

Best Practices When Building AI-based Medical Devices at Scale



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Developing
Regulated
Software is Hard

Deploying at Scale is Hard

**Developing & Deploying
Regulated Software at Scale
is Almost Impossible**

Background and Experience



Built tools like
Mathematica,
Wolfram|Alpha, and the
Wolfram Cloud

Studied and worked at



M.S. EECS
MBA



Princeton Plasma Physics
Laboratory (PPPL)

Visiting
Researcher

CEO and Founder of Ketryx

Empowering teams to
build safe and reliable
software



Former head of AI/ML for
Amgen's combination
product division

Committee Member






AAMI TIR 115
Medical Device
Cloud

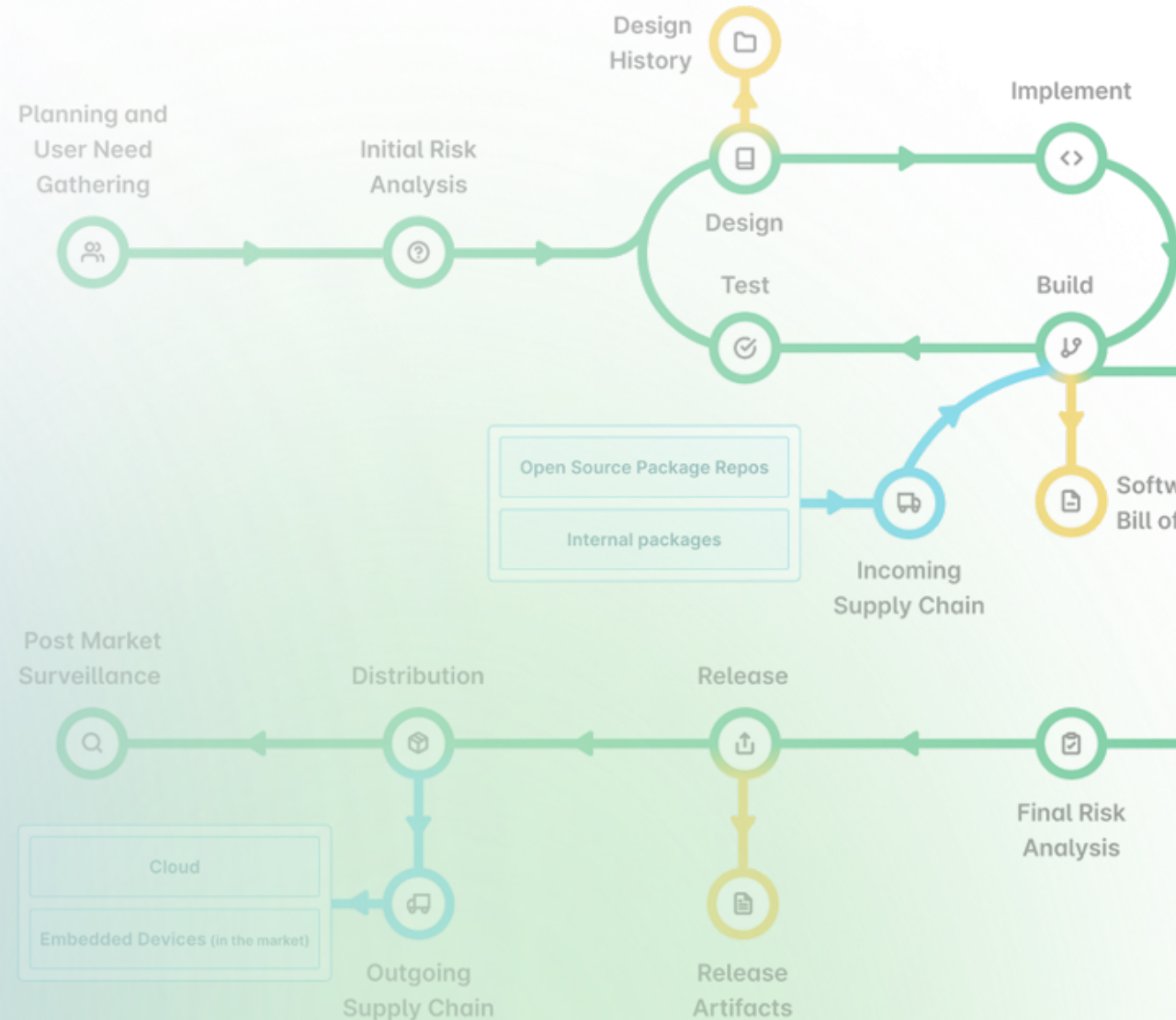
Former Platoon Sergeant

Israel Defense
Forces



The Current State of AI/ML System Validating

- 
Design Controls are difficult to manage in a CI/CD environment
- 
Teams perform an immense amount of manual work
- 
Current change management tools and workflows are an obstacle to change



The Current Challenges of AI/ML System Validating

 Regulation/Standard compliance

 Regional nature of compliance

 Complexity^N

Validated Application

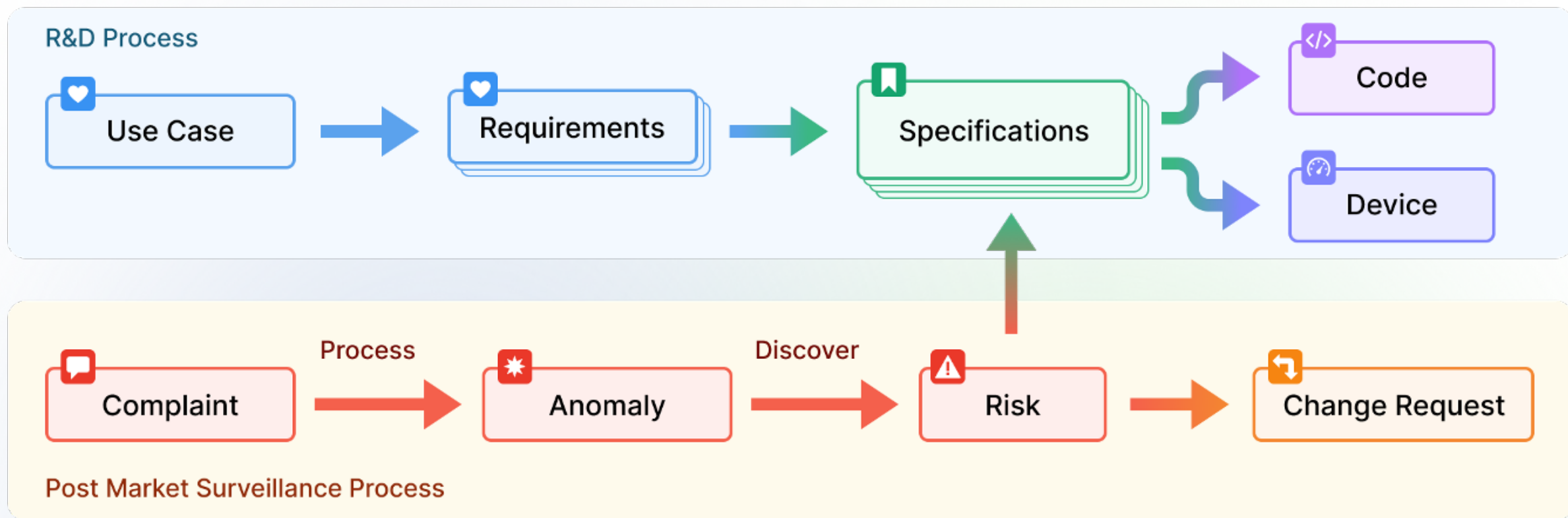
Software Supply Chain

Application Configuration

Validated Infrastructure (NPS)

Infrastructure Configuration

Decoupling Ideas to Identify and Mitigate Risk



The Regulated Development Journey



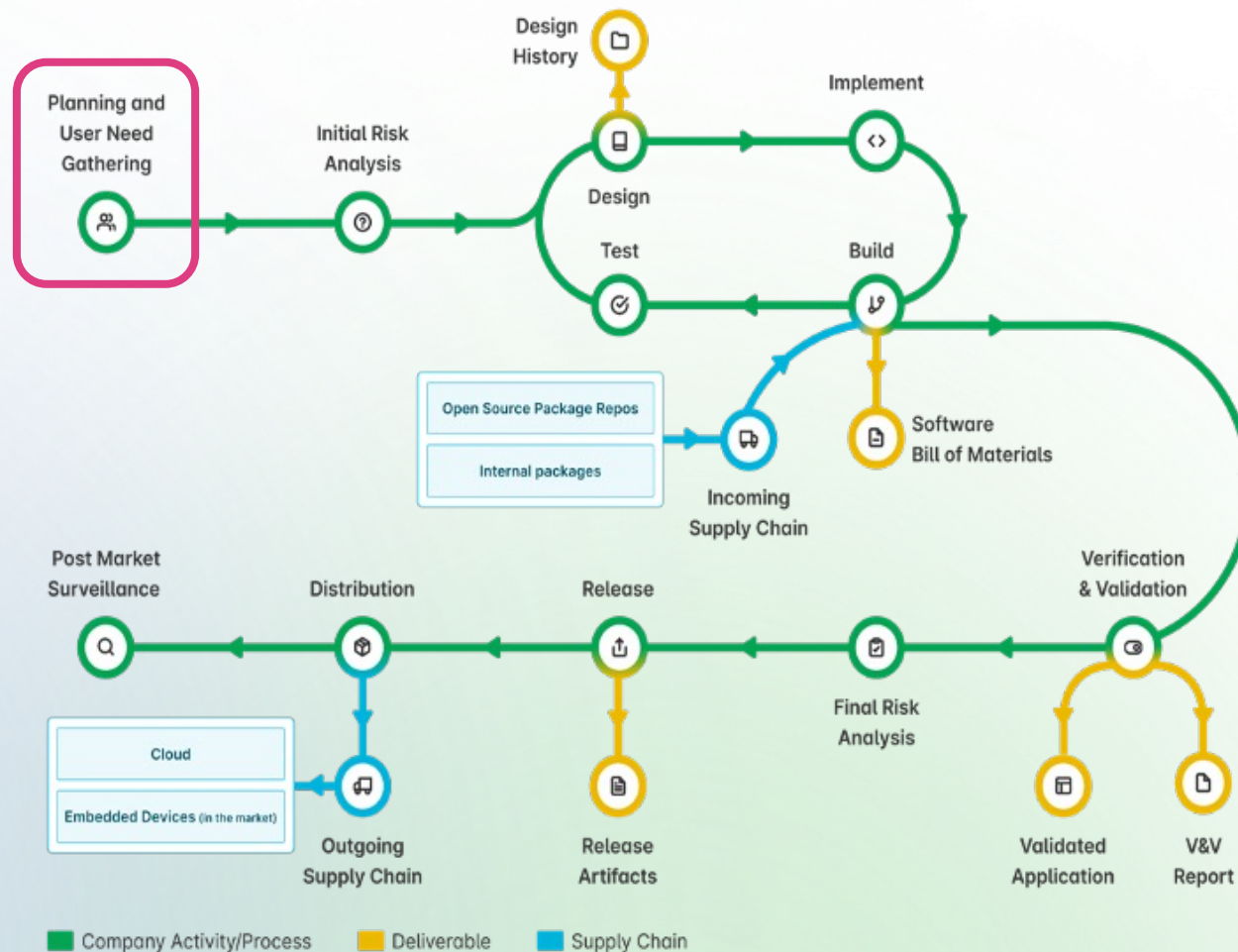
The Regulated Development Journey

Planning

Plan for the long term

Configure systems for purpose

Understand NPS validation burden



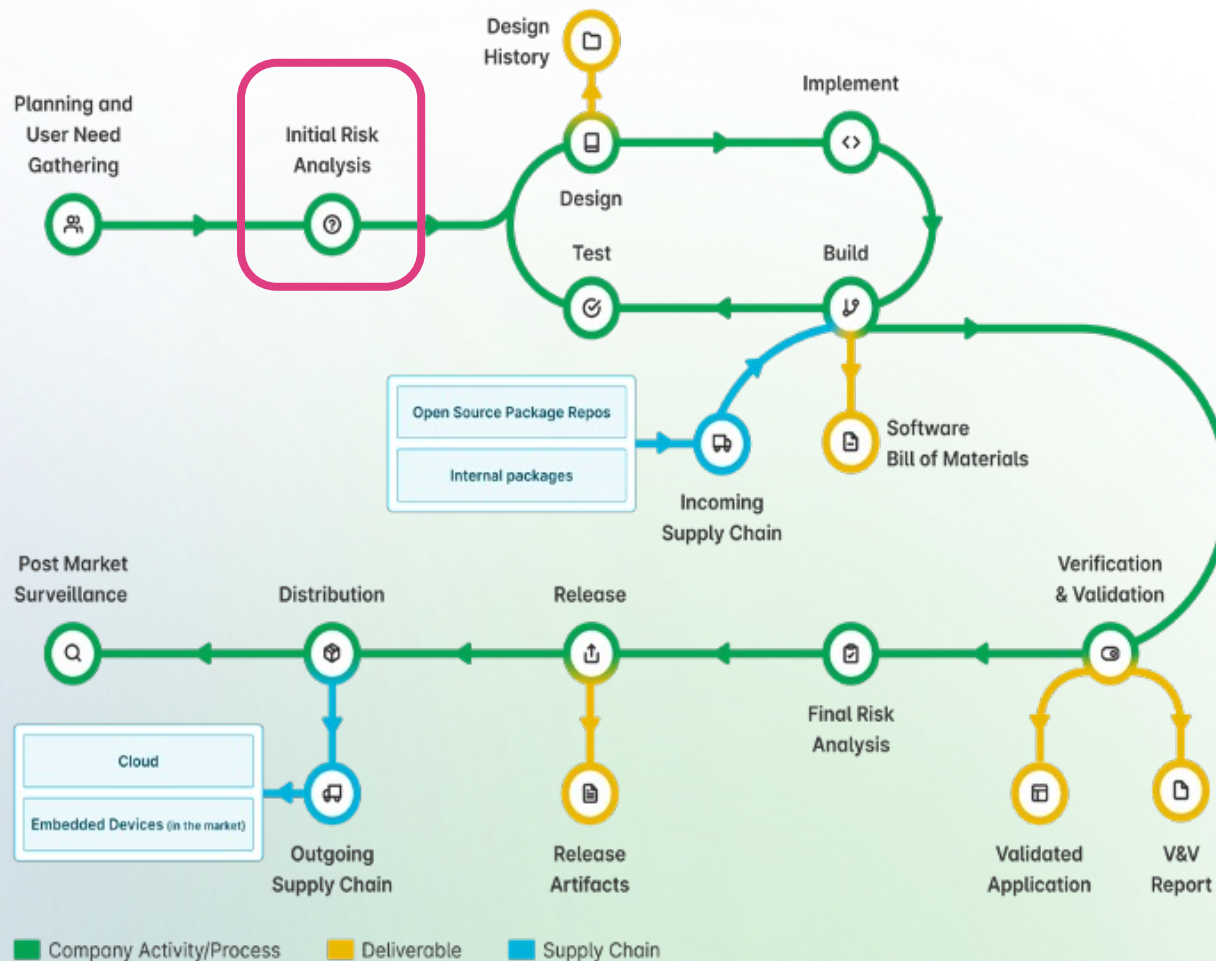
The Regulated Development Journey

Risk Analysis

Risk Analysis (ISO 14971)

Risk Controls should be tracked automatically

Risk based software development



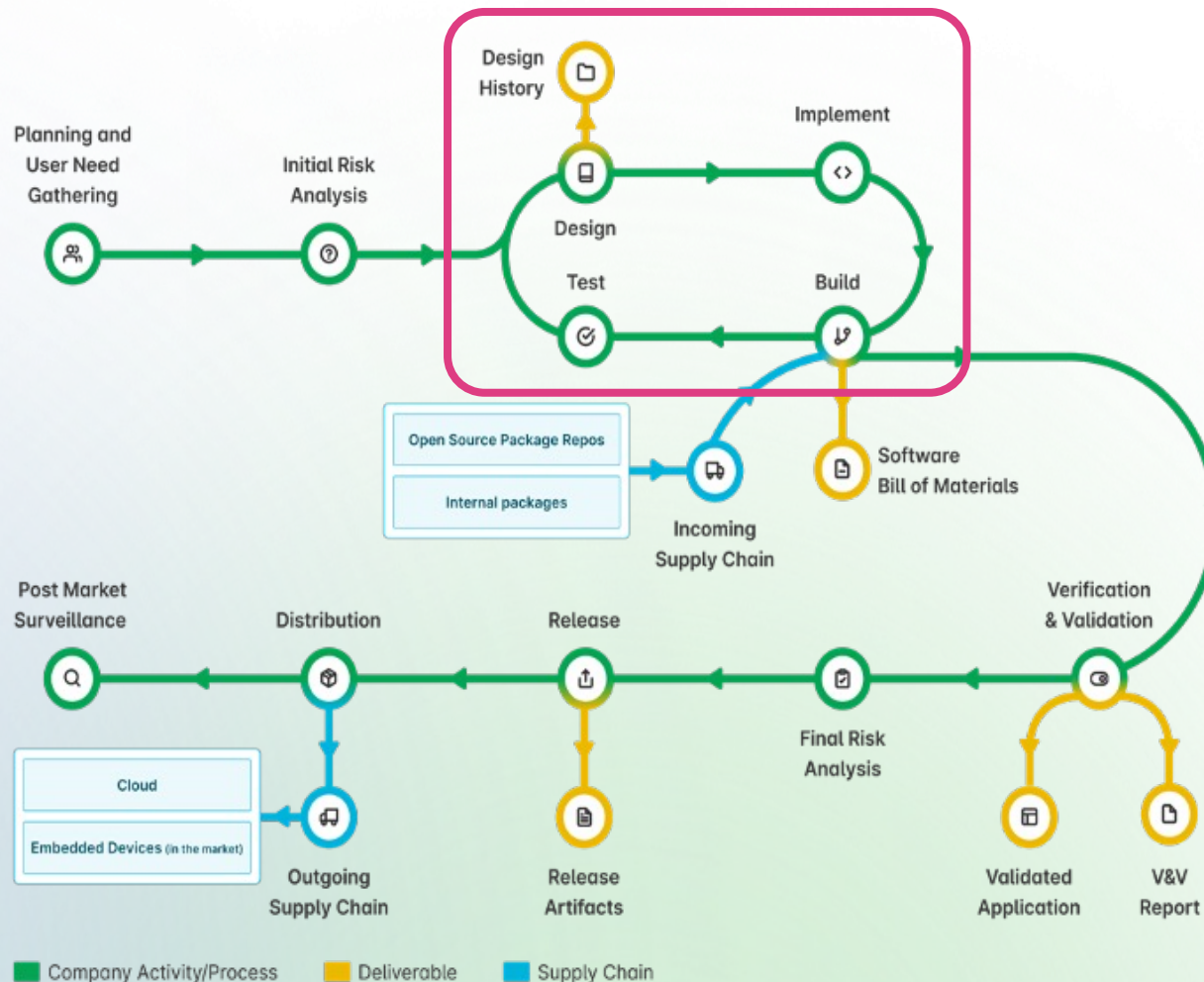
The Regulated Development Journey

Design & Development

Use the tools you prefer

Move fast

Utilize traceability to build complex systems



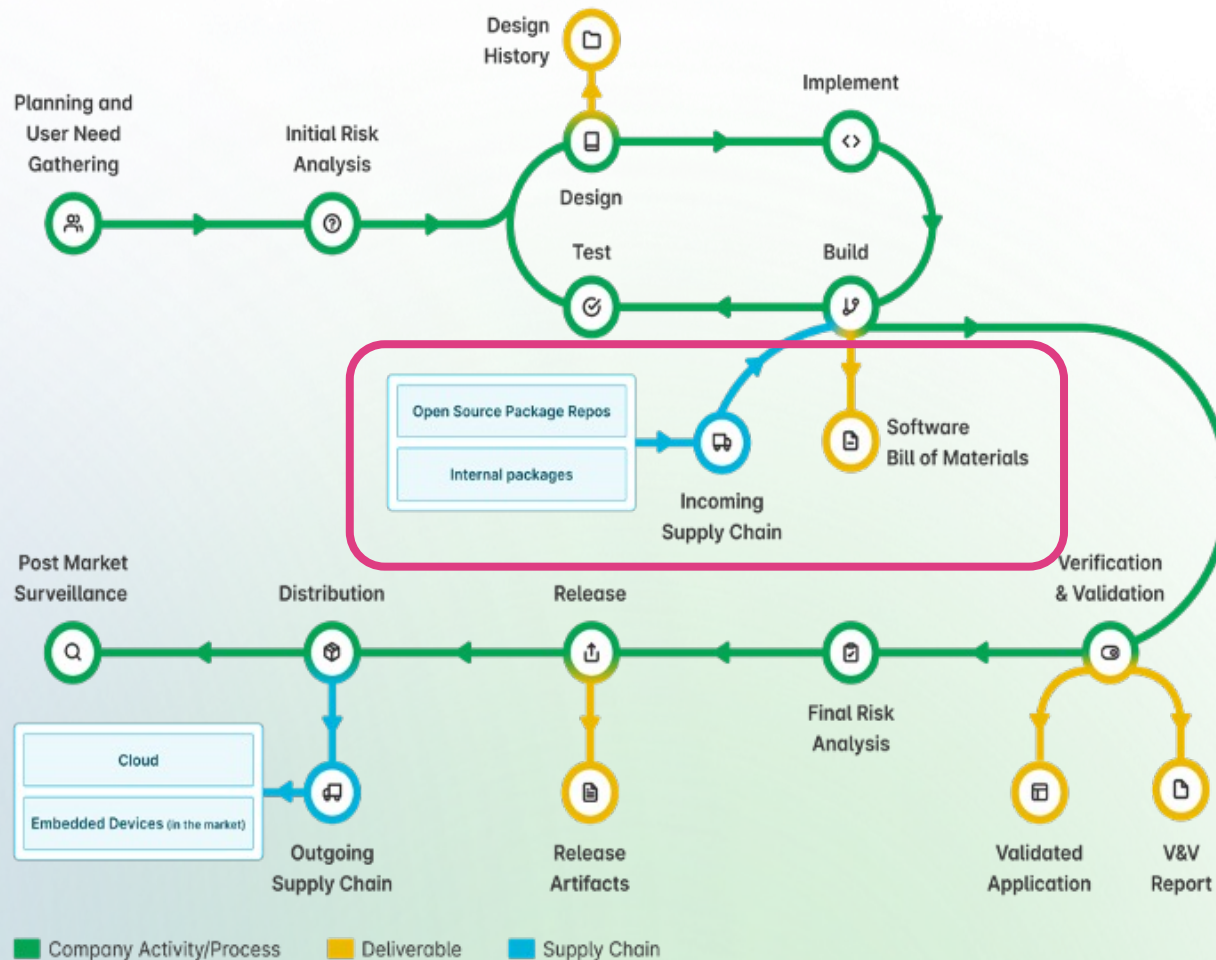
The Regulated Development Journey

Software Supply Chain

SOUP & Risk

CI/CD

Cloud Infrastructure and APIs



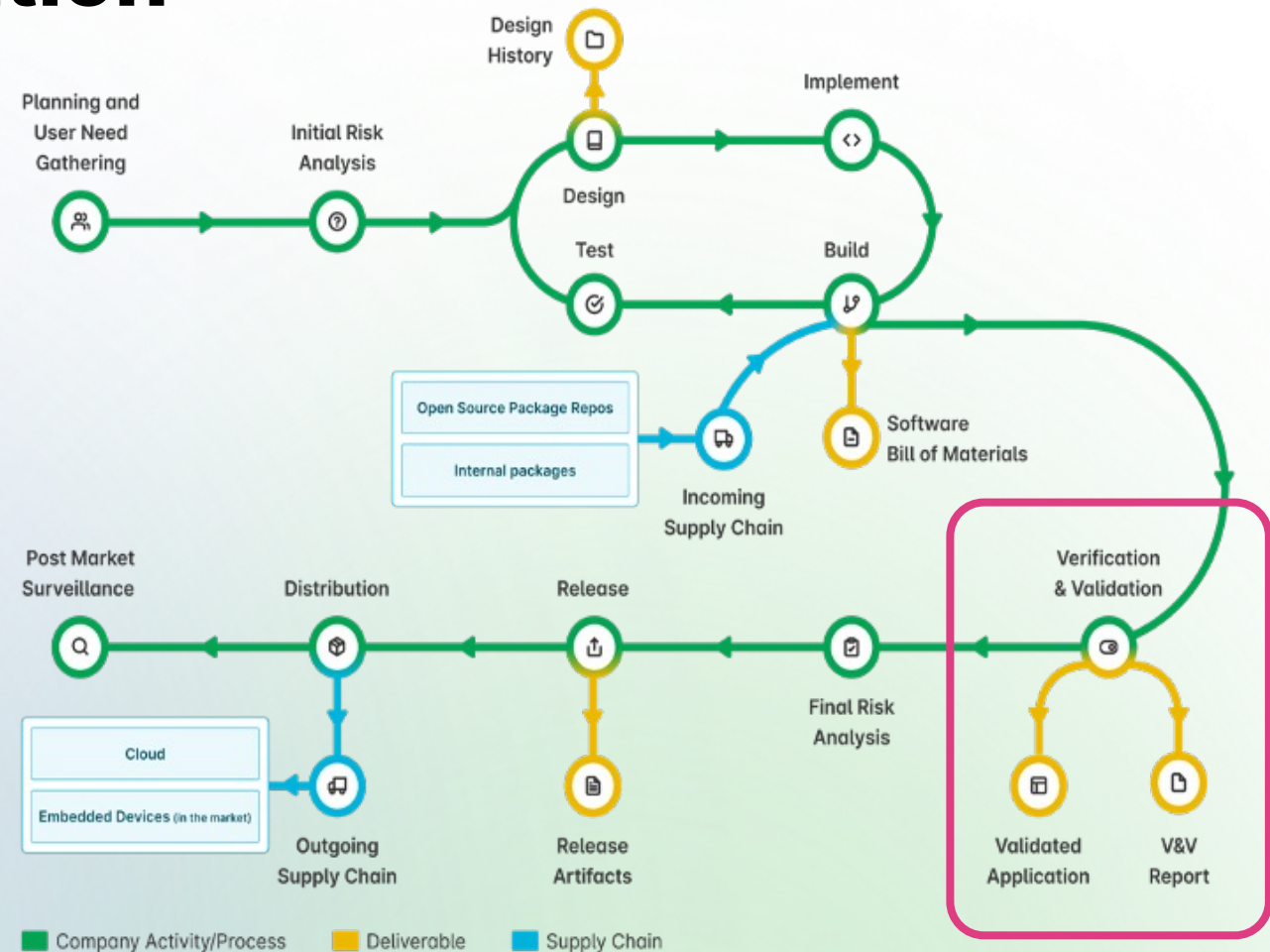
The Regulated Development Journey

Verification and Validation

Computationally enforce
V&V acceptance criteria

Generate documentation
from source systems

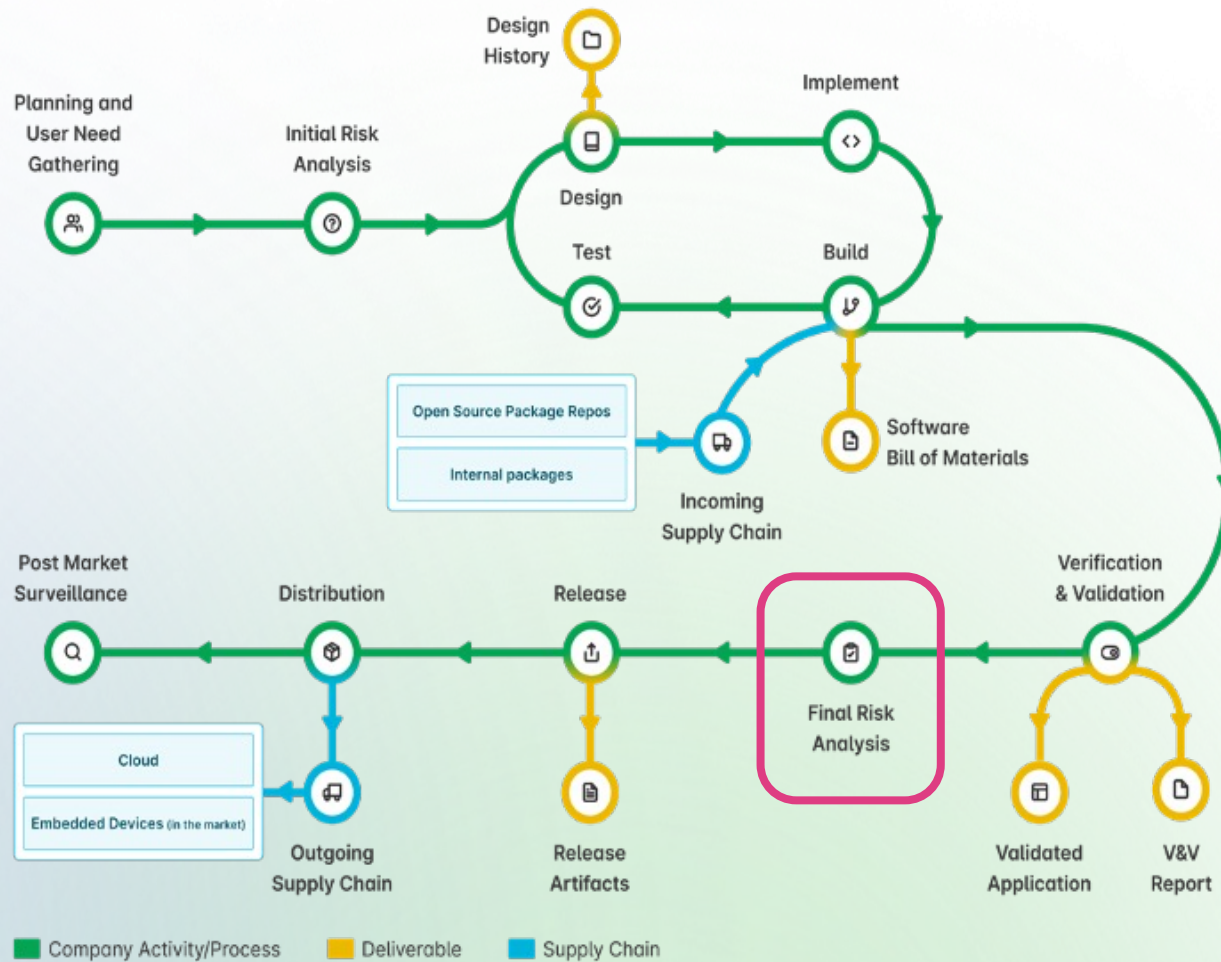
Leverage traceability
throughout development
cycle



The Regulated Development Journey

Final Risk Analysis

Implements gates into computer systems for final risk analysis

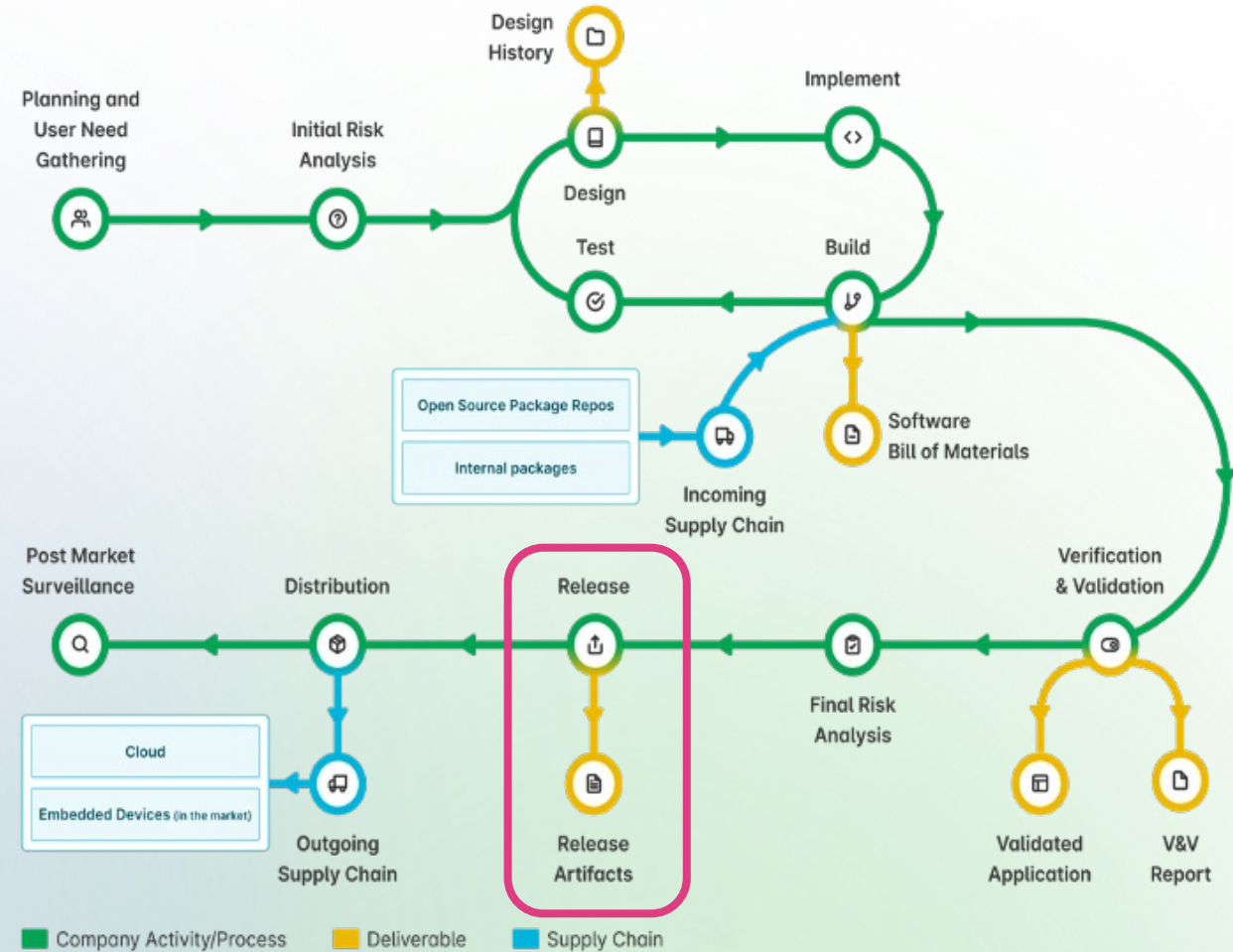


The Regulated Development Journey

Release

Create artifacts

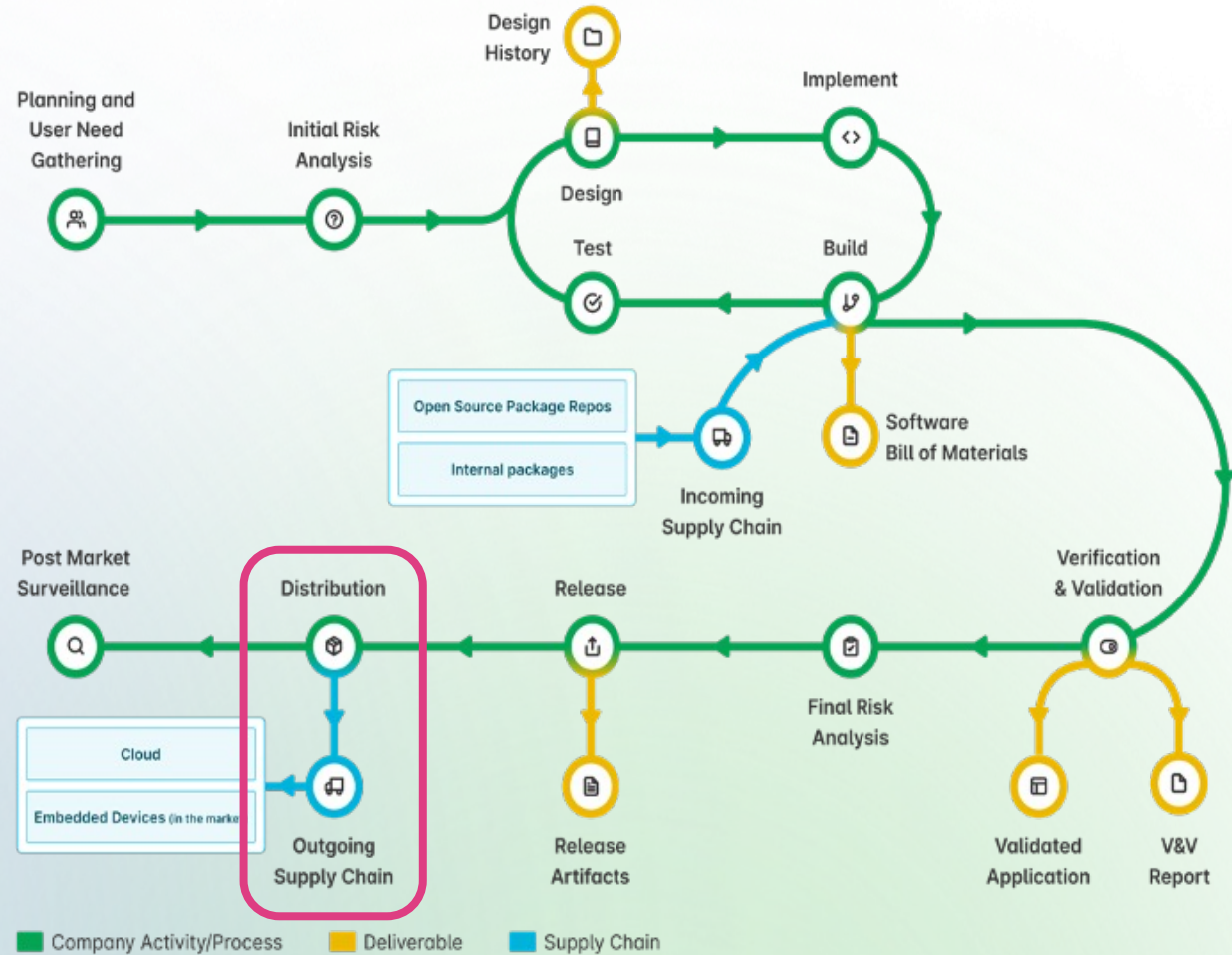
Connect to CI/CD



The Regulated AI Development Journey

Cloud

Devices in the field

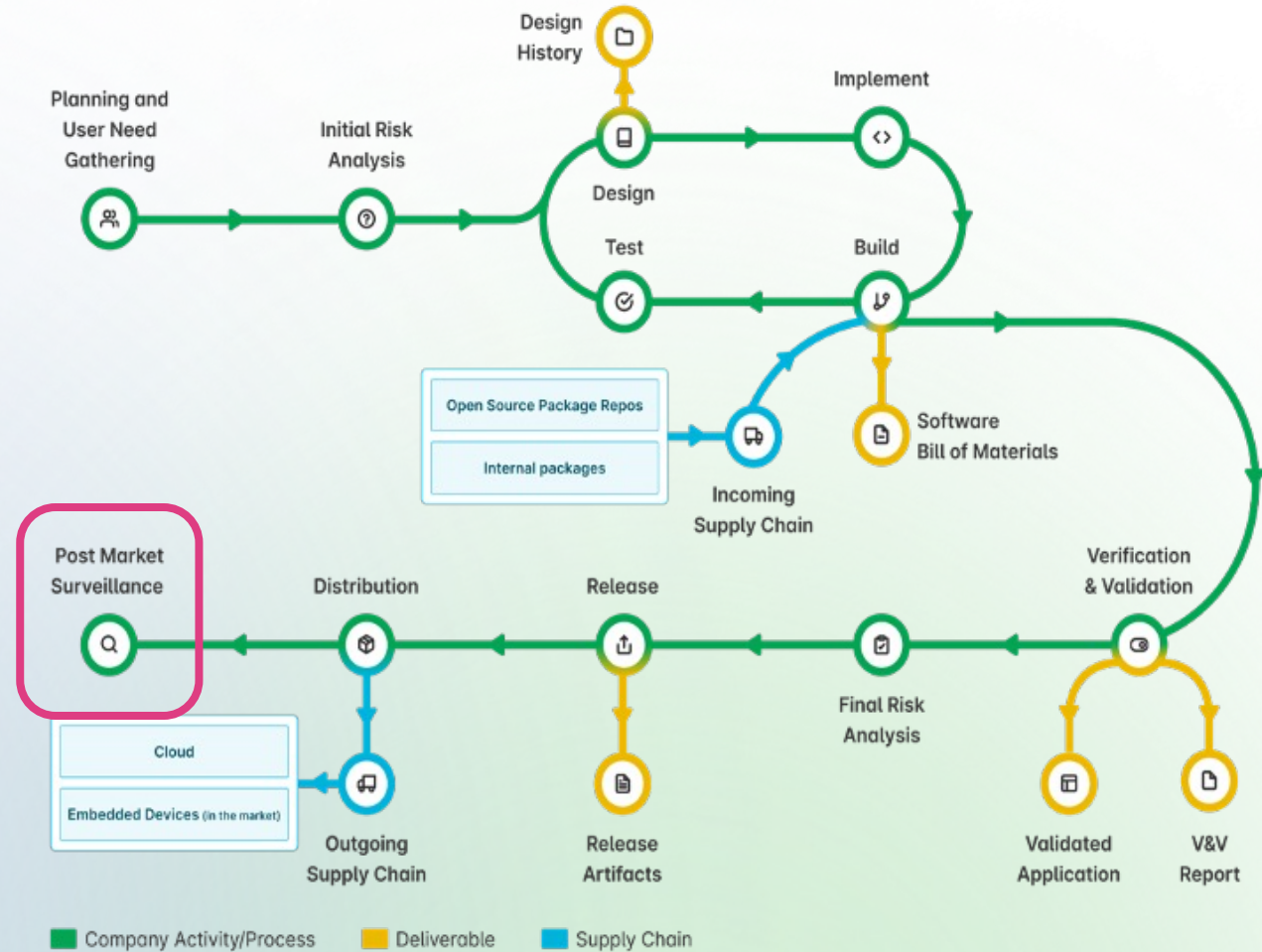


Post Market Surveillance

Speed

Granularity

Agility



What if you could build any system?

The Simple AI-driven Combination Product

1000s

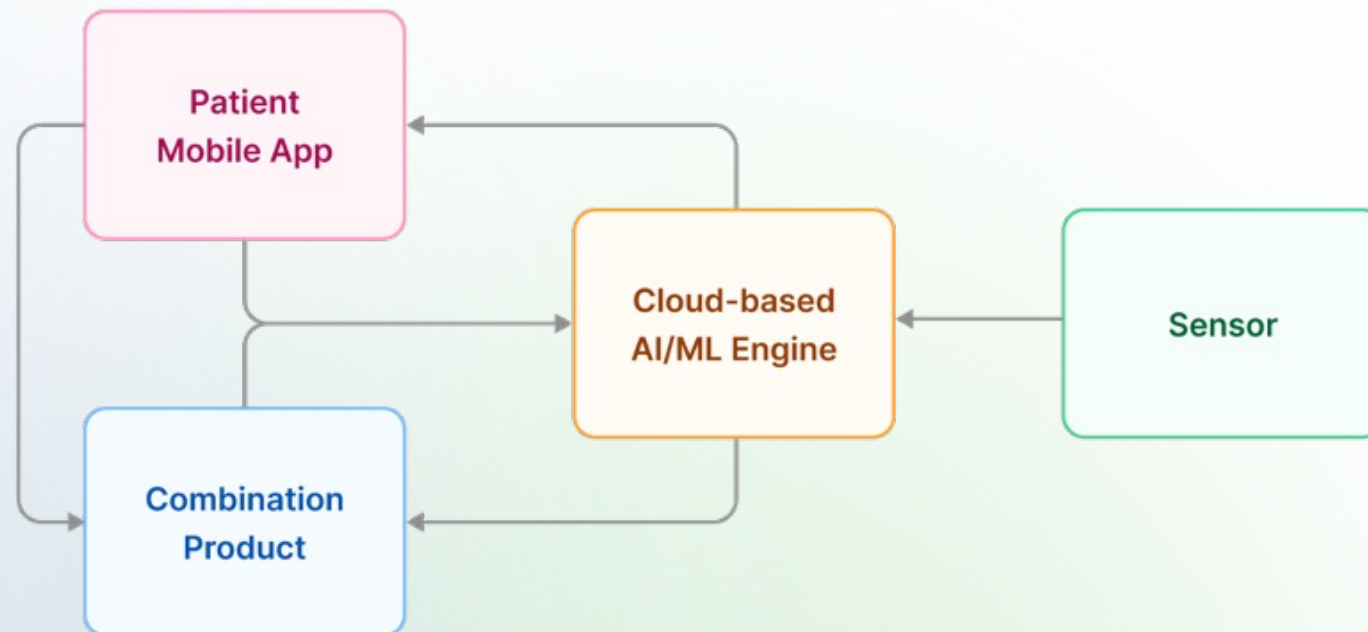
of design controls

1000s

of open source dependencies

100s

of people building it



We Want to Talk to Software Teams



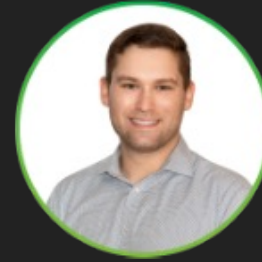
Software as a
Medical Device



Software in a
Medical Device



Existing Center
of Excellence



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