WEBINAR

Applications of Systems Engineering in Healthcare

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Medical industry faces many challenges

- **Constant time pressure launching safe and effective products**
  - ~70% of medical products are delivered late
  - Time to define requirements has increased 29% and unplanned requirements churn has increased 81%
- **Shifting regulatory landscape**
  - E.g., SaMD, SiMD, MDR, IVDR, etc.
  - Cost of adherence and impact on business strategy
- **Quality issues represent significant financial impact**
  - Non-routine quality events cost the industry between $2.5 and $5 billion per year on average
  - On average, one company per year has seen a 10% drop in share price after a single, major quality event
- **Constant increasing complexity, particularly with SW**
  - Software has become the biggest cause of medical device recalls
  - E.g., The global artificial intelligence/machine learning medical device market was an estimated $4 billion in 2022 and is anticipated to reach $35.5 billion by 2032
  - E.g., Remote patient monitoring market was valued at $2.1 billion in 2022 and expected to reach $8.1 by 2030
  - Increasing risk of cybersecurity concerns
- **Heavy focus on acquisition and geographically distributed development teams**
  - E.g., The medical devices sector in Q2 2023 witnessed deals worth $33 billion, a growth of 42% compared to Q1 2023 and 87% compared to Q2 2022.

Sources: McKinsey Center for Government The Business Case for Medical Device Quality

What is the difference between a “Market Driven” and “Contract Driven” Industry?

Market Driven

Success = profits (faster to market with better value than the competition, at cost)

Many customers

Stakeholders = Internal to business

Budget and time negotiable with business

Requirements are a “tool” to be negotiated with marketing and product Mgt

Contract Driven

Success = satisfying the contract

One (or few) customers

Stakeholders = Internal to business

Budget and time fixed by contract

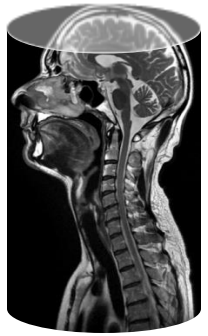
Requirements are a commitment to be customer needing formal change control

Systems Engineering: From Needs to Solutions

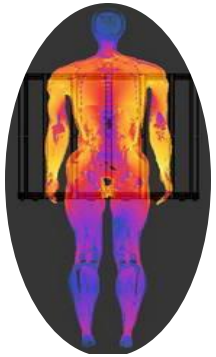
- The product seamlessly integrates into the customer's workflow and systems, reliably meets all their needs, and delights the customer,
- robust delivery of clear market differentiation (DFSS CTQs),
- technical scope/program work is clearly tied to market impact,
- technical risks are retired early and robustly,
- design decisions are identified and closed predictably (and stay closed),
- Implementations integrate easily,
- quality problems (when they exist) are found and resolved early, and
- creative ideas come from everyone and designs are optimized across organizational boundaries,
- institutional knowledge is available to everyone when and how they need it.

Winning Products happen when **Systems** ~~Engineers~~ **Thinkers** are effective

What is Systems Engineering at GEHC?

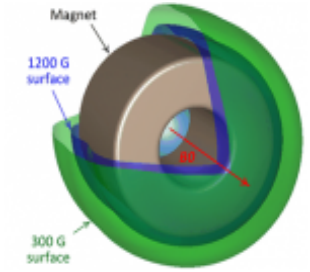


Essential Performance

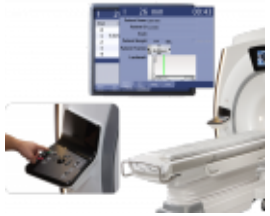


Safety & Regulatory

Usability

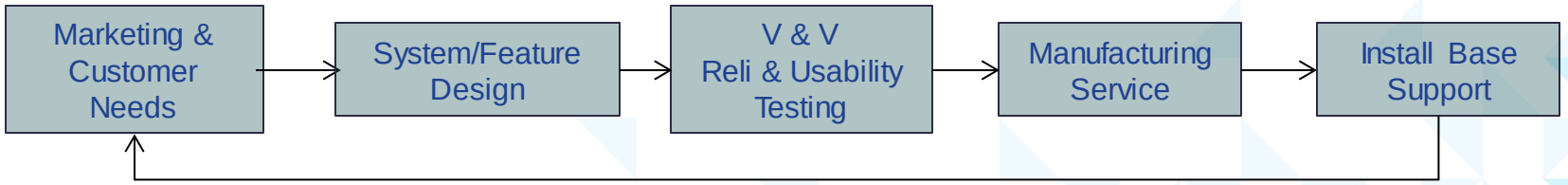


Performance



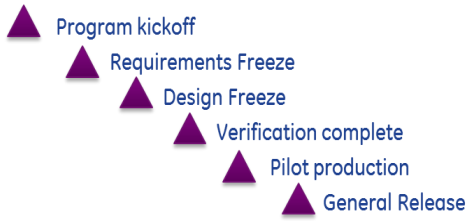
Reliability

Serviceability

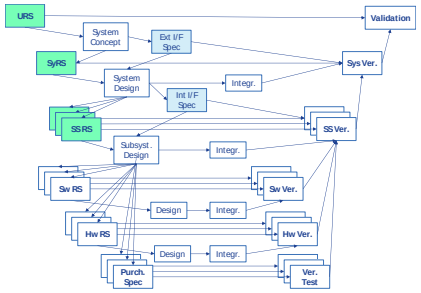


How is systems engineering organized at GEHC?

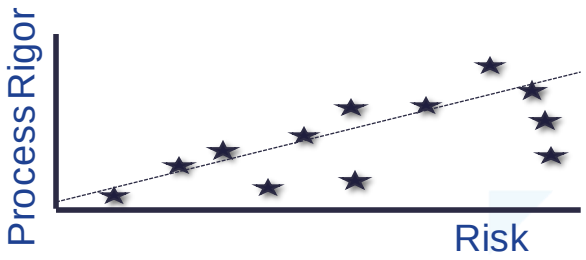
Common Program Milestones



Common System Lifecycle



Differing Risk Profile



Locations all over the world: organized by product line (and segment)

Size of the organization: Lots of Systems Engineers; but SE team sizes vary from <10 to 100+.

Scale of programs: <10 engineers to many hundreds. Less than a year duration to 3+ years, with basic technology developed over prior decade.

Organization: Product Centralized (SE GM) to decentralized (no SE managers)

How to customize SE in the Healthcare Industry

Attribute	Complexity Measure	Example Customization
Technical Risk	Hazard Analysis	Level of functional excellence rigor Rigor of technical design reviews
Team Experience	Subjective… Local senior engineers	Local level of SE functional rigor + independent technical reviews Level of signoff
Globally Distributed Team	# of sites Max time differential	Rigor and detail in the program communication plan; level of review
Team Size	# of Engineers	Rigor and detail in the program communication plan; level of review
Product and Technology Maturity	New technology vs. cost out	Level of ease of use/'quality' required Documentation rigor Senior engineer allocation

Example of Tailoring the SE Process

CT Scanner

~1000 System Requirements

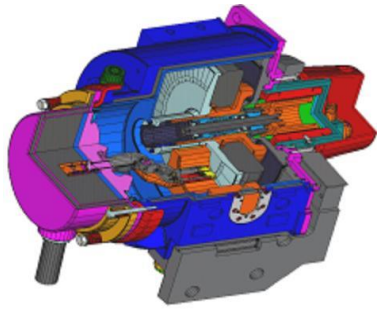
~30 options

~30 process critical parameters

Response

High Traceability, using Requirements Mgt Tools

XRay Tube



~30 Subsystem Requirements

~15 **very** process critical parameters

Response

Design for Six Sigma/Reliability, using Minitab and Reliasoft

Effective Systems Engineering Strategies

Back to the Basics

Focus on the Customer – Usability and Reliability

Scope Management

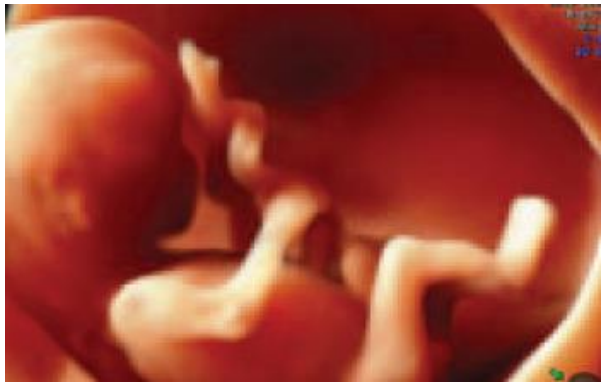
Decision Management

Technical Risk Management

Active Integration

First, Focus on the Customer: Usability & Reliability

Design for Usability



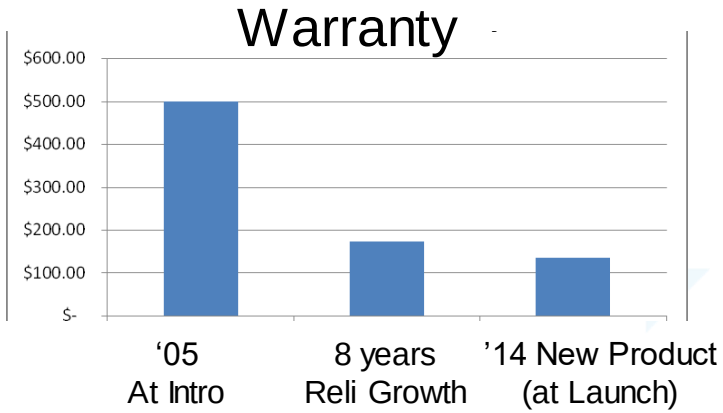
Usability “Work Instruction” (compliance to FDA regulation)

Formative & summative testing, including “expected user abuses”

Usability CoE (central resources for coaching, best practices and reviews)

Global Design Team

Design for Reliability



Formal six step reliability process

Formal reliability practitioner certification

Improved field data access and analytics

Central support (coaches, design tools, test equipment)

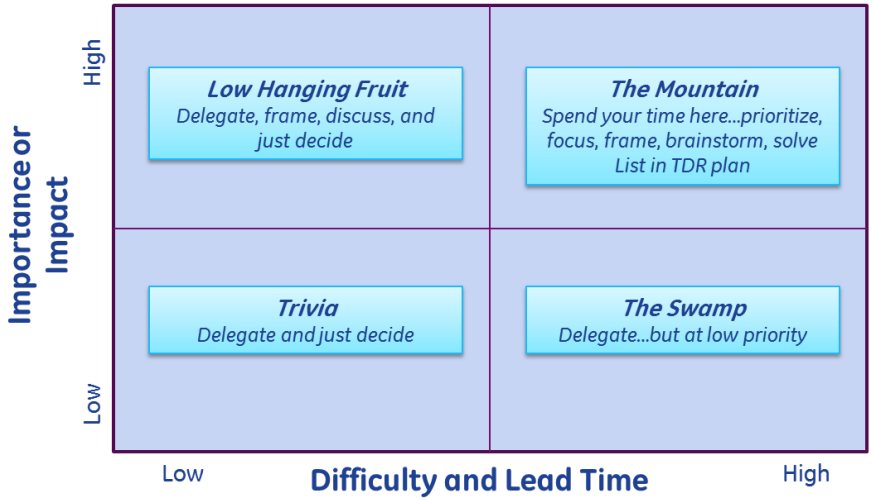
Manage Scope to Fit Time and Resources

Category	"IN" – Confirmed for NPI	To be confirmed for NPI at M1	Next-Gen MGPP (Rel 2 or Rel 3)
Core Applications	Std. Mammo (2D) DBT Stereotaxy CESM	CESM guided biopsy	DBT guided biopsy CE-DBT Implant breast imaging Install in Van (Mobile) Biopsy sample imaging Try & Buy / Pay-per use Apps
Simplification & VCP	Integrated 3D Gantry XFOV detector (w. static grid) Gantry ICV reduction Next-gen Needle guide (Stereo) Simplified paddles, mag-stand Simplified control station	Channel 70 tube Collimator re-design (Ag, LED, gantry) PMMA phantom replacement Relaxed bad pixel specs	
Patient Experience and Workflow	Patient-self compression Patient Manager - Improved workflow Simplified 2D 2D like at acquisition Shared annotation, Dose reports, Key notes Breast positioning assistance Faster DBT availability at review	2D/3D combo mode 3D display at acquisition IHE and non-IHE support Physicist report export / snapshot Integrated workflow for Non-Interventional Instant Messenger Radiologist and Tech Multi-vendor MG review at acquisition	Smaller tube-head Workflow protocols Breast support ambient temperature Recumbent for DBT / biopsy Multi-vendor (all mod) review at acquisition Faster 2D - sequence optimization Priors multi-modality review Automated +/- 15 Stereo pair Integrated workflow (Interventional & non- interventional) CESM DBT combo Prior data review at acquisition
Clinical confidence and IQ/dose optimization		Dose optimization of CESM HDR - Optimized dose/IQ for thick breasts ASIR for 2D/3D, MBIR for 3D Breast density assessment at acquisition	CESM improved algorithm
Infrastructure	Linux Neuvo data management Up to date on IT security (incl. DoD) Latest Insite	GPU integration capability SISU positioner SW 3D native viewer OnWatch Predictive services	Permanent or pluggable (power supply)

The Scope Ensures the **Clinical, Customer, and Business** aspects of the program

- **Manages 'features'**, more than specific requirements…tie priorities to the business case
- Includes **required, stretch, and dropped functions**
- Covers **all cross-functional business expectations** (service, MFG, regulatory…)
- Includes both quality goals, and engineering constraints (platforms, standards)

Manage Your Design Decisions…Delegation and Rigor



Decision Description	Importance /Impac	Complexity /Lead Tin	Impact Factor	Statu	Decision Made
Head Coil mounting position on the patient table.	High	Low	LHF	Closed	The head coil was placed to maximize the scan range (DOC1107876 - DRF - HNU Mounting for FF Patient Position).
Attenuation correction of phantoms.	High	High	Mountain	Closed	The scanner will automatically register pre-defined PIFAs to correct PET phantoms for attenuation. The PIFA will be saved on the scanner for > 1 day. User defined-PIFAs are out of scope.
HNU attenuation specification.	High	High	Mountain	Closed	The HNU attenuation specification is set at < 10%. This implies to use of EPP foam not a plastic former.
Fault Tolerant Recon	Low	High	Swamp	Closed	Fault Tolerant Recon is out of scope because of implementation effort (DOC1251440 - DRF - Fault Tolerant Recon vs Operation)
Fault Tolerant Operation	Low	High	Swamp	Closed	Fault Tolerant Operation is out of scope because of implementation effort (DOC1251440 - DRF - Fault Tolerant Recon vs Operation)
Out of Field Scatter	Low	High	Swamp	Closed	Out of Field Scatter is out of scope because it does not significantly improve the image quality and it has 12 months of effort.
Linear vs Switch Power Supplies for Detector	High	High	Mountain	WIP	
HNU coil matrix (6x6 or 8x8)	High	Low	LHF	Closed	The HNU coil matrix will be 8x8 because of a predicted 10% SNR improvement.
VQC Algorithm Implementation (MR or PET SW)	High	High	Mountain	Closed	The VQC Algorithm will be implemented in PET using 4 degrees of freedom because this is considered sufficient..
MR Events Syncronized with PET Events	High	Low	LHF	Closed	The MR events will be syncronized with the PET events by inserting MR scan start and stop in the PET list mode.
Editing anatomical boundaries	Low	Low	Trivia	Closed	The user will/will not be able to view/edit anatomical boundaries in retro recon
PET Detector Leak Detection	High	Low	LHF	Closed	There will be a leak detection sensor (see DOC1142256 - DRF - Leak Detection)
CMA Removal	High	Low	LHF	Closed	The CMA will not be quick removal. The CMA will be able to be removed by the customer.
Randoms Correction for high count rate studies.	Low	Low	Trivia	Closed	Out of scope.

The critical decisions are listed…

- Any decision gating team productivity is listed…the team agrees to the list and priority
- The **decisions listed are truly decisions**, not just topics (there are **options** to choose between with **decision criteria** which guide the down selection)

The proper level of attention is applied to each decision

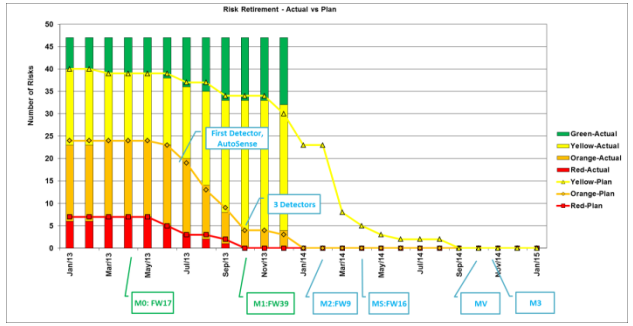
- **Complex, important decisions** have a decision plan which includes **stakeholder analysis and pre-briefings** to ensure consensus and decision buy-in
- Simple tracker (excel) to ensure **focus and execution** and **publicly record decisions**

Manage Technical Risk

Assess Risk Classes

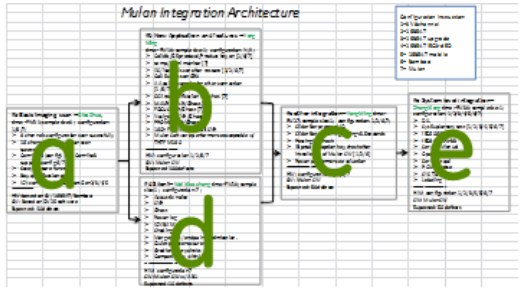
Probability Impact	5. High	4. Significant	3. Moderate	2. Minor	1. Low
5.High	25	20	15	10	5
4. Significant	20	16	12	8	4
3. Moderate	15	12	9	6	3
2. Minor	10	8	6	4	2
1. Low	5	4	3	2	1

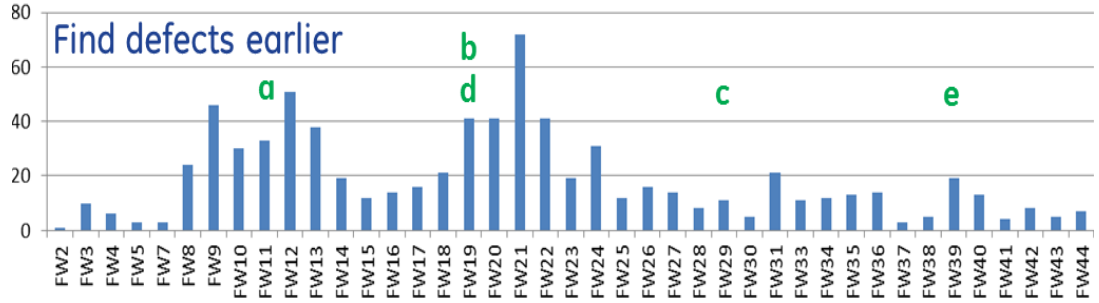
Annotated Risk Waterfall



- The Technical Risk Management Plan covers all cross-functional scope
- Focus on risk classes, not a “score”; Simple criteria on risk classes tied to business tollgates
- Guidelines (objective criteria) for assessing probability and impact
- Technical risks have an appropriate level of senior technical ownership & review
- There are clear completion (feasibility) criteria for each technical risk, with incremental steps (reviews, tests, repeatability, customer testing, …) tied to program plans…with contingency plans as appropriate
- *Future: make the risk classes ‘asymmetric’…more focus on impact (black swans)*

Plan “Active” Integration





95% confidence at each integration step that **we are done**: ”ready for release”

Verification is an ongoing process throughout design & development.

- Strategic plan for minimal rework and regression testing
- **Each integration step is tested as though it were ready to ship**, with cross-functional involvement where appropriate**.**
- Defects are fixed promptly when found, so there is only a **small backlog of planned fixes.**

The goal of testing is to find problems.

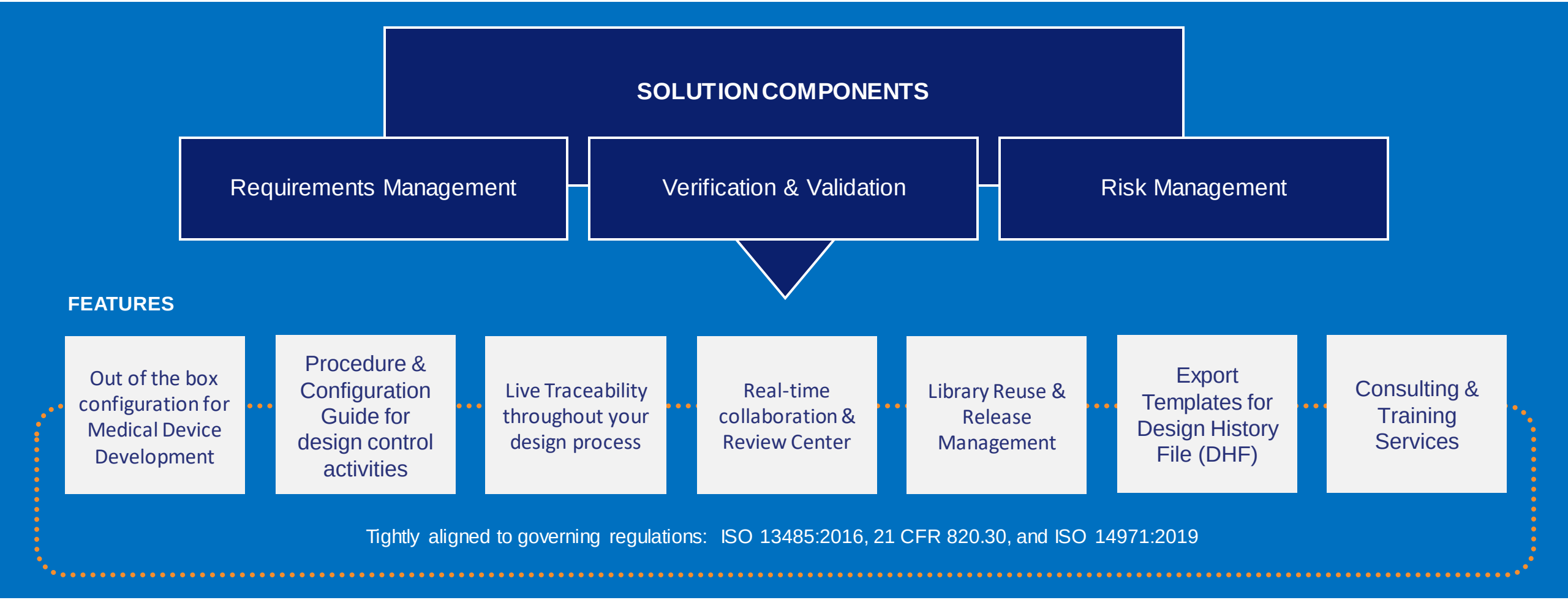
- A variety of methods and tools are used for performing verification throughout the program, not just testing of the final implementation. (Challenging testing, usability testing, reliability)

Future*: better integration with Agile philosophy, and better integration with use case testing and function verification…not just requirements traceability*

Conclusions

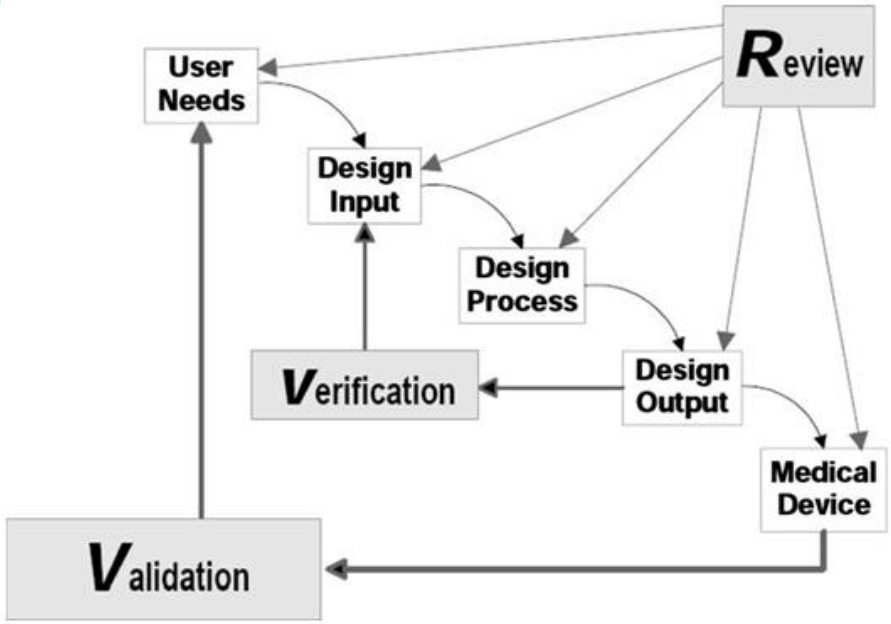
- Focusing on the basics (but at world class performance levels) generates high returns
- “Market Driven” business means focusing on competitive value creation and use cases more than “requirements”
- Ideal state seems to be a hybrid of Agile, Lean Startup, and “more traditional” systems approach

Jama Connect for Medical Device & Life Science Development

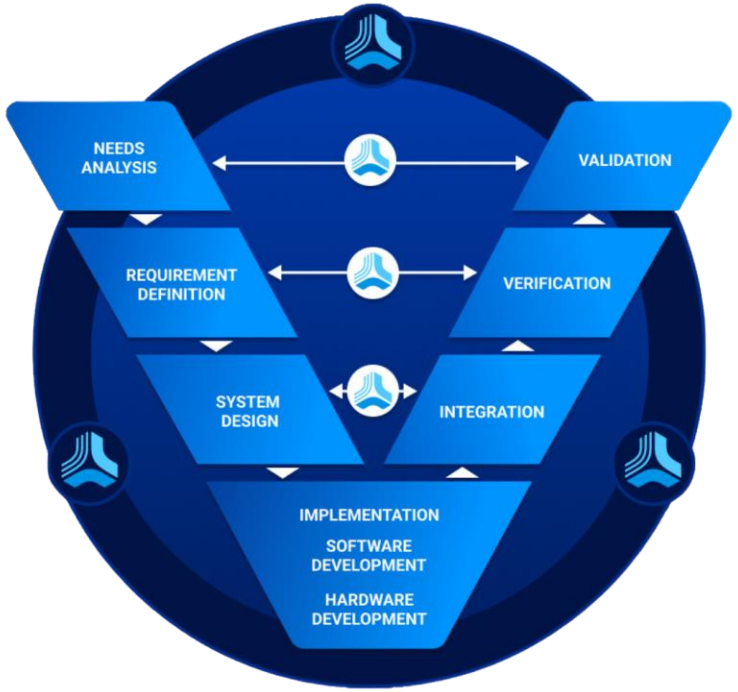


Flexible Solution Framework

COMMON MEDICAL AND LIFE SCIENCES DATA MODELS



FDA Waterfall



Systems Engineering V

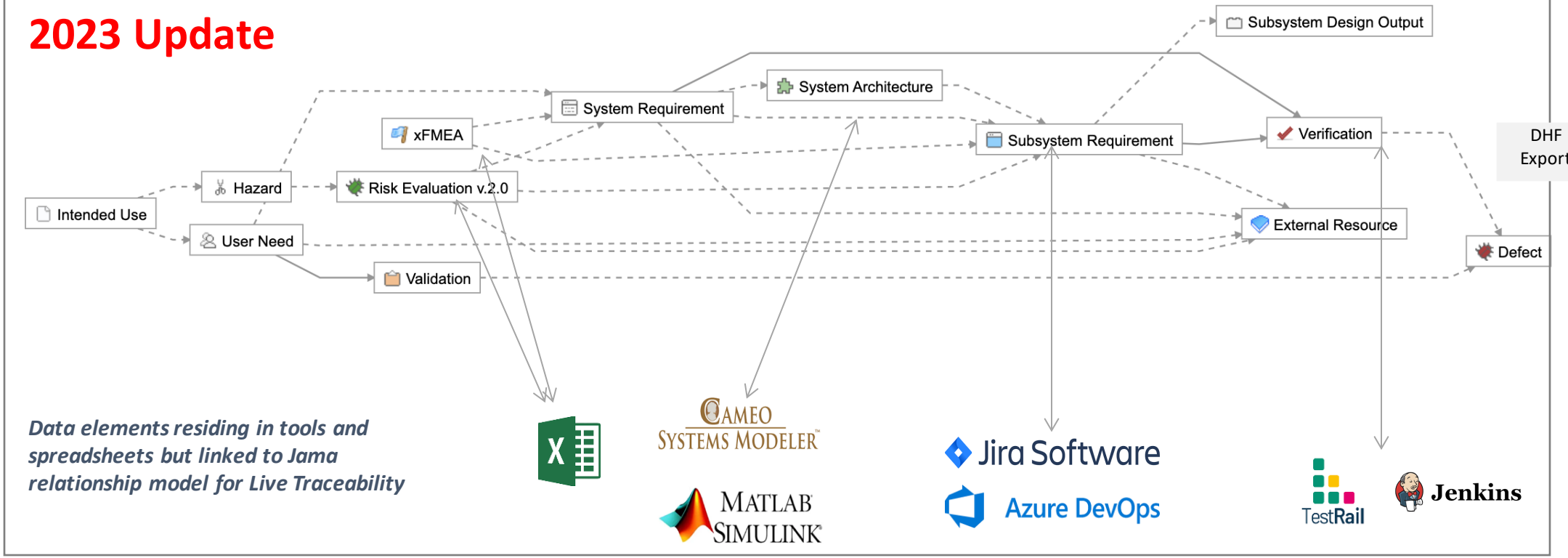
Agile Method

Product Development Process | Live Trace Across Best-of-Breed Tools

TRACEABILITY ENABLING **ISO 13485:2016, 21 CFR 820.30, ISO 14971:2019, IEC 62304** AND MORE

jama connect™ | Product Development Toolchain

2023 Update



Data elements residing in tools and spreadsheets but linked to Jama relationship model for Live Traceability

Critical, best-of-breed tools for traceability shown in this example. Competitive alternatives to those listed are also supported.

Updated Medical Solution Dataset

AVAILABLE IN AUGUST 2023

Overview & General Improvements

- Lookup Matrix Feature (Risk)
- Industry Standards Traceability use case
- New and updated reports templates
  - Design Traceability
  - Risk Management

New / Updated Solutions

- Software as Medical Device (SaMD)
- Design History File (DHF) Project Structure
- Research Use Only (RUO) solution
  - RUO → IVD Transition
- Self-Guided Onboarding Framework

Contact Jama Software to learn more

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Q&A

THANK YOU