Product Development under a Quality Management System for a Medical Device Company

CIS

December 7. 2023

Speaker Introduction

David Saunders

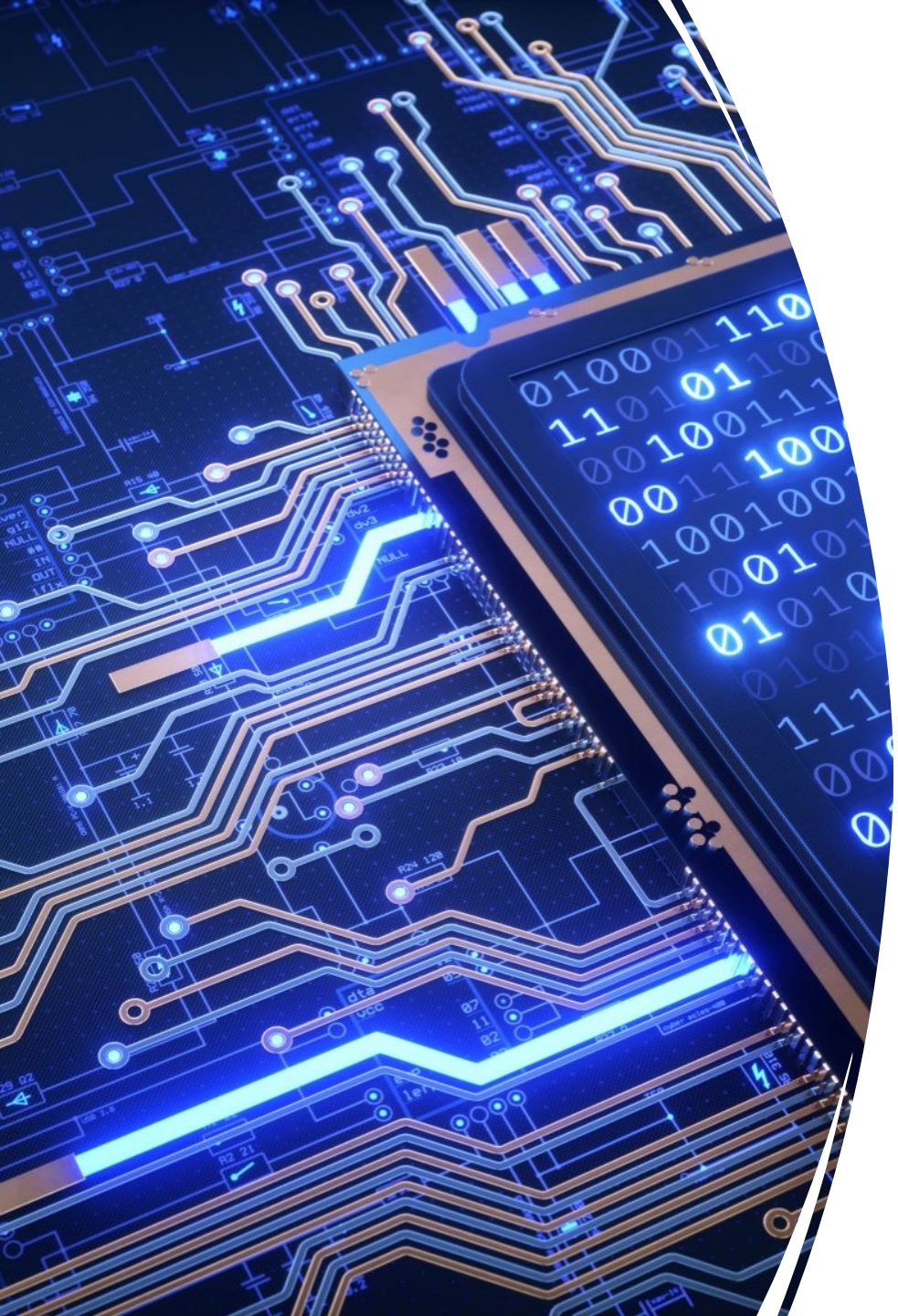
- CTO/Co-Founder Galen Robotics
- Bell Labs Research Manager
- Lord High Executioner

What is a Medical Device Quality Management System?

A Quality Management System (QMS) documents the processes used by a medical device manufacturer to plan, design, test, manufacture, and support medical devices used by the public to diagnose or treat medical conditions.

Governs the activities performed from the decision to create a medical device (i.e., after it has left the R&D Lab) through to the last sale and support task.

This presentation will focus on the QMS activities needed to get the product to market (i.e., Product Development Activities)

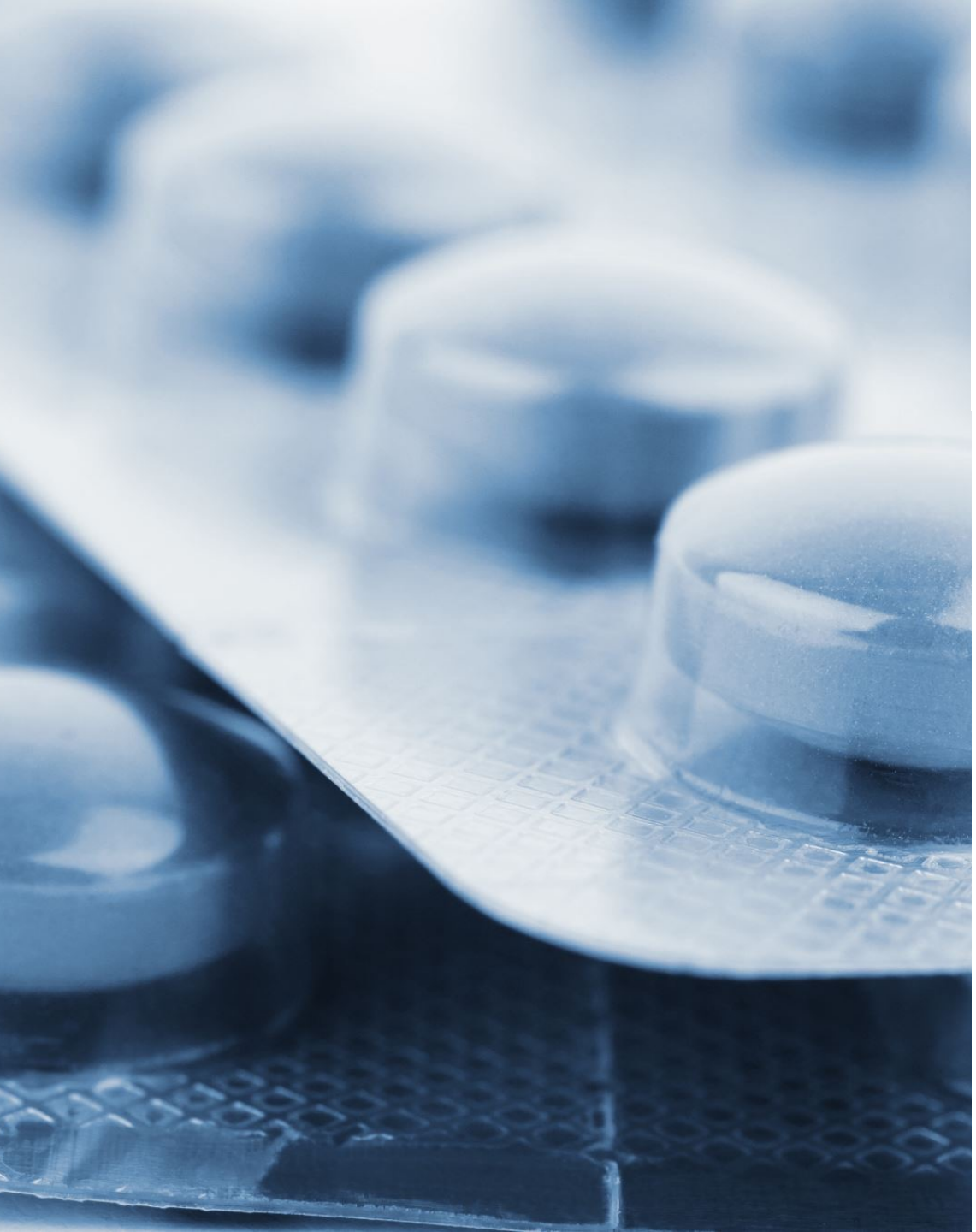


QMS Components Used in the Product Development Process

As previously mentioned, not all aspects of a company QMS will be used during the device product development process. Specifically, the following portions will be used:

- **Document Control and Change Management** – To control the creation, review, and approval of project deliverables

- **Risk Management** – To identify potentially hazardous situations, components, processes that would adversely impact the use of the device, and to identify mitigation(s) to reduce the impact of those risks



Why is a QMS and a Product Development Process Required for Medical Device Development?

The FDA and other world-wide regulatory bodies require medical device companies to have a QMS before selling medical devices.

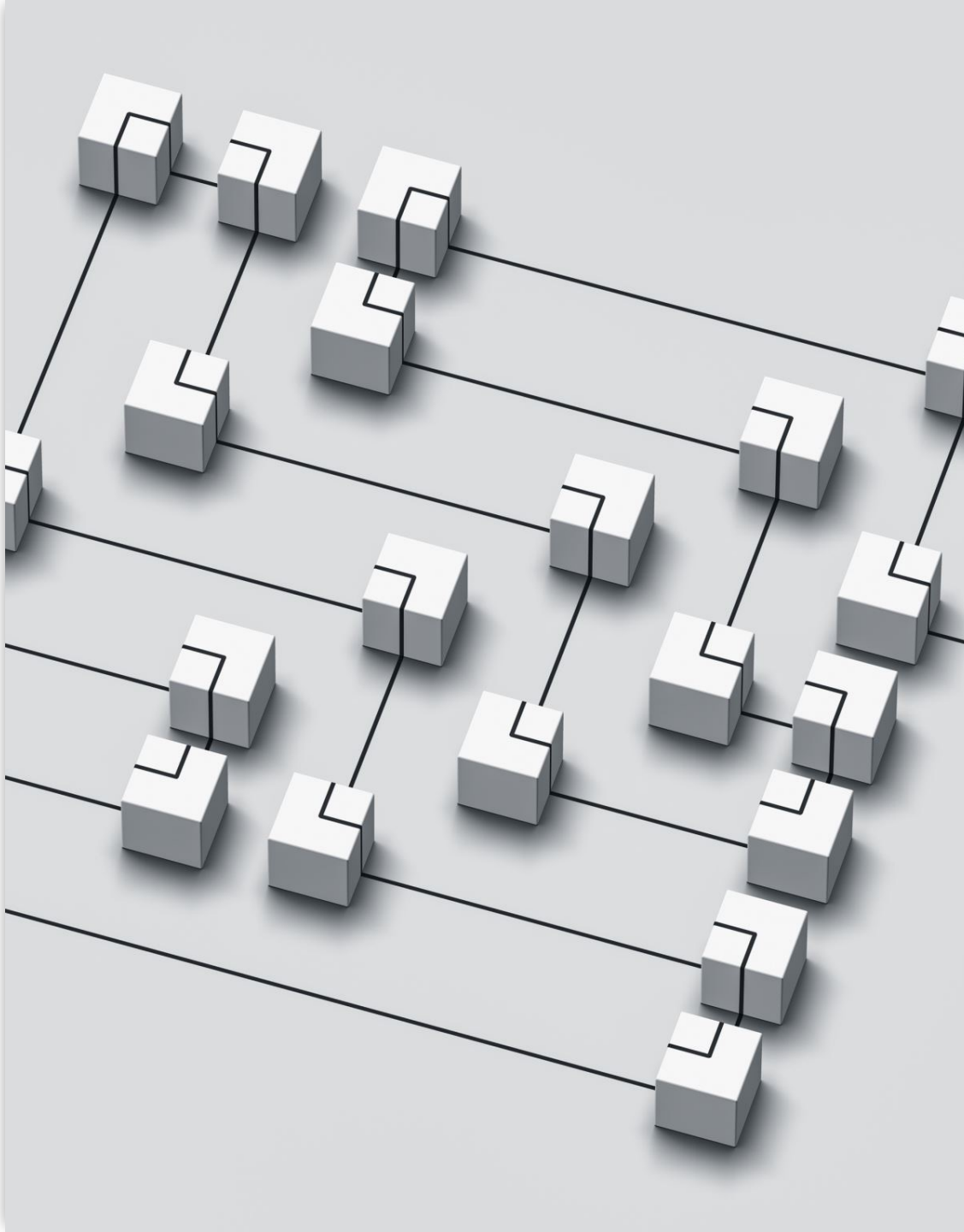
It has been proven that a structured, deliberate product development process is ***instrumental*** to the release of a safe and effective device. This process "forces" a company to

- plan out the development of a medical device
- define the device's attributes
- create the actual device
- test the device (to make sure it satisfies the stated attributes)

Overview of a Product Development Process

A typical Product Development Process is comprised of the following steps:

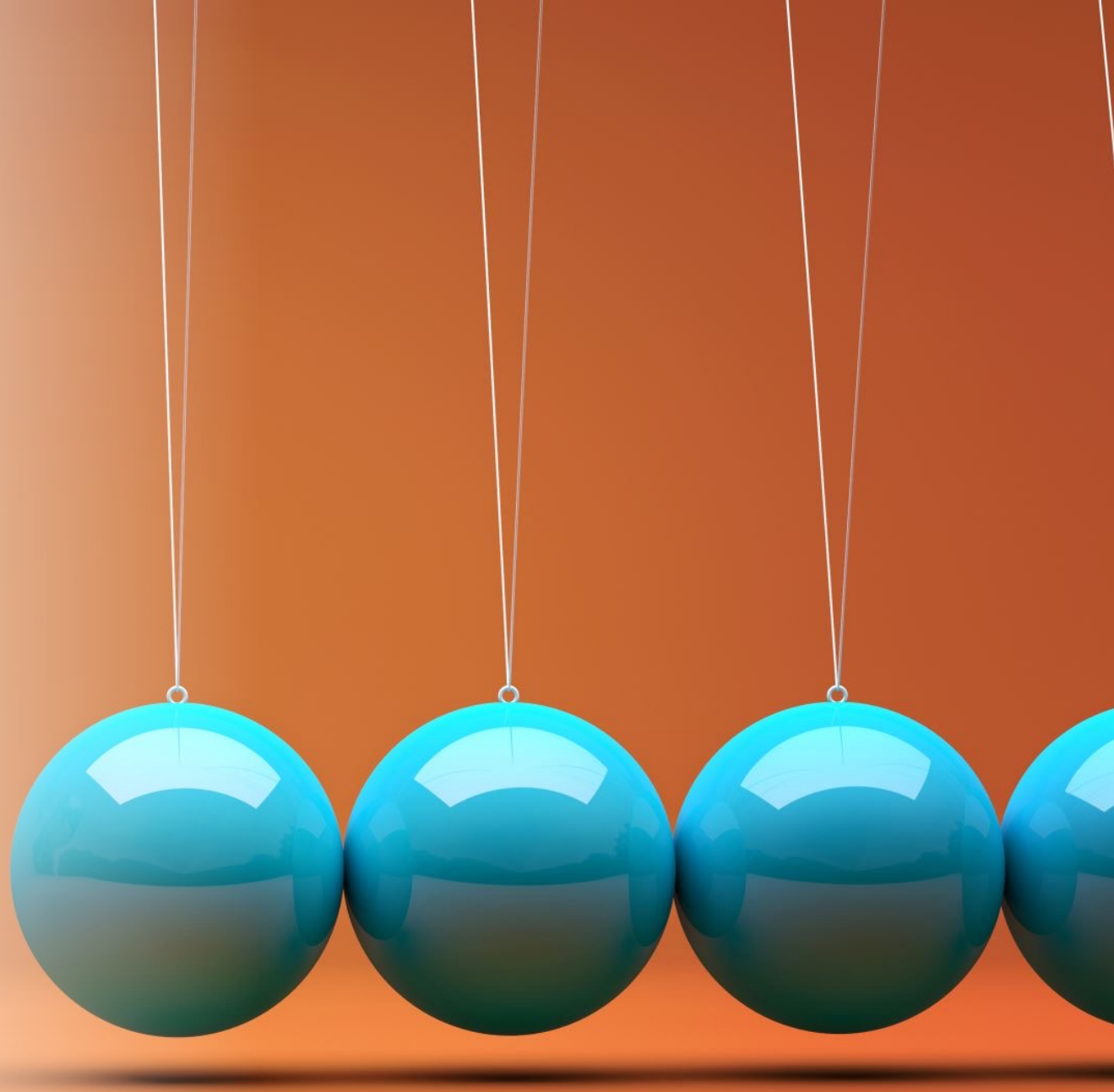
- Conceptualization and ideation (***not*** subject to QMS governance)
- Project Planning
- Identification of International Performance Standards required for device compliance
- Creation of device requirements (i.e., identify ***what*** the device must do)
- Device design and prototyping (i.e., determining ***how*** the device will meet the requirements)
- Verification and Validation
- Certification to International Performance Standards
- Submission to FDA for Regulatory Approval (to sell in the US)



Product Development – Conceptualization and Ideation

- Tasks typically performed by the Research and Development resources

- Activities not governed by the QMS or Product Development procedures but must be performed and recorded properly in order to preserve patent rights and protections



Product Development – Project Planning

A potential device concept has been selected by the company to commercialize. The development of this medical device is officially begun.

Additional details are added to the company's high-level QMS requirements to create the project-specific plans that will govern the development of the device:

- Requirements identification
- Risk Management
- Verification and Validation
- Change Management
- Document Control

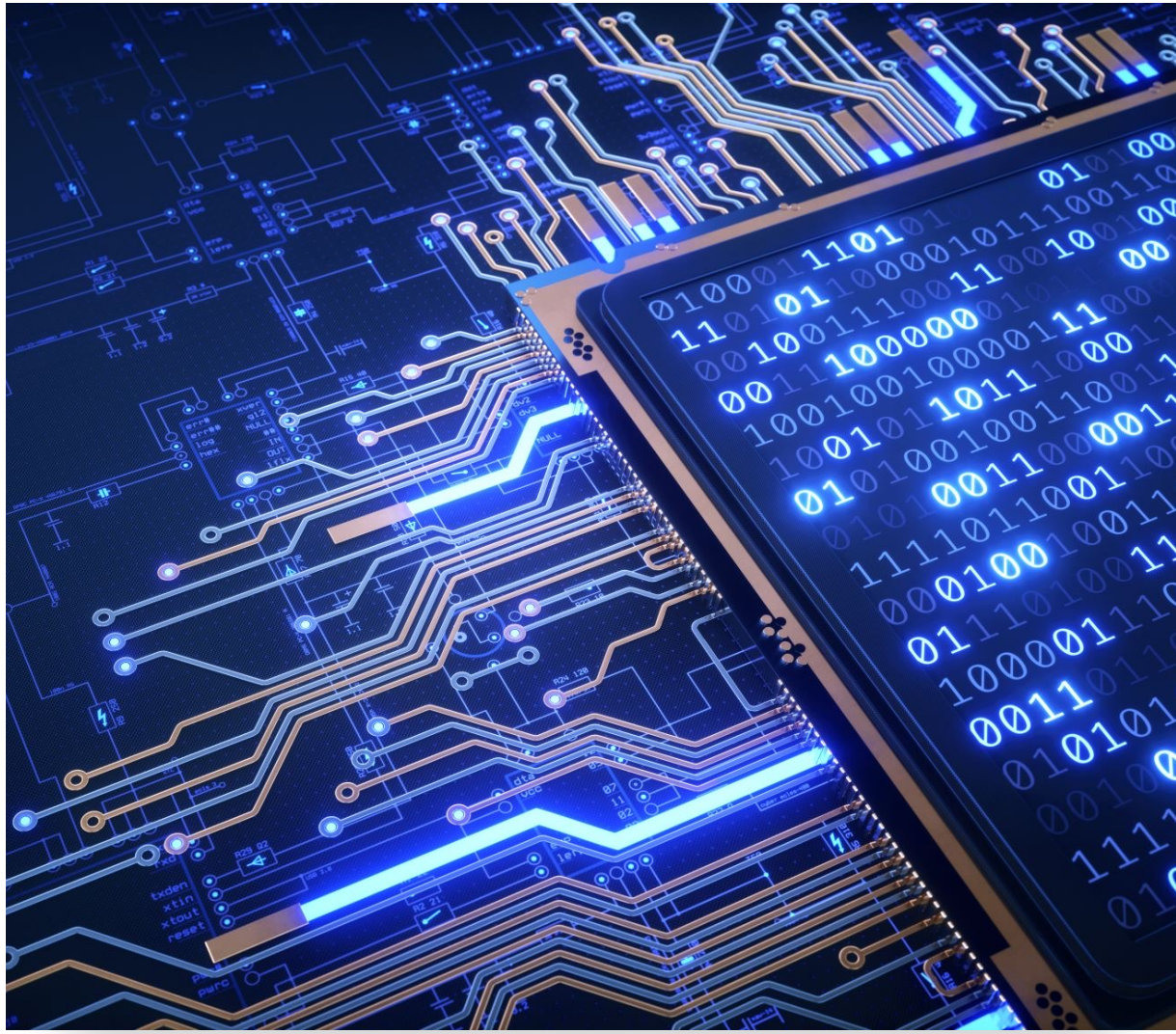
Product Development – Identification of International Product Performance Standards

Most devices, and products in general, must comply with internationally developed standard(s) created to ensure said products are safe to use:

- IEC 60601-1: *Medical electrical equipment Part 1: General requirements for basic safety and essential performance*
- IEC 62304: *Medical device software – Software life-cycle processes*

As a part of the early development activities, the company ***must*** identify

- the standard(s) governing device compliance
- the requirements established by the standard(s) that must be integrated into the device (e.g., water/dust resistance, alarms, colors)



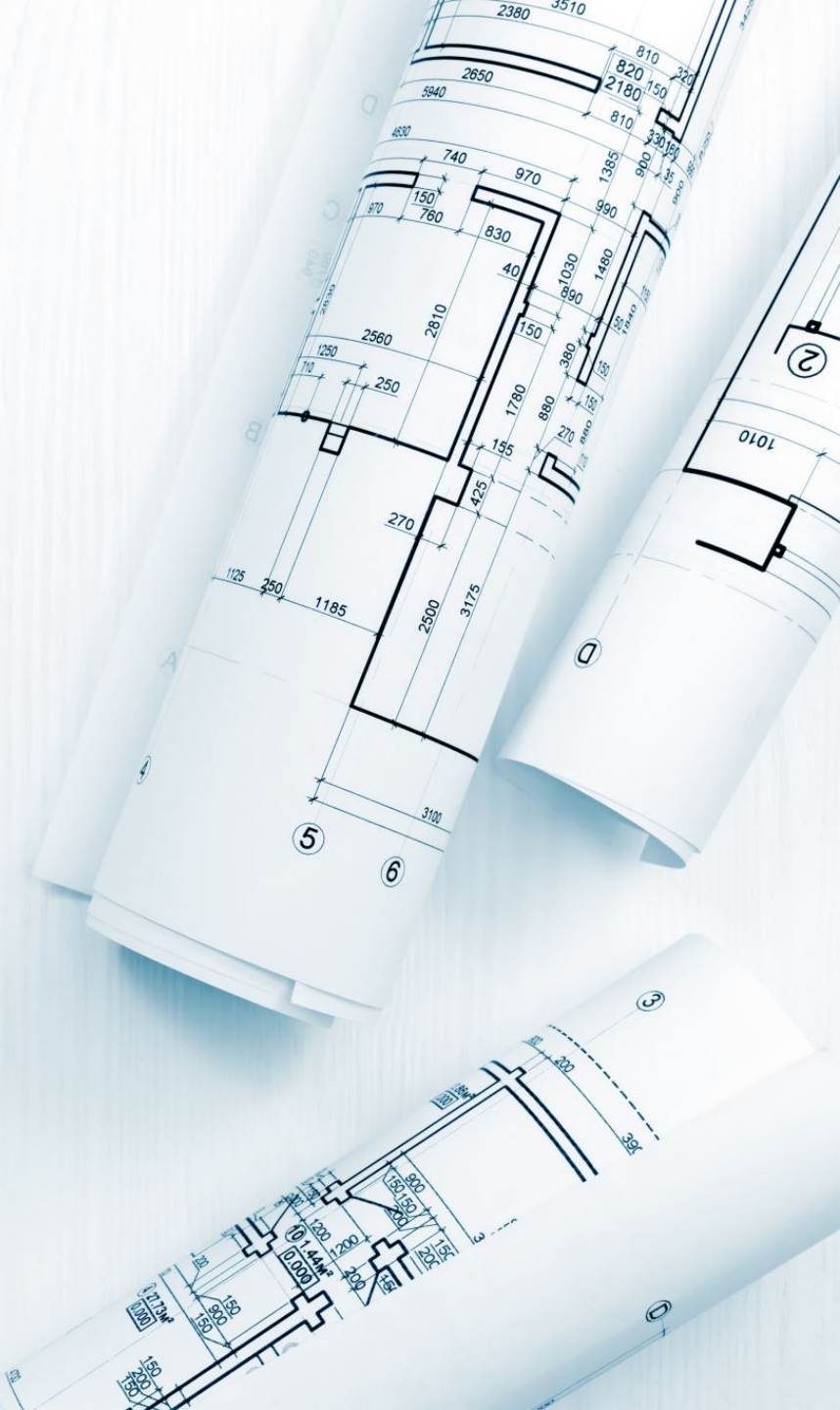
Product Development – Device Requirements

A set of requirements detailing device intentions must be created. Here are examples:

- Device must occupy a volume of less than 2 square meters
- Must have two (2) emergency stops to prevent further movement of the device
- Must have a touchscreen able to be used by persons with surgical gloves on

These requirements must be reviewed and approved, in accordance with the company document control rules

These requirements will serve as the basis for the validation activities performed later in the process



Product Development – Device Design and Prototyping

A physical device (device candidate) is created that satisfies the product requirements approved previously

The device candidate is then evaluated by company resources and (device user) subject matter experts. This evaluation determines if the candidate meets the stated requirements

During these evaluations, modifications may be made to the requirements and/or planning documents based on feedback received

Once the design is finalized, it is considered a Design Candidate, and any further changes must be formally reviewed and approved

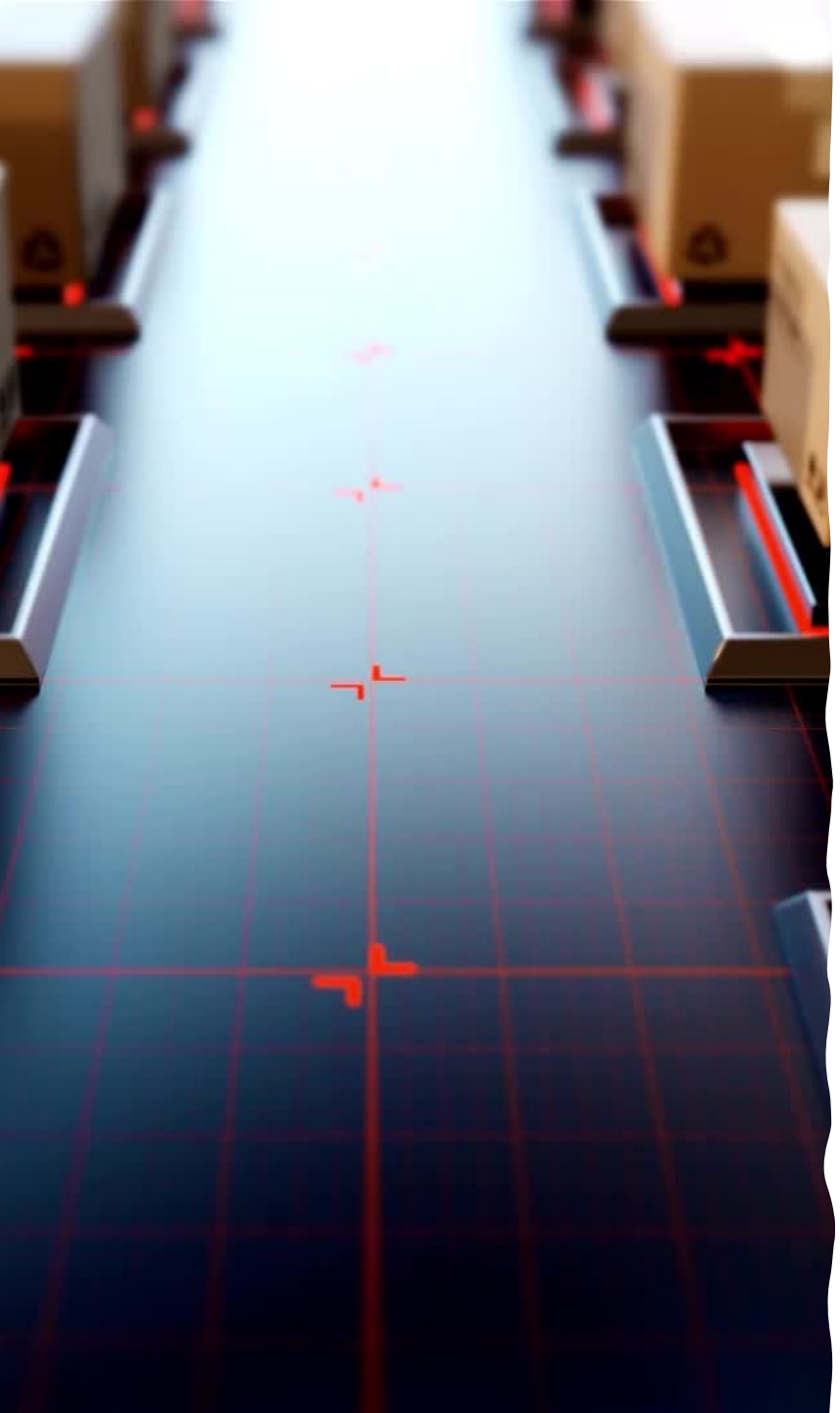
Product Development – Verification and Validation (V&V)

During this phase, there are two (2) sets of tasks that, when combined, demonstrate that the device was built properly and meets customer requirements:

(Design) Verification – Activities that demonstrate that the device satisfies the defined requirements (e.g., Is the house built correctly, according to the plans)?

(Design) Validation – Activities that demonstrate that the device meets the needs of the intended user(s) (e.g., Is the house satisfying, did we understand what the buyers wanted us to build)?

The results of these activities may require the device requirements or design to be changed, and portions of the V&V activities to be re-executed.



Product Development – Certification to International Performance Standards

Once the V&V activities have been completed (i.e., it is certain that no material changes will be made to the device), the device is submitted to a testing house that is certified to conduct performance standard testing.

The design of the device will be evaluated, and any physical testing required (e.g., electrical safety, EMI) will be performed

Once testing is completed, a certificate of conformance will be issued

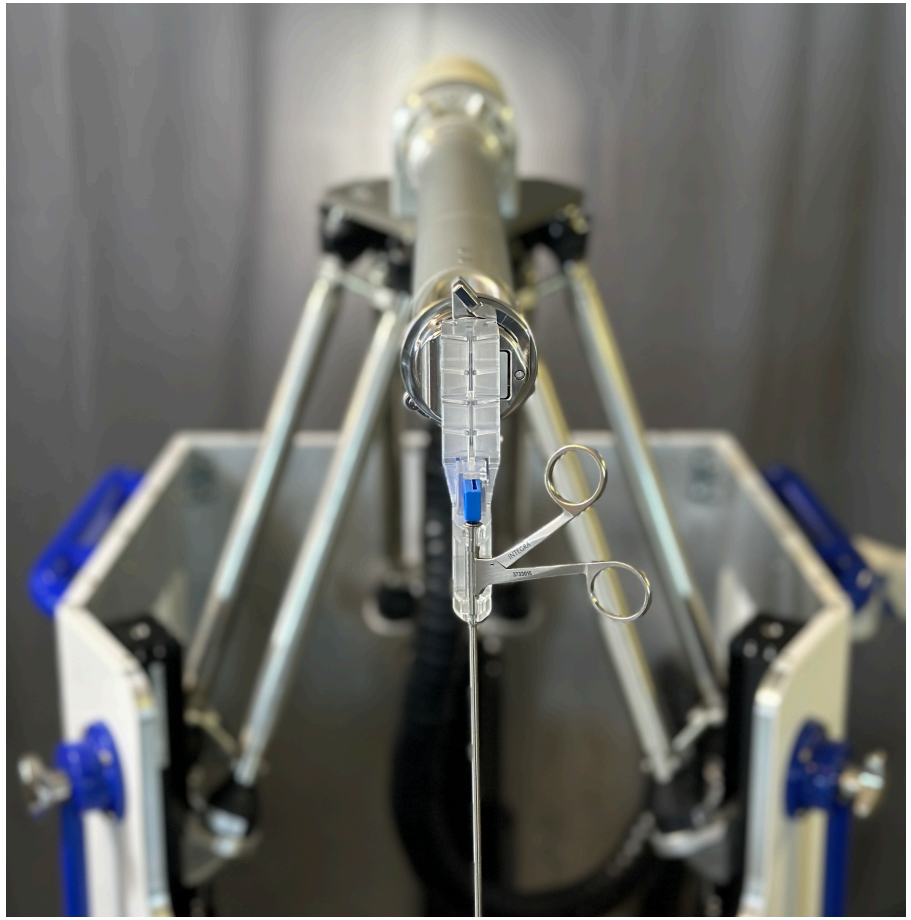
Product Development – Submission to FDA for Regulatory Approval

Once all the previous tasks have been submitted, a submission package is created. The package contains all the design and development related information required by the FDA to evaluate the safety and performance of the device

The package is electronically submitted to the FDA and evaluated by them in accordance with the selected regulatory pathway (e.g., 510(k), De Novo or PMA)

Case Study and Examples

- Established QMS (2016)
- Developed Mark 1 w/ JHU as prototype
  - No design controls
  - Cataloged all parts and designs
  - Followed QMS in spirit
- Developed Mark 2 and Mark 3 under design controls
  - Failures in Mark 2 were documented and applied as changed to Mark 3 design in formal process



Questions??

Key Takeaways

Although these deliberate, administrative type tasks appear not to add value, their implementation provides an organization to stop and make sure they understand what the customer truly wants, and if we are designing it

Typically, the development time using a structured process is shorter than those that do not use one.

Carnegie Mellon capability maturity model research (CMM) shows that a defect is 40 times more costly to resolve than if it was found earlier in the design process.