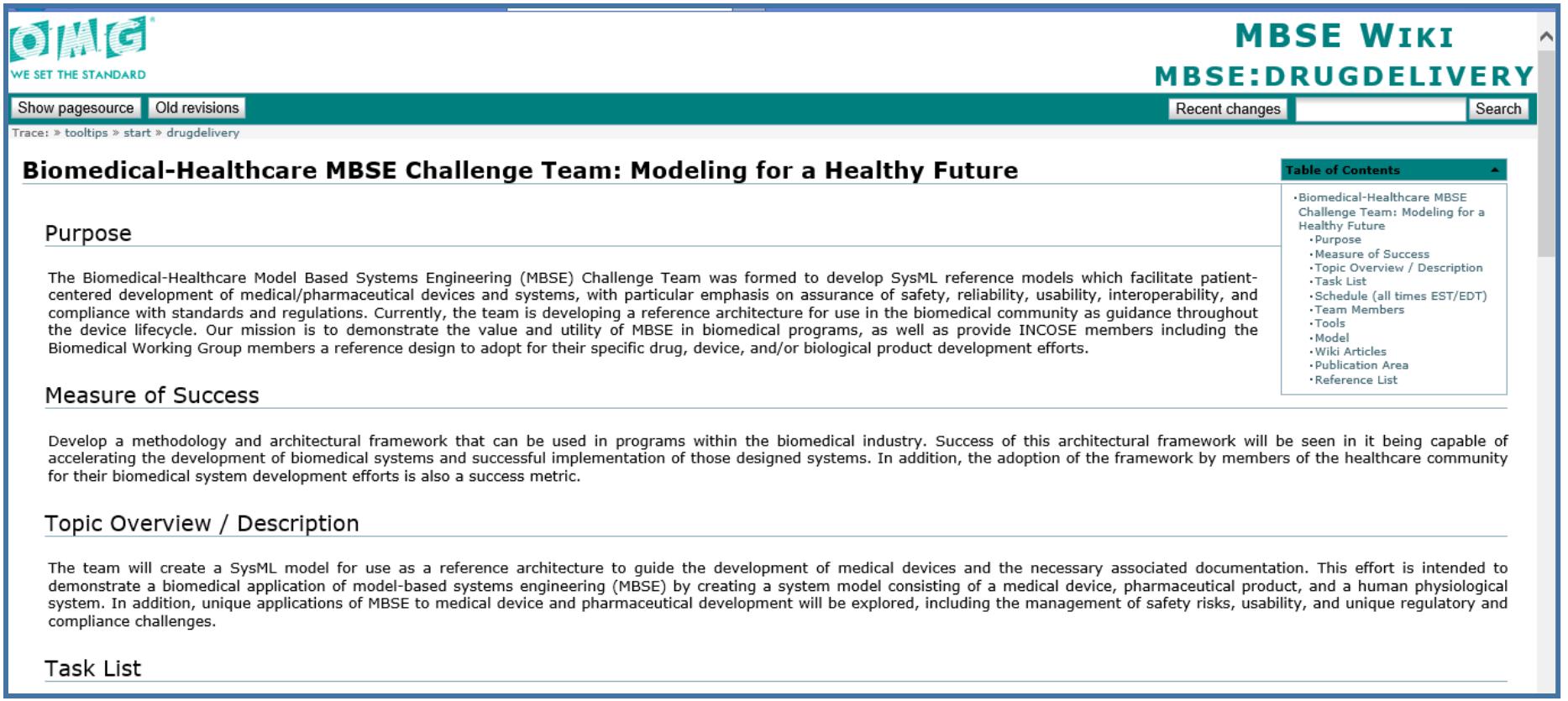


Goals

- Guidelines for using the framework developed
- Expansion of library of components and methods
- Continue integration of ISO/IEC standards and compliance
- Others?

Our OMG Wiki Page (Public)



OMG
WE SET THE STANDARD

MBSE WIKI
MBSE:DRUGDELIVERY

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Trace: » tooltips » start » drugdelivery

Biomedical-Healthcare MBSE Challenge Team: Modeling for a Healthy Future

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Purpose

The Biomedical-Healthcare Model Based Systems Engineering (MBSE) Challenge Team was formed to develop SysML reference models which facilitate patient-centered development of medical/pharmaceutical devices and systems, with particular emphasis on assurance of safety, reliability, usability, interoperability, and compliance with standards and regulations. Currently, the team is developing a reference architecture for use in the biomedical community as guidance throughout the device lifecycle. Our mission is to demonstrate the value and utility of MBSE in biomedical programs, as well as provide INCOSE members including the Biomedical Working Group members a reference design to adopt for their specific drug, device, and/or biological product development efforts.

Measure of Success

Develop a methodology and architectural framework that can be used in programs within the biomedical industry. Success of this architectural framework will be seen in it being capable of accelerating the development of biomedical systems and successful implementation of those designed systems. In addition, the adoption of the framework by members of the healthcare community for their biomedical system development efforts is also a success metric.

Topic Overview / Description

The team will create a SysML model for use as a reference architecture to guide the development of medical devices and the necessary associated documentation. This effort is intended to demonstrate a biomedical application of model-based systems engineering (MBSE) by creating a system model consisting of a medical device, pharmaceutical product, and a human physiological system. In addition, unique applications of MBSE to medical device and pharmaceutical development will be explored, including the management of safety risks, usability, and unique regulatory and compliance challenges.

Task List

http://www.omgwiki.org/MBSE/doku.php?id=mbse:drugdelivery

Thank you