PURDUE PLM CENTER PROJECT

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PRODUCT LIFECYCLE MANAGEMENT
CENTER OF EXCELLENCE

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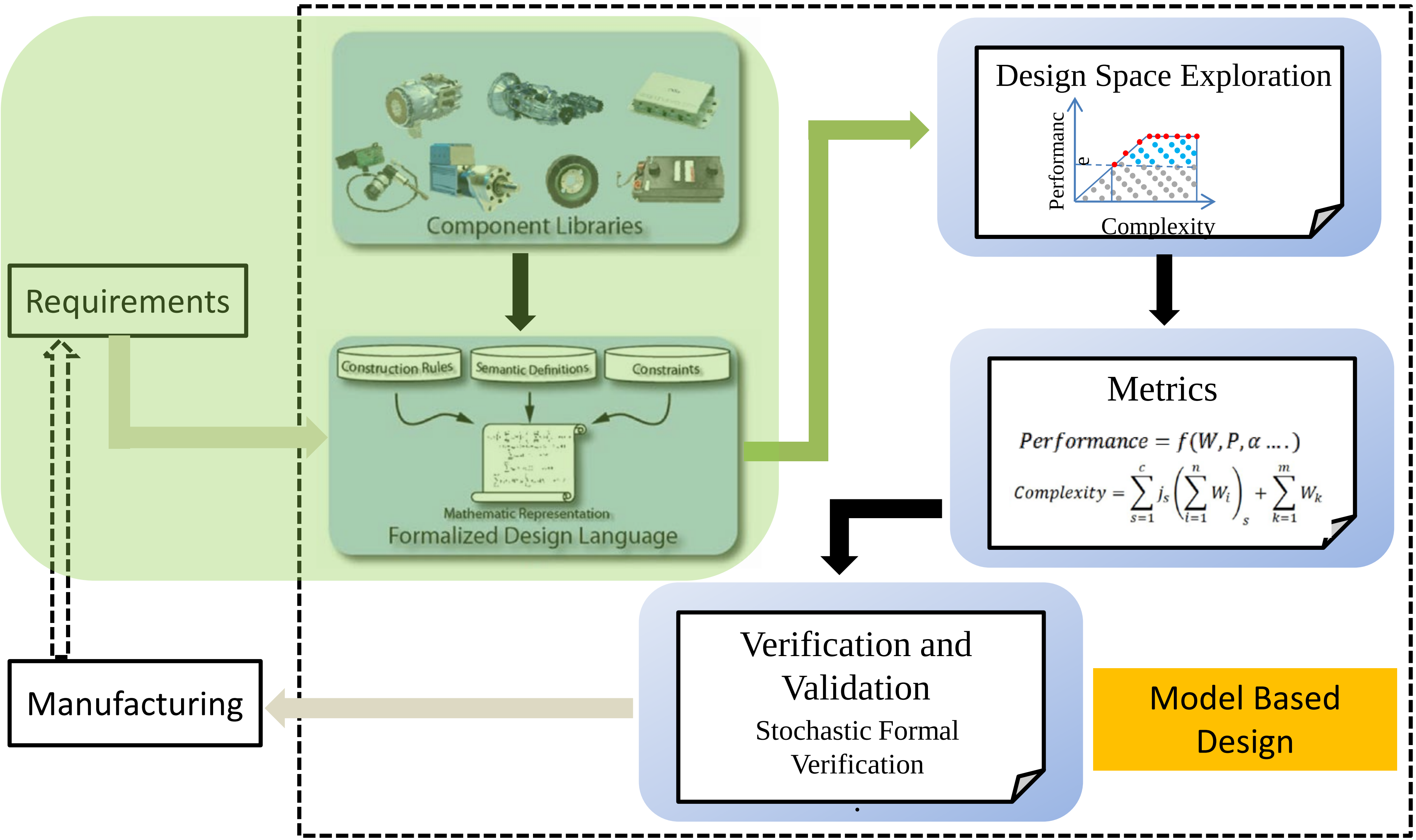
Overview

- Model-Based Design
- Science of Integration
- MBSE-CAD Integration
- Case Study

Next Generation Design Process



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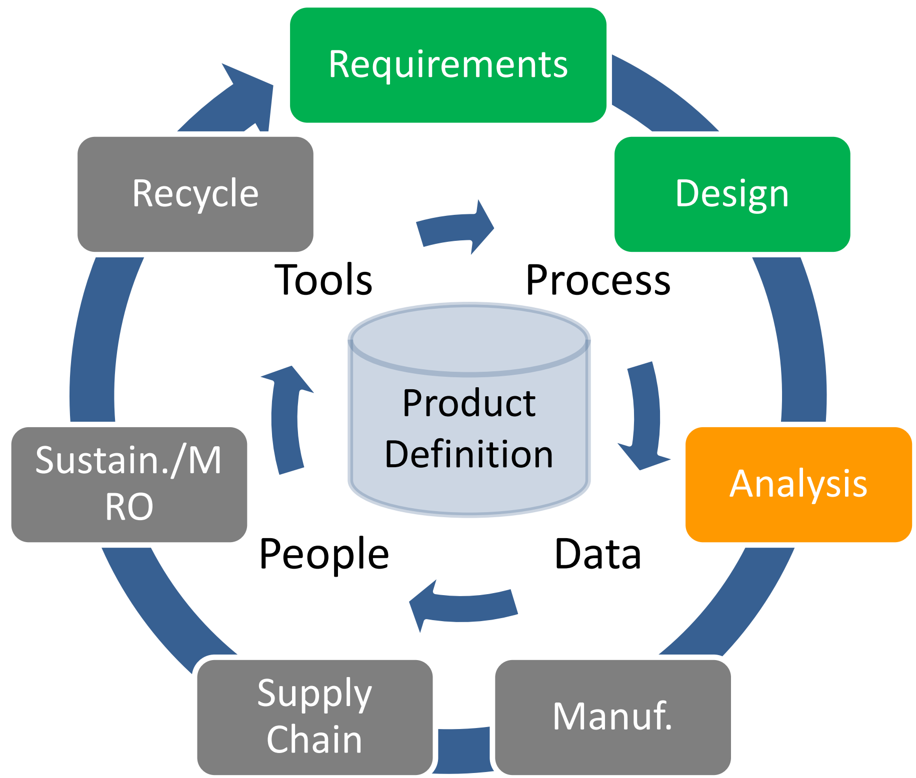
Science of Integration

- Current research
  - Requirements Management
  - Process Representation
  - Design Representation (partial)

- More complete lifecycle representations
  - Model-based definition: shape, behavior, and context
  - Connect to simulation and analysis tools

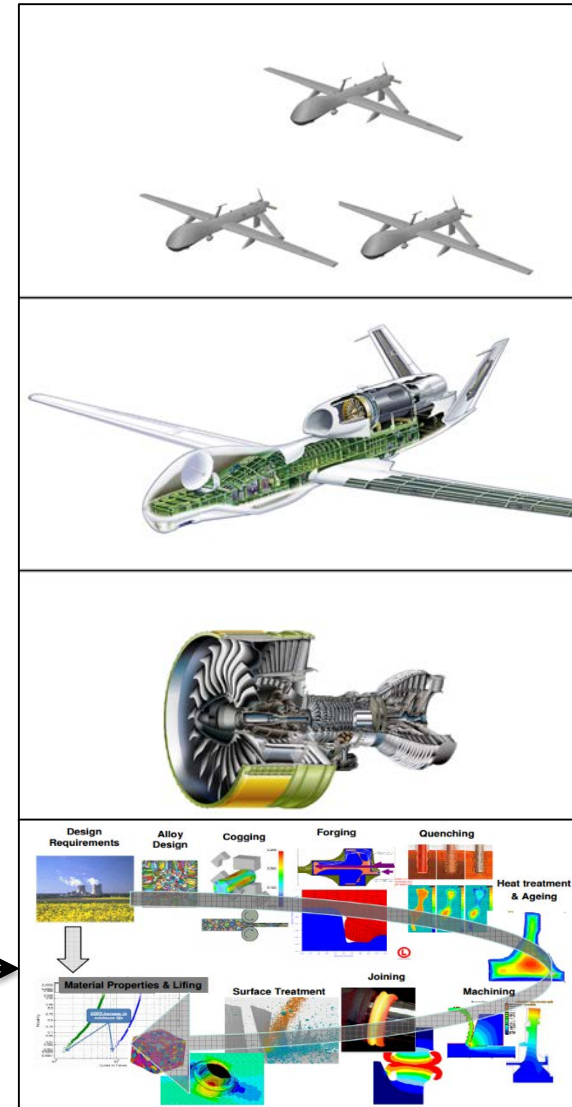


*The PLM Circle**

** Nate Hartman, Director, Purdue Center for Product Life Cycle Management*

Example: Integration Across Hierarchy

- Decisions on integration exist at multiple levels (e.g., material-components-engine-aircraft)
  - Greater opportunity for innovation
  - Greater uncertainty
- More than optimization, need complexity-guided design space exploration
  - Operational profiles and design architectures
- MBSE methods to link design representations to metrics
  - Feed cost and manufacturing projections



Integrated Computational Materials Engineering (ICME)

Image source: Engine- http://www.cfmaeroengines.com/img/engines/CFM56-leap-engine.jpg; ICME- "Application of ICME to Turbine Engine Component Design Optimization" http://arc.aiaa.org/doi/abs/10.2514/6.2011-1738

MBSE-CAD Integration

System-of-Systems Model

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Aircraft System Model
- Point Performance
- Lifecycle Properties

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CAD/CAE
- Geometry
- Context
- Behavior

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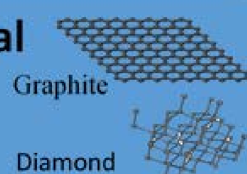
Material
- Structure
- Properties



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Aircraft OEM

Suppliers OEM

Suppliers

Related Key Publications

- Maheshwari, Apoorv. *Industrial Adoption of Model-Based Systems Engineering: Challenges and Strategies.* Diss. PURDUE UNIVERSITY, 2015.

- Bonanne, Kevin H. *A Model-Based Approach to System-of-Systems Engineering via the Systems Modeling Language*. Diss. PURDUE UNIVERSITY, 2014.

- Maheshwari, Apoorv, C. Robert Kenley, and Daniel A. DeLaurentis. "Creating Executable Agent-Based Models Using SysML." *INCOSE International Symposium*. Vol. 25. No. 1. 2015.

25th Annual INCOSE International Symposium (IS2015)
Bellevue, WA, July 13 – July 16, 2015

Creating Executable Agent-Based Models Using SysML

Apoorv Maheshwari, C. Robert Kenley, and Daniel A. DeLaurentis

Purdue University

Application of Systems Engineering to Regulatory Compliance Activities

CASE STUDY

Objectives

- 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

- Reference Model for Infusion Pump

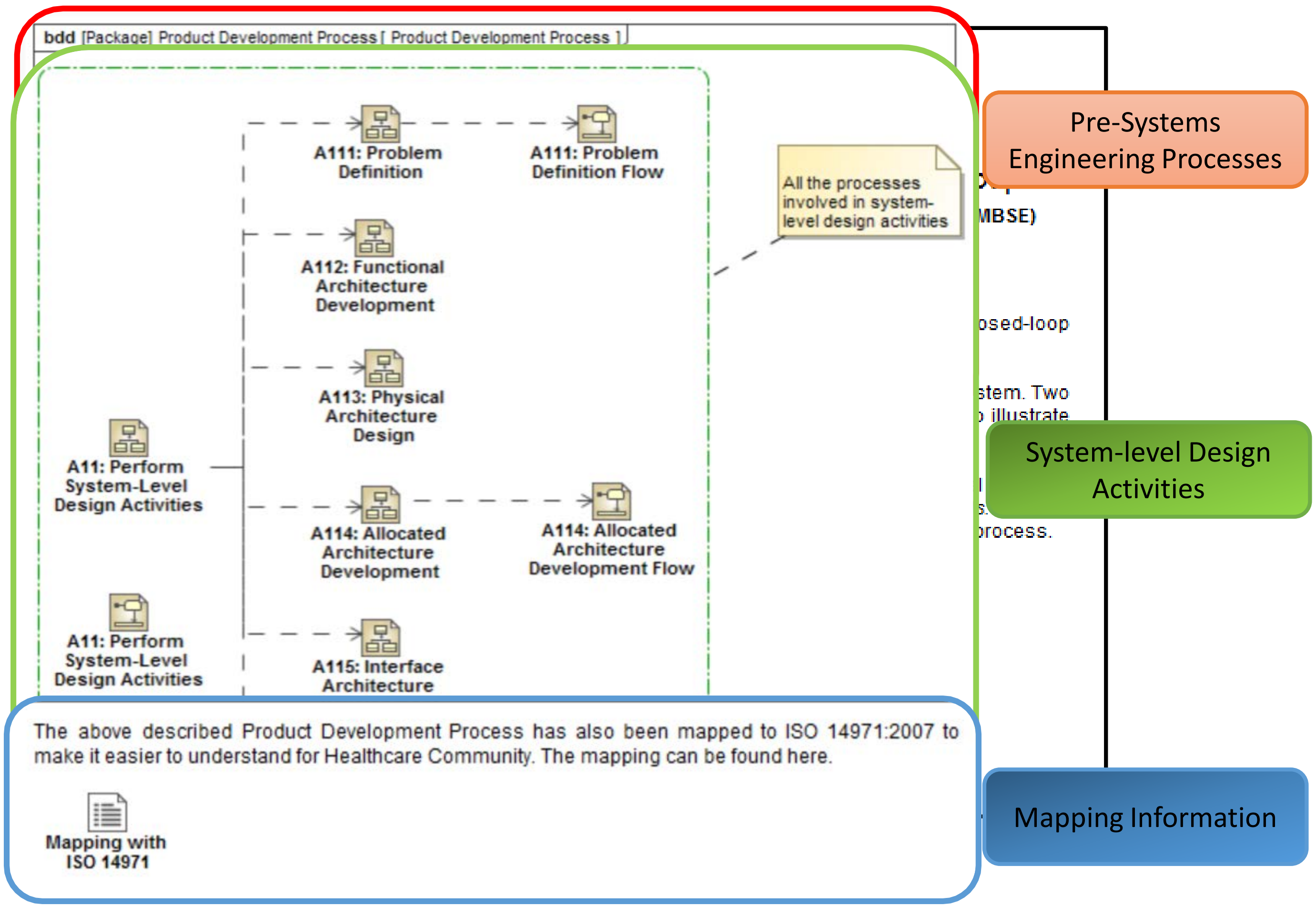
An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts.

Approach

- Adapted SE Process Diagrams from Buede's 2009 textbook, *The Engineering Design of Systems*

- Harmonized 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

Quick Demonstration



Mapping ISO 14971

14971	Buede's Diagrams		
Risk Analysis Step	**Produced by**	**Part of Artifact**	**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

- Regulatory information can be captured in the model-based form
- Additionally, it maps regulatory information to specific design activities (in the product lifecycle) making the design process more efficient and robust (with respect to the compliance activities)

- Differences in vernacular terminology
- Crucial to pick the right problem and define it right

Conclusions

How do we balance the evolution of model-based technologies with the policies and practices of the regulatory and certification communities?

- More such case studies to understand the advantages (and disadvantages) of using the model-based technologies from regulatory perspective
- Dissemination of SE knowledge

What is the role of standards and policy in the context of this discussion?

- More open/flexible to new concepts
- Interface standards for analysis tools

QUESTIONS?

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