The Complete Guide to FDA Design Controls

Jon D. Speer

Founder & VP QA/RA of greenlight.guru

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ABOUT THE PRESENTER

Jon D. Speer
is the founder and VP of QA/RA of greenlight.guru

- **20+ years in medical device industry**
- **Product development engineer, quality manager, regulatory specialist**
- **40+ products to market**
- **Expert at QMS implementations**
- **Dozens of ISO audits & FDA inspections**

greenlight.guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.

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YOU'LL LEARN ABOUT INTENDED USE, USER NEEDS, DESIGN INPUTS, DESIGN REVIEWS, DESIGN HISTORY FILE (DHF) AND RISK MANAGEMENT.

SPECIFICALLY:

- **The importance of getting your intended use right up front**
- **The difference between a user need and a design input that's verifiable**
- **What stakeholders need to be involved in the process and why**
- **When and how many design reviews you should hold**
- **Why FMEA alone is NOT risk management and how to integrate risk into the design and development process**

YOU'LL LEARN ABOUT DESIGN OUTPUTS, DEVICE MASTER RECORD (DMR), DESIGN VERIFICATION AND VALIDATION (V&V), DESIGN TRANSFER AND REGULATORY SUBMISSIONS.

SPECIFICALLY:

- **Why your design outputs need to be more than a drawing and their relationship to your DMR**
- **How usability and human factors fits into the overall product development**
- **Making sure you build the correct device and build it correctly with design V&V**
- **Common mistakes people make during design transfer to production and how to avoid them**
- **When you can and should make your regulatory submission**

DESIGN CONTROLS

An introduction

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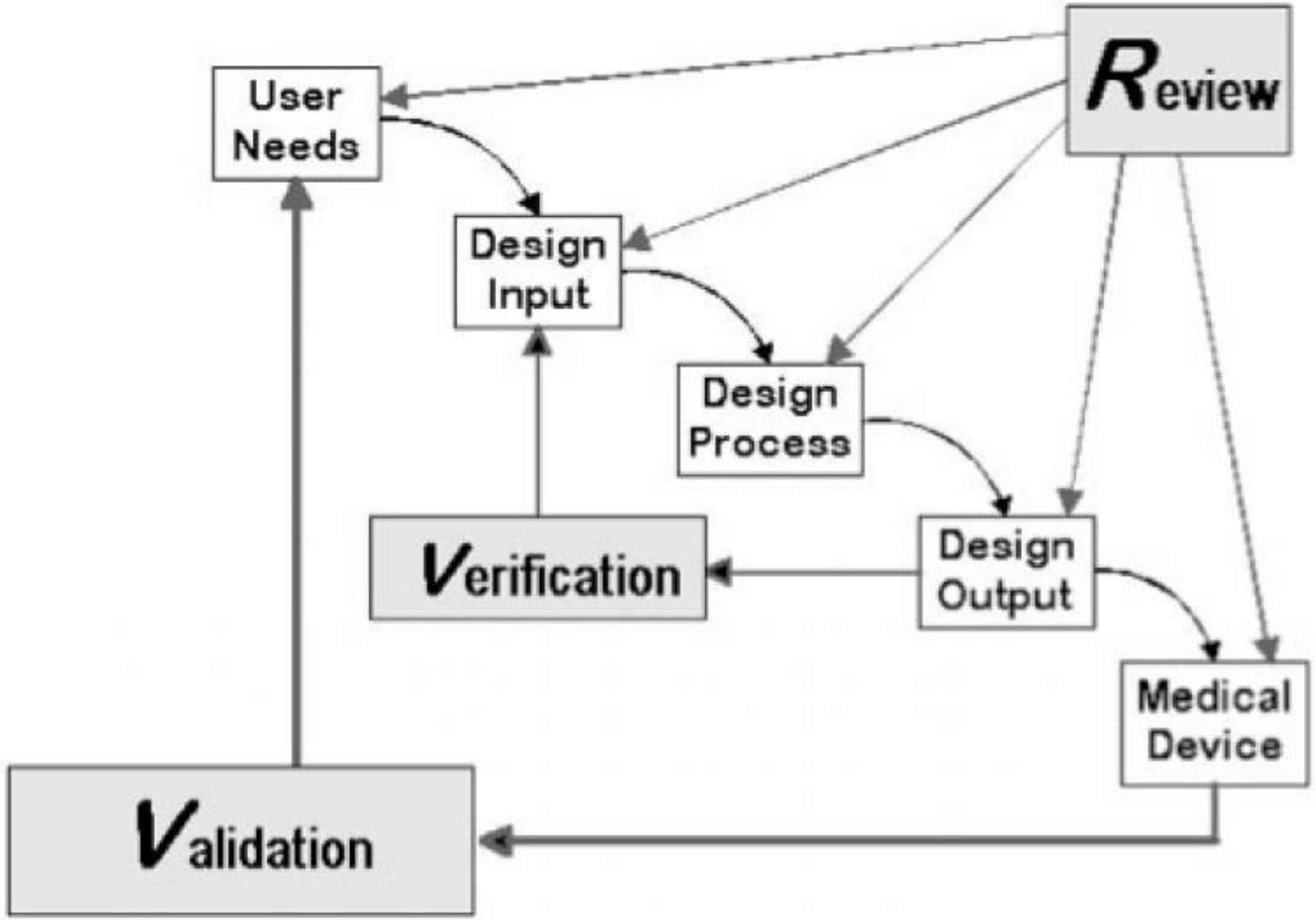
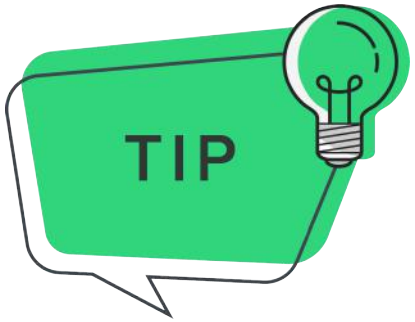
Design Controls FDA 820.30	Design & Development ISO 13485
(a) General	7.3.1 General
(b) Design & Development Planning	7.3.2 Design & Development Planning
(c) Design Input	7.3.3 Design & Development Inputs
(d) Design Output	7.3.4 Design & Development Outputs
(e) Design Review	7.3.5 Design & Development Review
(f) Design Verification	7.3.6 Design & Development Verification
(g) Design Validation	7.3.7 Design & Development Validation
(h) Design Transfer	7.3.8 Design & Development Transfer
(i) Design Changes	7.3.9 Control of Design & Development Changes
(j) Design History File	7.3.10 Design & Development Files


Review
User Needs
Design Input
Design Process
Design Output
Verification
Medical Device
Validation

DESIGN PLANNING

Resources, timelines and scope – what are you developing and how?

THE EXTENT OF DESIGN AND DEVELOPMENT PLANNING SHOULD REFLECT COMPANY SIZE AND COMPLEXITY AND ANY OUTSOURCING.



- **Refining is OK – especially for new portfolio products**
- **Identify key milestones and dates only**
- **Detail should be dependent on risk**
- **If outsourcing development work, identify the resources and integration**

USER NEEDS & DESIGN INPUT

The FDA differentiates between user needs and technical requirements

THE EXTENT OF DESIGN AND DEVELOPMENT PLANNING SHOULD REFLECT COMPANY SIZE AND COMPLEXITY AND ANY OUTSOURCING.

"THERE'S NEVER TIME TO DO IT RIGHT BUT THERE'S ALWAYS TIME TO DO IT OVER!"

- **Comprehensive – per risk**
- **Methodical**
- **Linked to clinical or other rationale**

Design Inputs

"DRILLING DOWN" INPUTS IS CRITICAL.

- User Needs
- Marketing Needs
- Customer Needs
- Other Stakeholder Needs

"Concept" Documents per FDA Guidance 1997 Design Controls

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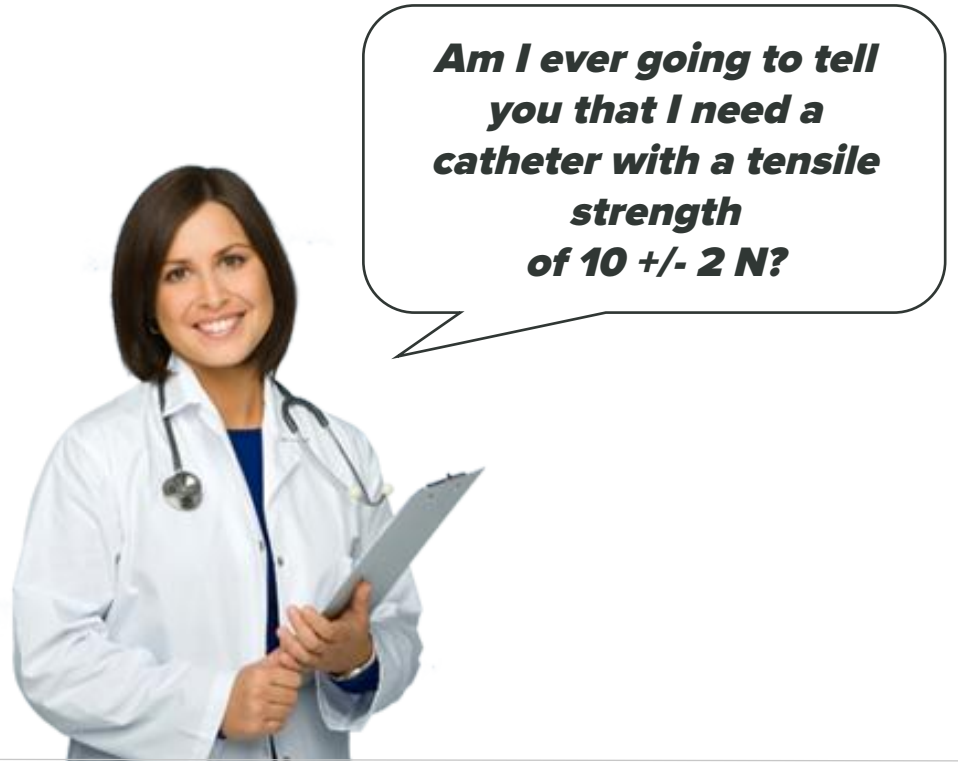


Design Inputs

"DRILLING DOWN" INPUTS IS CRITICAL.

- User Needs
- Marketing Needs
- Customer Needs
- Other Stakeholder Needs

→ Product Requirements

- ***Solution independent***
- ***Clear***
- ***Concise***
- ***Verifiable***

Design Inputs

"DRILLING DOWN" INPUTS IS CRITICAL.

- User Needs
- Marketing Needs
- Customer Needs
- Other Stakeholder Needs

WHAT? → Product Requirements

HOW! → Specifications

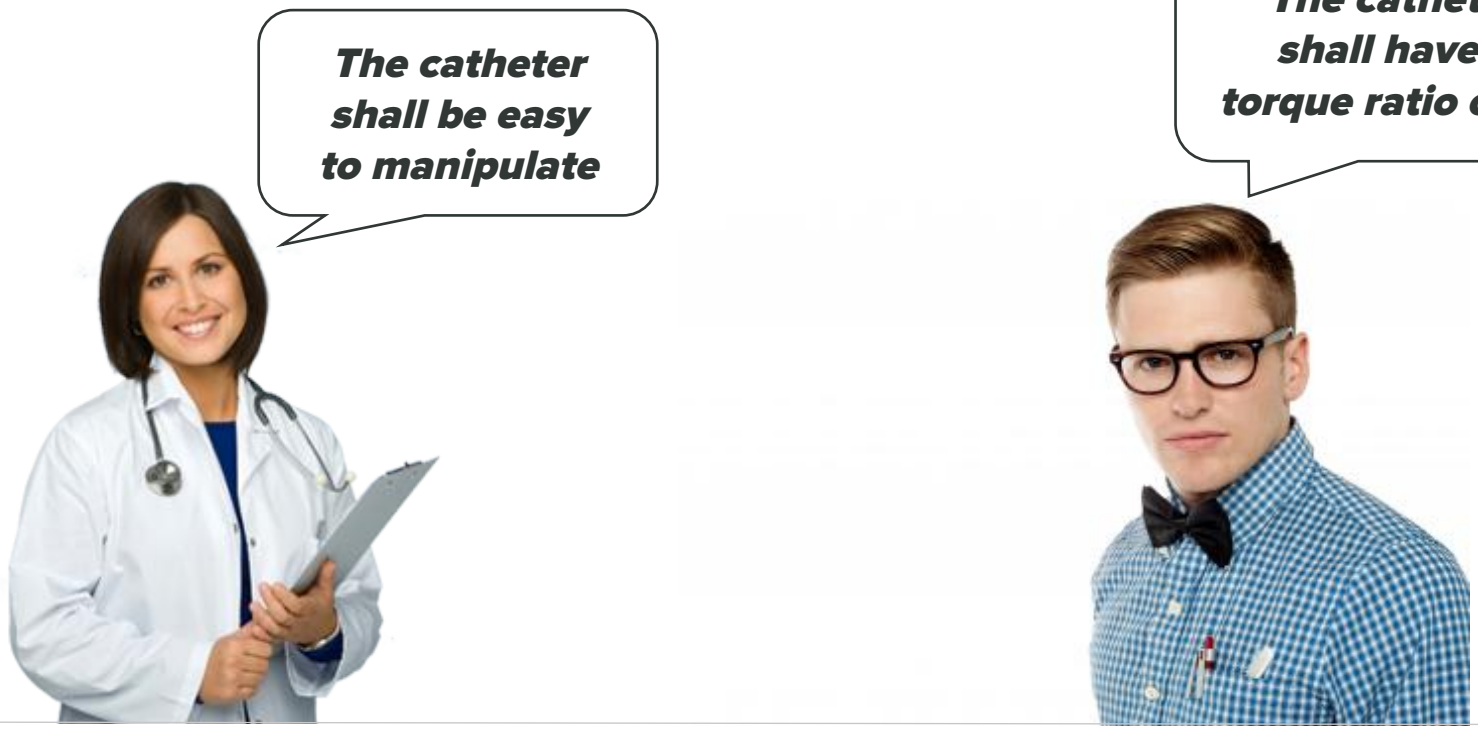
820.30(c) ISO 13485:2016 7.3.3

Design Inputs

User Need (Requirement)

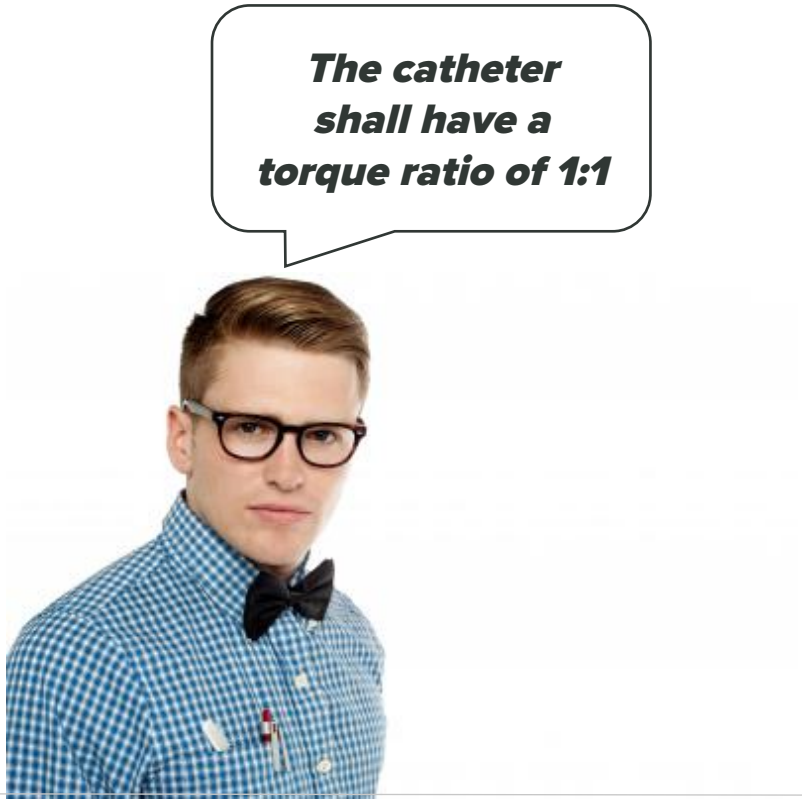
Design Input (Requirement)

Design Output (Specification)



- Material specifications
- Test methods
- Drawings

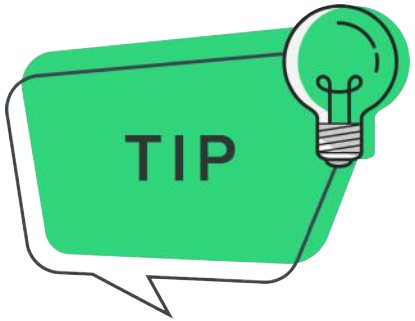
User Need (Requirement)



THIS MAY INVOLVE ITERATIVE TESTING UNTIL THE DESIGN INPUT REQUIREMENT IS DETERMINED.

- **TBD in initial drafts of DI documents are acceptable – help guide feasibility testing!**
- **May shift over time**
- **Impact assessment**

DESIGN INPUTS MUST BE CLEAR (UNAMBIGUOUS) AND VERIFIABLE.



- **If basing design inputs on a standard, make sure the standard reference is specific, clear, and test-able**
- **When you think of design inputs, think “engineering” and “getting technical”**
- **Find a resource for writing requirements**

DESIGN INPUTS MUST BE CLEAR (UNAMBIGUOUS) AND VERIFIABLE.

"Device shall be portable"....

DESIGN INPUTS MUST BE CLEAR (UNAMBIGUOUS) AND VERIFIABLE.

"Device shall be compliant to ISO 10993-1..."

Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

DESIGN INPUTS MUST BE CLEAR (UNAMBIGUOUS) AND VERIFIABLE.

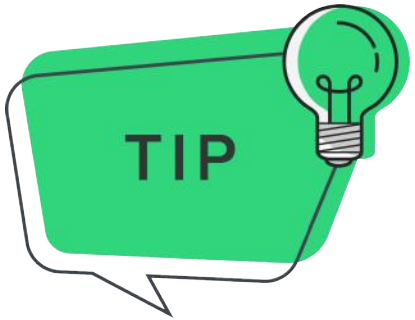
Device shall be flexible

VS

Device shall be formed into a 50 mm diameter coil and straightened out for a total of 50 times with no evidence of cracking or deformity.

NOTE: ***assess the level of granularity or detail based on requirement criticality/ risk.***

FPIS

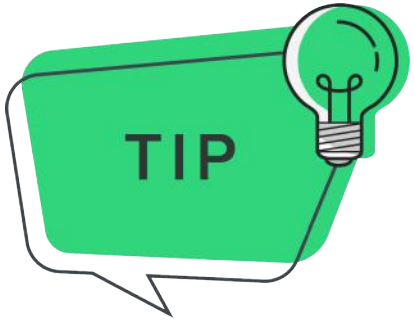


- **Functional: what does the device do?**
- **Performance: accuracy, conditions, operational limits, reliability, etc.**
- **Interface: what does the device need to have to work with accessories or external items?**
- **Safety: does the device need precautionary measures or safety margins?**

A NOTE ON DRAFTING REQUIREMENTS.

- Language is important
  a. ‘Shall’ vs. ‘Should’
    a. “Must have” vs. “Nice to have”
  b. Avoid “as applicable” or “as required” in final DI
- Avoid contradicting requirements
- System → sub-system
  a. Particularly useful for contracting

DON'T STRESS ABOUT DOCUMENTING DESIGN INPUTS IN PROOF OF CONCEPT OR FEASIBILITY PHASES. BE AGILE!



- **FDA distinguishes between R&D and finished product – remember this!**
- **Design inputs apply to the commercial product ("how do I know the design is in control?")**

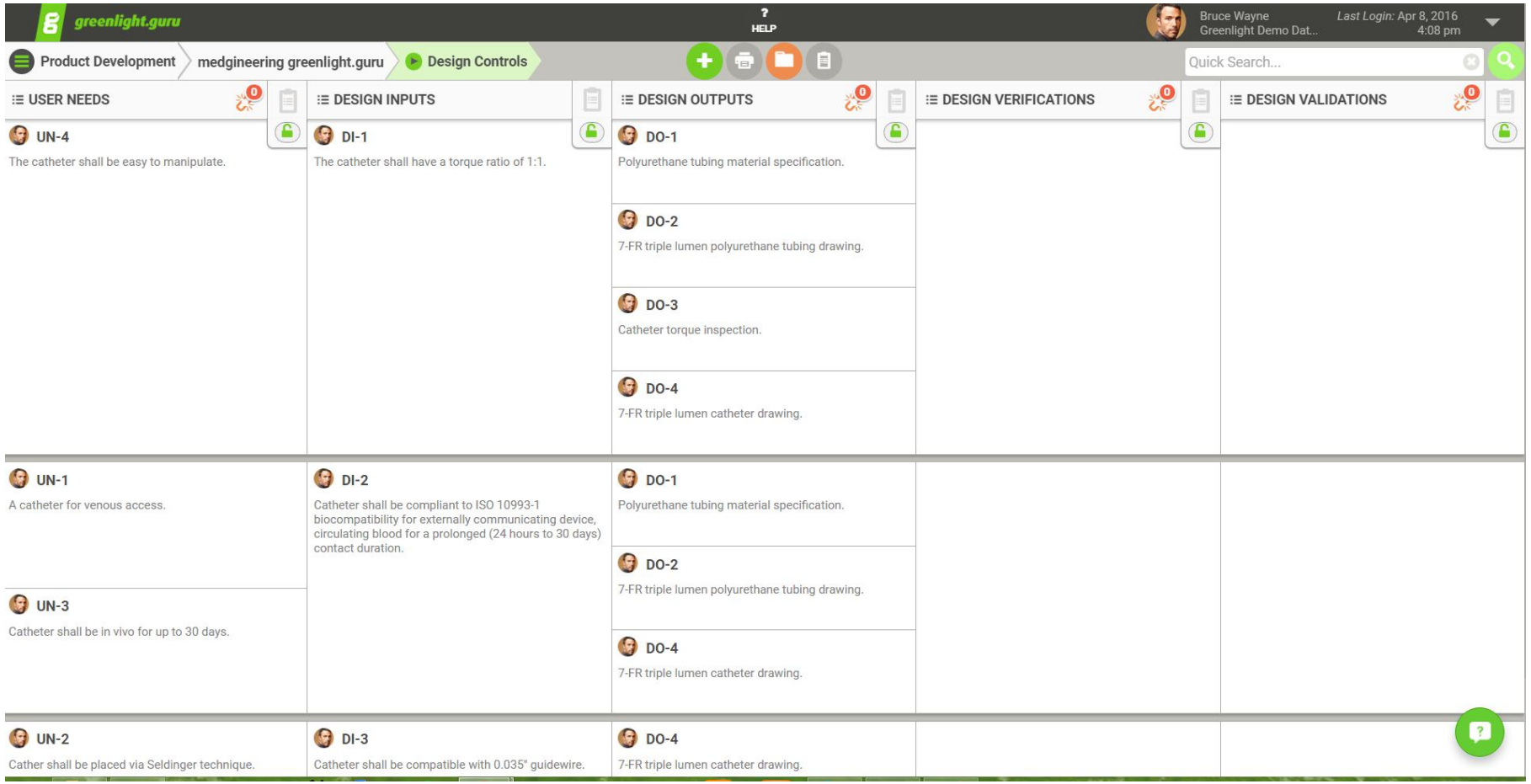
THE IMPORTANCE OF TRACEABILITY.

"Failure to establish and maintain adequate procedures for verifying the device design, as required by 21 CFR 820.30(f).

Specifically, design outputs were not always evaluated to demonstrate that the outputs met design inputs."

7.3.2(e) "the methods to ensure traceability of design and development outputs to design and development inputs"

7.5.9 ". . . The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained . . ."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The catheter shall have a torque ratio of 1:1.
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Polyurethane tubing material specification.
DO-2
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Cather shall be placed via Seldinger technique.
DI-3
Catheter shall be compatible with 0.035" guidewire.
DO-4
7-FR triple lumen catheter drawing.

RISK MANAGEMENT

An overview

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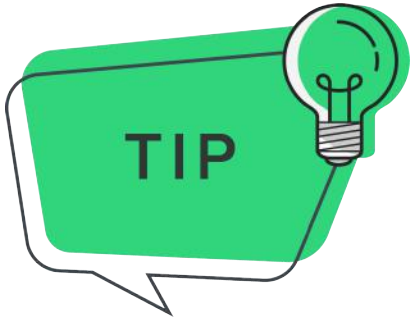
INTENDED USE IS IMPORTANT FOR DESIGN CONTROLS & RISK MANAGEMENT.

RISK MANAGEMENT & DESIGN CONTROLS ARE ABOUT DEMONSTRATING A MEDICAL DEVICE IS SAFE AND EFFECTIVE.

PRODUCT RISK MANAGEMENT IS A CYCLE, EVEN DURING PRODUCT DEVELOPMENT.



- **Start Risk Management process early**
- **Use Risk Management process to improve product design**
- **Use Design Controls to support Risk Controls / Mitigations**


ISO
14971

ISO 14971 Risk Management

Key Terms

RISK MANAGEMENT —

systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk

RISK —

combination of the probability of occurrence of harm and the severity of that harm

ISO 14971 Risk Management

Key Terms

HAZARD —

potential source of harm

HAZARDOUS SITUATION —

circumstance in which people, property, or the environment are exposed to one or more hazard(s)

HARM —

physical injury or damage to the health of people, or damage to property or the environment

SEVERITY —

measure of the possible consequences of a hazard

ISO 14971 Risk Management

Key Terms

RISK ANALYSIS —

systematic use of available information to identify hazards and to estimate the risk

RISK EVALUATION —

process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

RISK CONTROL —

process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

RISK ESTIMATION —

process used to assign values to the probability of occurrence of harm and the severity of that harm

RISK ASSESSMENT —

overall process comprising a risk analysis and a risk evaluation

RISK ASSESSMENT —

risk remaining after risk control measures have been taken

ISO 14971 Risk Management

Process Overview

1 Establish A Risk Management Framework

- ☐ Define your risk management process
- ☐ Establish management roles and responsibilities
- ☐ Document your risk management plan
- ☐ Establish a living risk management file

ESTABLISH FRAMEWORK (1)

RISK MANAGEMENT PROCESS (1-10)

ISO 14971 Risk Management

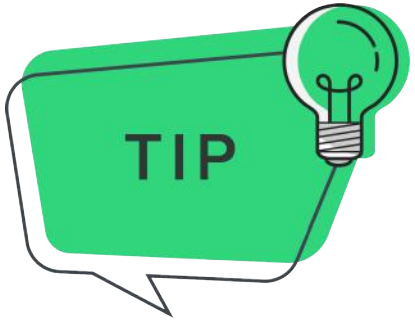
Risk Analysis

INCLUDE END-USERS AS PART OF THE PROCESS.

- Hazards
- Foreseeable Sequence of Events
- Hazardous Situations
- Harms


6 Evaluate The Risks Identified
• Are these risk levels acceptable?
• Is risk reduction required?
RISK ANALYSIS (6)
Risk Acceptability Matrix
Probability
Frequent
1 in 100
Probable
1 in 1,000
Occasional
1 in 10,000
Remote
1 in 100,000
Improbable
1 in 1,000,000
Requires RBA
Negligible
No or negligible risk to patient
Minor
Slight customer inconvenience; little to no effect on product performance, non-vital fault
Serious
Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation)
Major
Severe, long-term injury; potential disability
Critical
Loss of limb; life-threatening injury
Severity

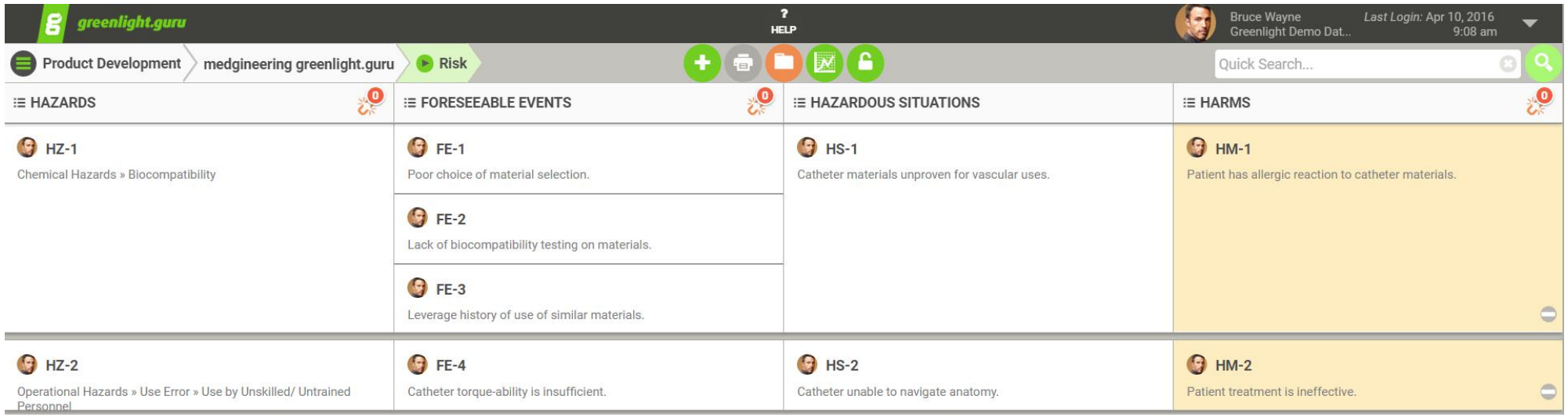
RISK EVALUATION CRITERIA SHALL BE ESTABLISHED AND SHOULD BE SPECIFIC TO YOUR PRODUCT.



- **Use sources like MAUDE and other industry databases.**
- **Consult with end-users to understand true severity.**
- **Evaluate other similar products.**
- **Leverage standards and guidance documents.**

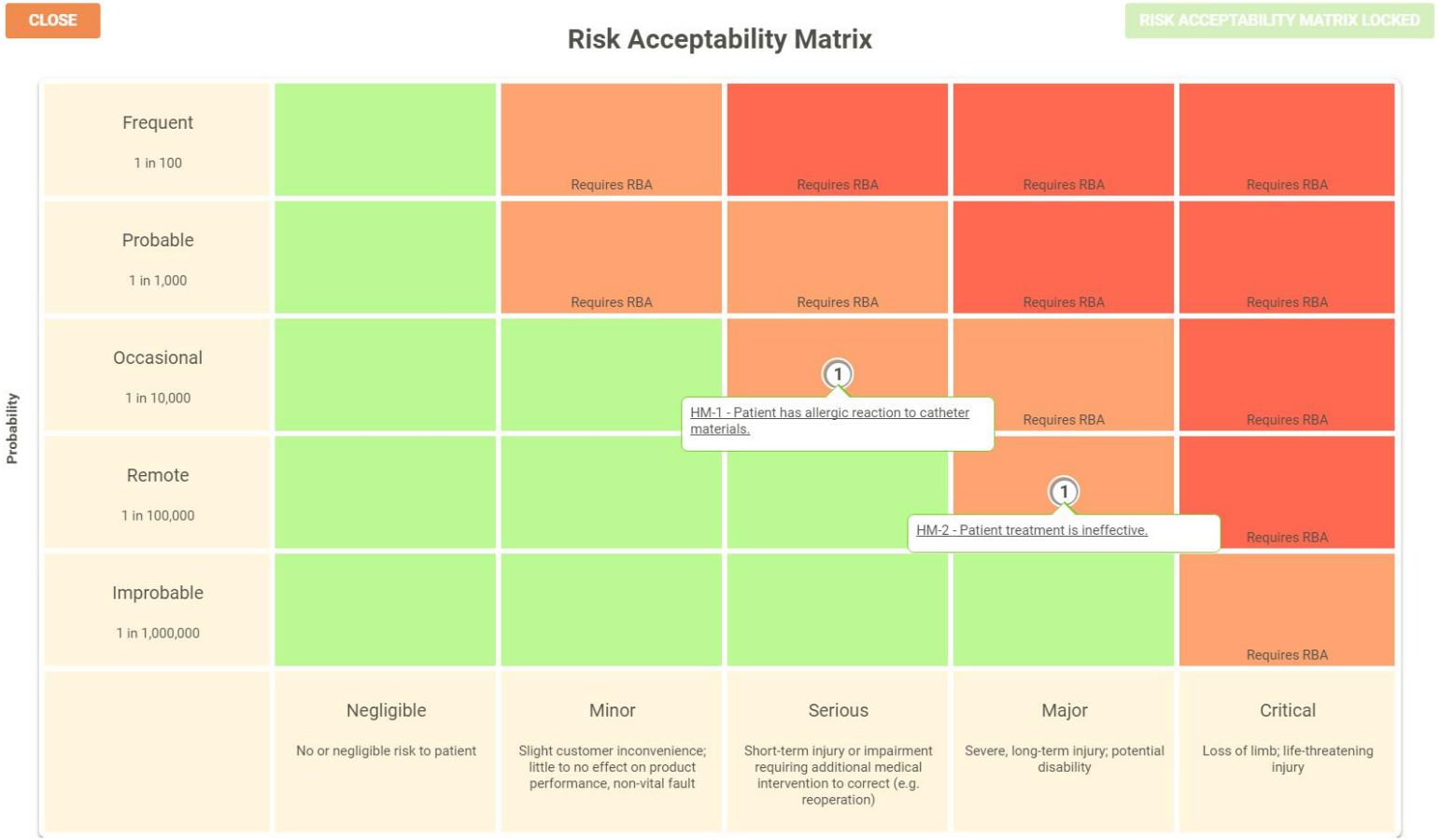
ISO 14971 Risk Management

Risk Assessment



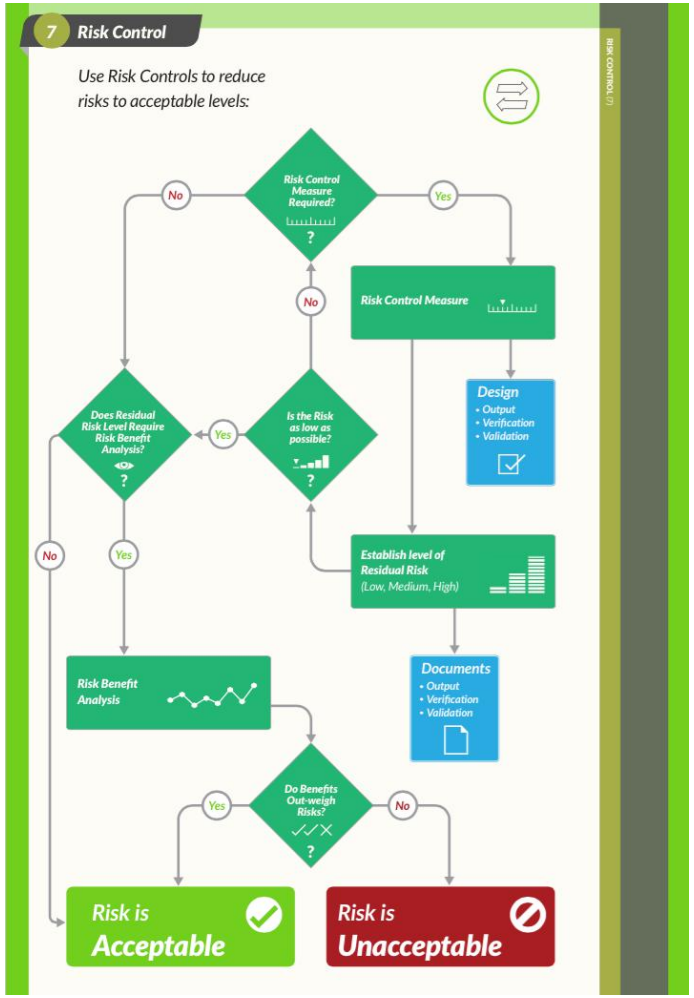
ISO 14971 Risk Management

Risk Assessment

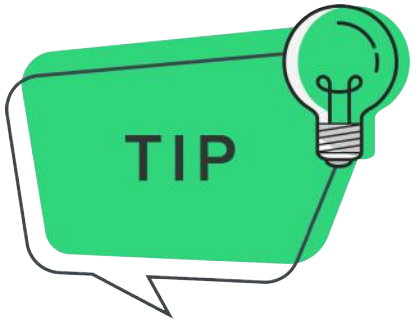


ISO 14971 Risk Management

Risk Control



RISK CONTROLS ARE MEANS TO DEMONSTRATE RISKS HAVE BEEN REDUCED TO ACCEPTABLE LEVELS.

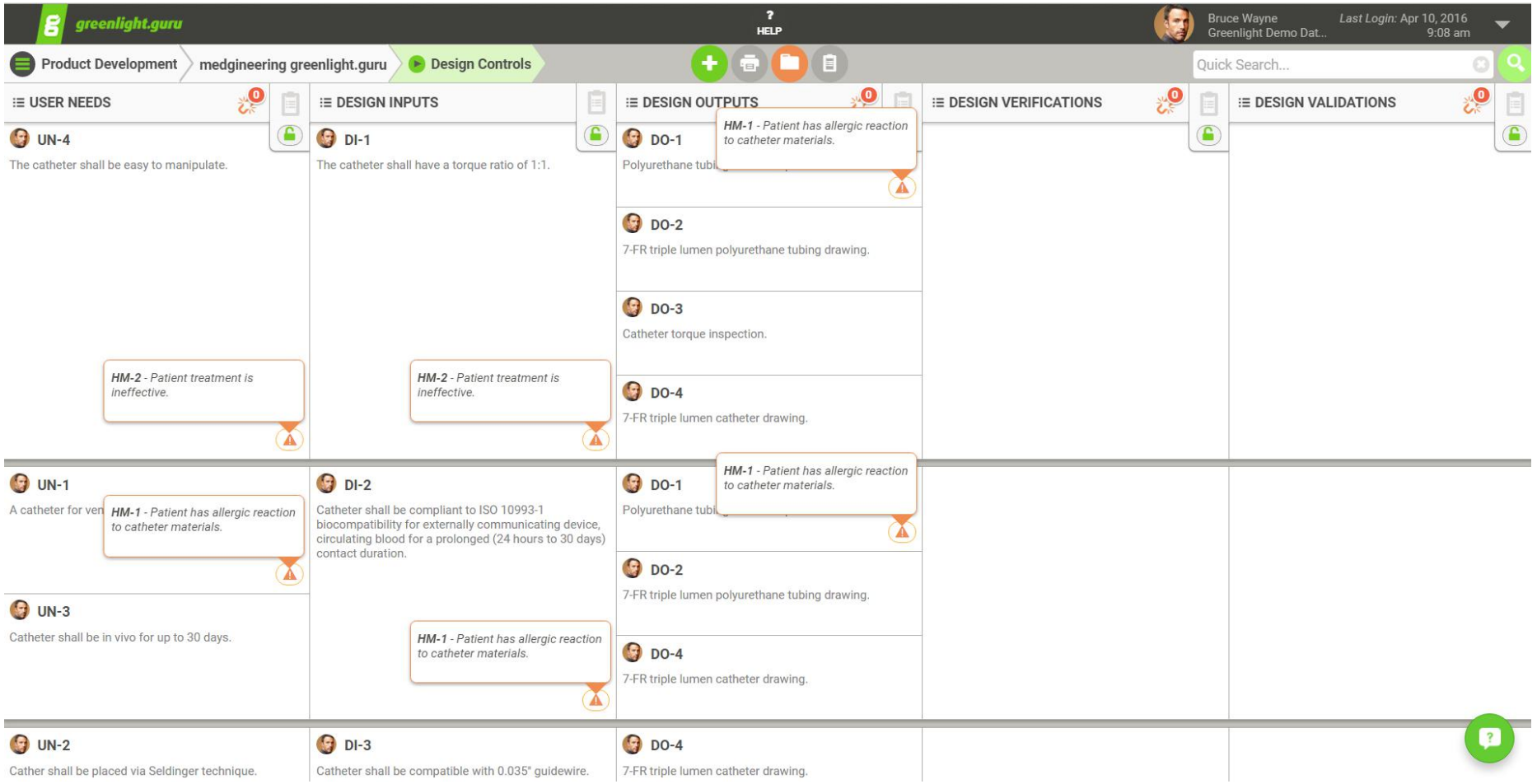


Priority of Risk Control options:

- **Inherent safety by design**
- **Protective measures in the medical device itself or in the manufacturing process.**
- **Information for safety.**

RECOMMEND IDENTIFYING RISK CONTROLS FOR ALL RISKS.

Risk Control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USER NEEDS
DESIGN INPUTS
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UN-4
The catheter shall be easy to manipulate.
DI-1
The catheter shall have a torque ratio of 1:1.
DO-1
Polyurethane tubi
HM-1 - Patient has allergic reaction to catheter materials.
DO-2
7-FR triple lumen polyurethane tubing drawing.
DO-3
Catheter torque inspection.
HM-2 - Patient treatment is ineffective.
HM-2 - Patient treatment is ineffective.
DO-4
7-FR triple lumen catheter drawing.
UN-1
A catheter for ven
HM-1 - Patient has allergic reaction to catheter materials.
DI-2
Catheter shall be compliant to ISO 10993-1 biocompatibility for externally communicating device, circulating blood for a prolonged (24 hours to 30 days) contact duration.
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DO-4
7-FR triple lumen catheter drawing.
UN-2
Cather shall be placed via Seldinger technique.
DI-3
Catheter shall be compatible with 0.035" guidewire.
DO-4
7-FR triple lumen catheter drawing.

8 Evaluation Of Overall Risk Acceptability

Evaluate risk of the product in its entirety.

- *Is the risk level acceptable?*
- *Do the benefits outweigh the potential risks?*

RISK ACCEPTABILITY (8)

MEDICAL BENEFITS OF THE MEDICAL DEVICE NEED TO OUTWEIGH THE RISKS TO PATIENTS AND END-USERS.

9 Risk Management Report

Carry out a risk management review and prepare a risk management report before sending your device to commercial production.

REVIEW AND REPORT (9)

10 Production And Post-production Information

Internal audits, CAPAs, complaints, customer feedback and non-conforming material all 'feed' into the risk management process.

Risk management is a total product lifecycle process.

PRODUCTION INFORMATION (10)

DESIGN REVIEW

An overview

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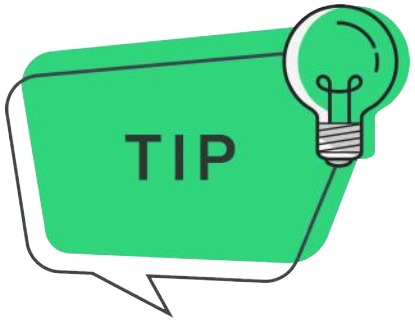
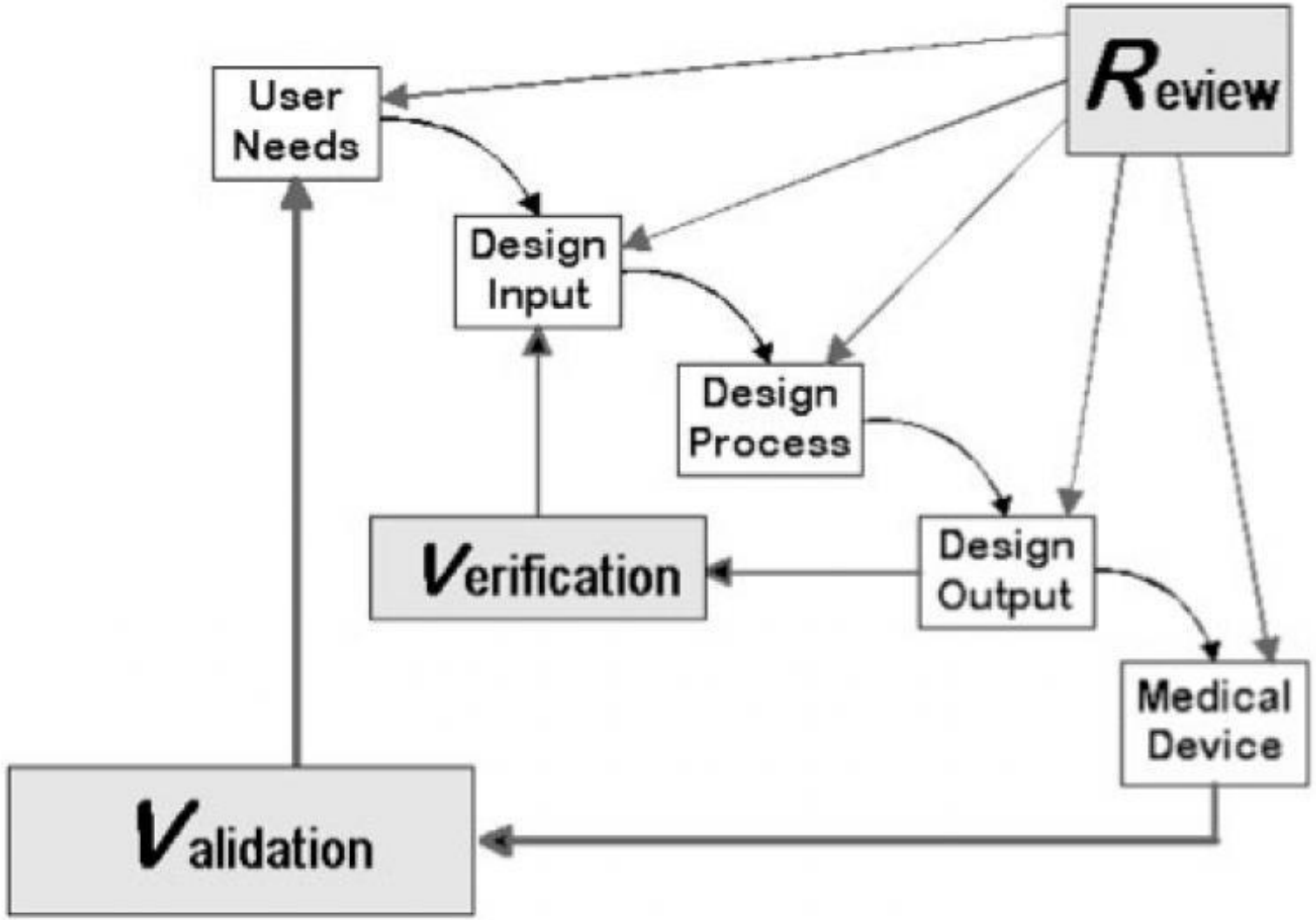
TIMING OF DESIGN REVIEWS IS A FUNCTION OF DESIGN PLANNING. FREQUENCY OF DESIGN REVIEWS SHOULD REFLECT COMPLEXITY OF PRODUCT DEVELOPMENT.



- **All design controls need to be part of design reviews.**
- **Design plan shall identify when design reviews are to happen.**
- **Design reviews shall include an “independent reviewer”.**
- **Design reviews shall include appropriate functions.**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DESIGN HISTORY FILE

What goes in DHF?

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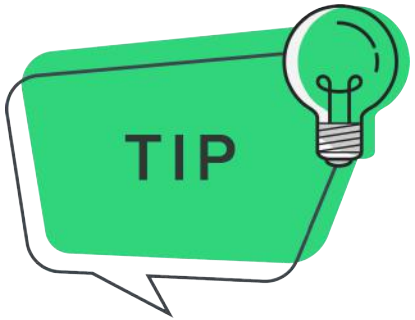
Design History File (DHF)

IF IT ISN'T DOCUMENTED, THEN IT DIDN'T HAPPEN. DOCUMENT ALL DESIGN CONTROLS AND KEEP RECORDS IN AN ORGANIZED DHF.



- **Establish a DHF per product.**
- **Use Design Reviews to confirm Design Controls have been documented.**
- **Compile DHF into a "single source of truth".**

DESIGN OUTPUTS & DMR

Design Outputs – more than just drawings!

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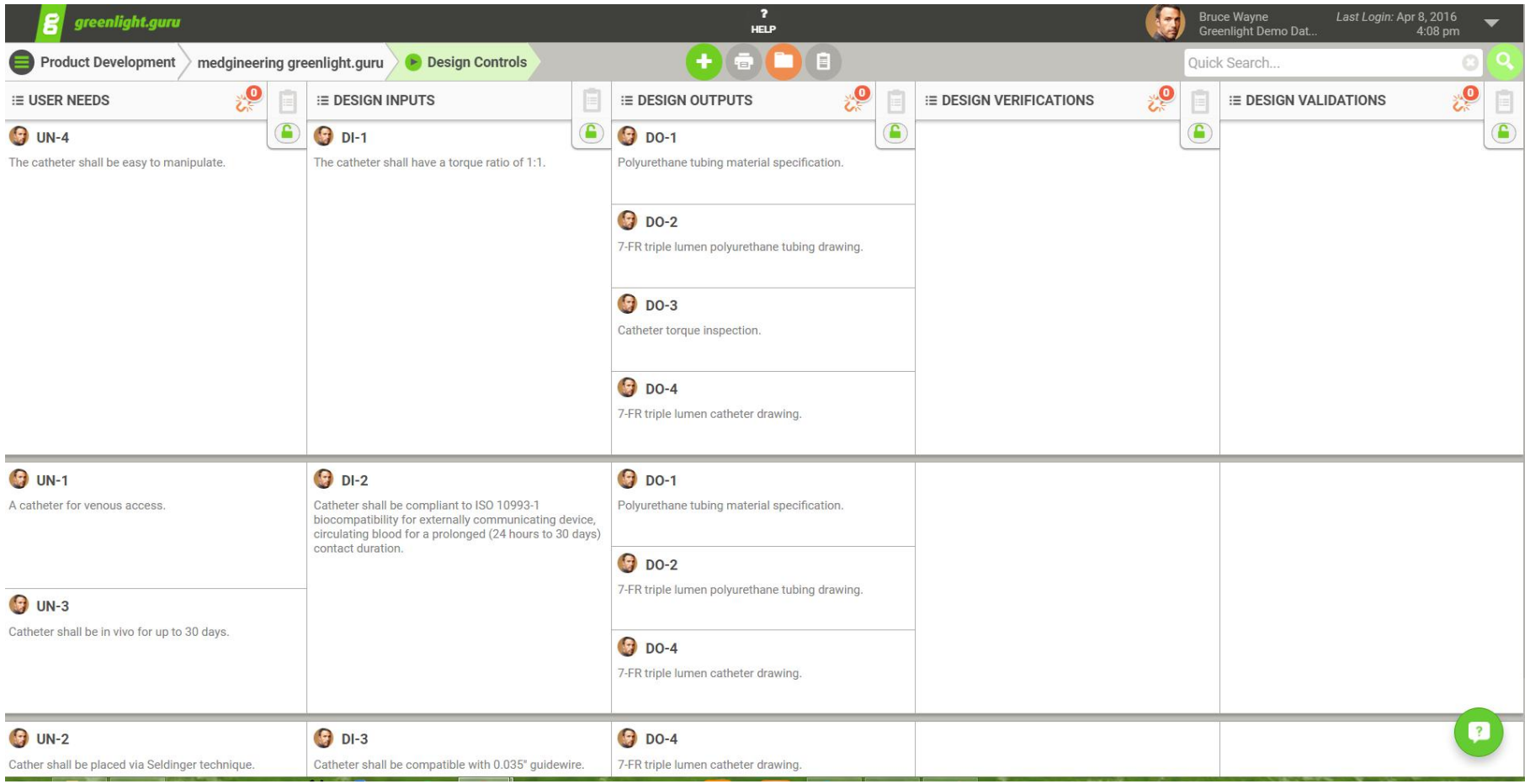
DESIGN OUTPUTS: FORMAT AND TYPE

- Drawings
- Material Specification
- Inspection Reports
- Service Instructions
- Mfg Instructions
- Batch Records
- Testing Instructions
- Software Code
- QA Specs/ Procedures
- Packaging/ Labeling

THE TOTAL FINISHED DESIGN OUTPUT CONSISTS OF THE DEVICE, ITS PACKAGING AND LABELING, AND THE DEVICE MASTER RECORD.

THE DMR IS THE “ONE STOP SHOP” FOR DESIGN OUTPUTS, OFTEN MAINTAINED IN A DMR INDEX.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DESIGN VERIFICATION & DESIGN VALIDATION

An overview

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Design Verification

Design Validation

820.30(f) ISO 13485:2016 7.3.6

Design Verification

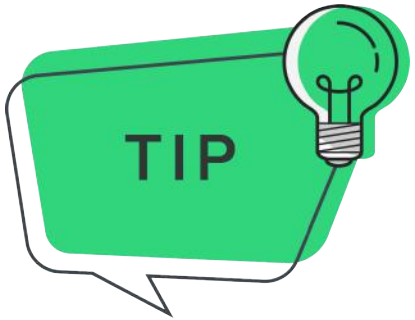
Design Input (Requirement)

Design Output (Specification)

Design Verification

Design Verification

DESIGN VERIFICATION SHALL PROVIDE CLEAR, OBJECTIVE EVIDENCE THAT DESIGN OUTPUTS MEET DESIGN INPUTS



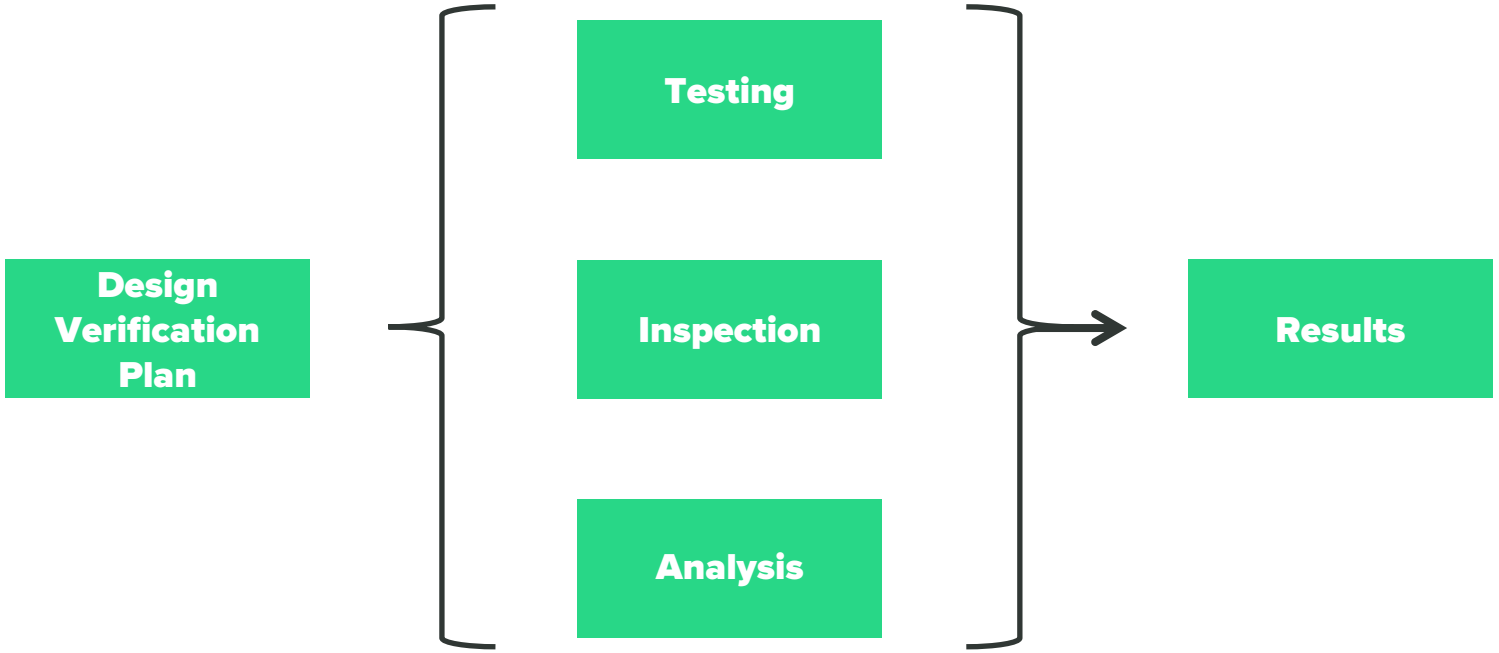
- **Consider Design Verification when defining Design Inputs**
- **Establish a Design Verification Plan (and do so early)**
- **Define verification methods**
- **Demonstrate acceptance criteria is met**

820.30(f) ISO 13485:2016 7.3.6

Design Verification

Design Input (Requirement)	Design Output (Specification)	Design Verification
The catheter shall have a torque ratio of 1:1	Material specifications	Plans
	Drawings	Methods
		Results

DESIGN VERIFICATION METHODS



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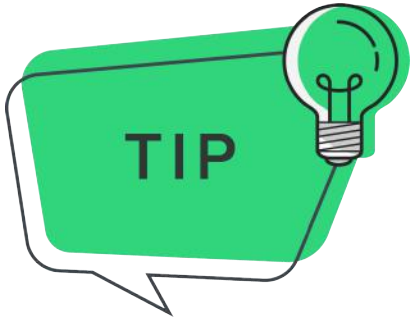
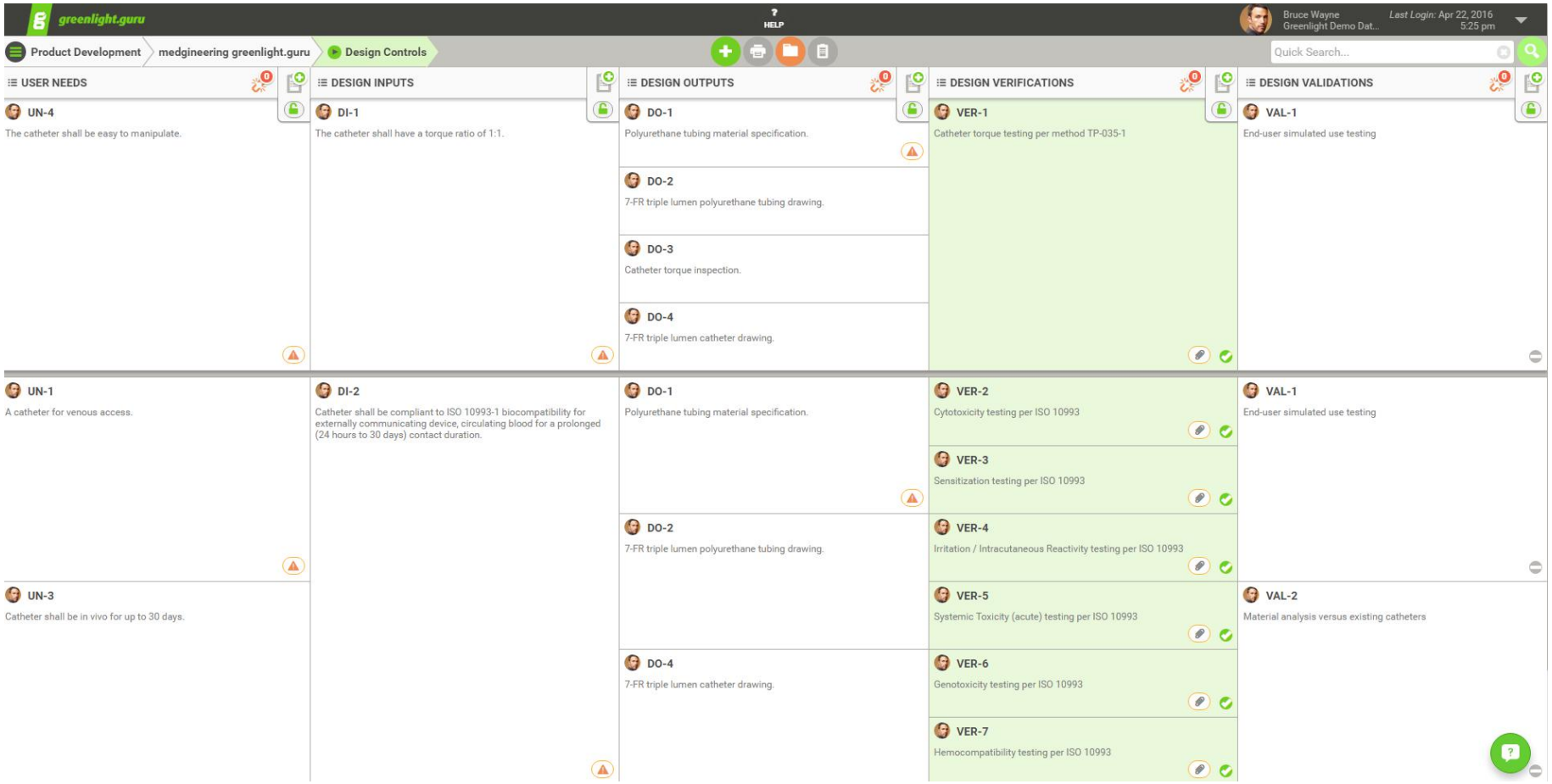


- **Design Inputs must be clear (unambiguous) and verifiable.**
- **Design Outputs must be defined so that conformance to Design Inputs may be demonstrated.**
- **Need to establish “acceptance criteria”.**
- **Establish (and validate) Design Verification methods.**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HELP
Bruce Wayne
Greenlight Demo Dat...
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Product Development
medgineering greenlight.guru
Design Controls
Quick Search...
USER NEEDS
DESIGN INPUTS
DESIGN OUTPUTS
DESIGN VERIFICATIONS
DESIGN VALIDATIONS
UN-4
The catheter shall be easy to manipulate.
DI-1
The catheter shall have a torque ratio of 1:1.
DO-1
Polyurethane tubing material specification.
DO-2
7-FR triple lumen polyurethane tubing drawing.
DO-3
Catheter torque inspection.
DO-4
7-FR triple lumen catheter drawing.
VER-1
Catheter torque testing per method TP-035-1
VAL-1
End-user simulated use testing
UN-1
A catheter for venous access.
DI-2
Catheter shall be compliant to ISO 10993-1 biocompatibility for externally communicating device, circulating blood for a prolonged (24 hours to 30 days) contact duration.
DO-1
Polyurethane tubing material specification.
DO-2
7-FR triple lumen polyurethane tubing drawing.
DO-4
7-FR triple lumen catheter drawing.
VER-2
Cytotoxicity testing per ISO 10993
VER-3
Sensitization testing per ISO 10993
VER-4
Irritation / Intracutaneous Reactivity testing per ISO 10993
VER-5
Systemic Toxicity (acute) testing per ISO 10993
VER-6
Genotoxicity testing per ISO 10993
VER-7
Hemocompatibility testing per ISO 10993
VAL-1
End-user simulated use testing
UN-3
Catheter shall be in vivo for up to 30 days.
VAL-2
Material analysis versus existing catheters

820.30(g) ISO 13485:2016 7.3.7

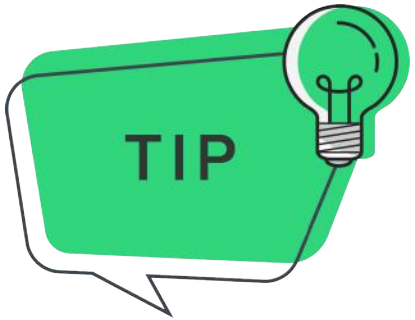
Design Validation

User Needs

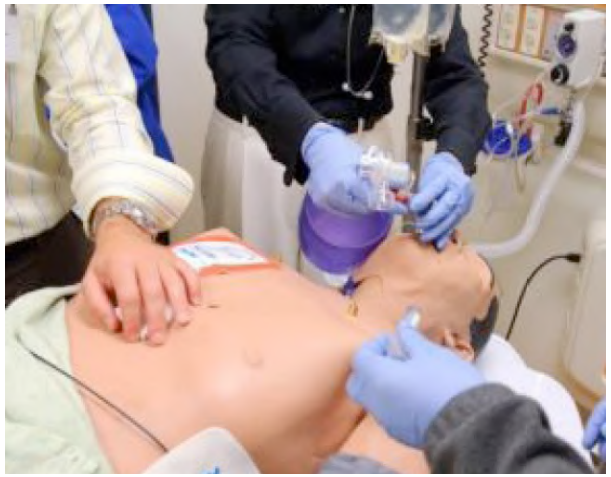
Medical Device

Design Validation

DESIGN VALIDATION SHALL PROVIDE CLEAR, OBJECTIVE EVIDENCE THAT THE MEDICAL DEVICE MEETS THE NEEDS OF THE END-USERS.



- **Establish a Design Validation Plan (and do so early)**
- **Use regulatory product classification**
- **Involves “clinical evaluation” in actual or simulated use with actual end-users**
- **Product is production equivalent**
- **Includes the entire product, including packaging and labeling**



- **“Clinical evaluation” does NOT just mean actual use.**
- **Actual use will likely require addressing additional regulatory criteria.**
- **For many devices, simulated use is more than sufficient.**

820.30(g) ISO 13485:2016 7.3.7

Design Validation

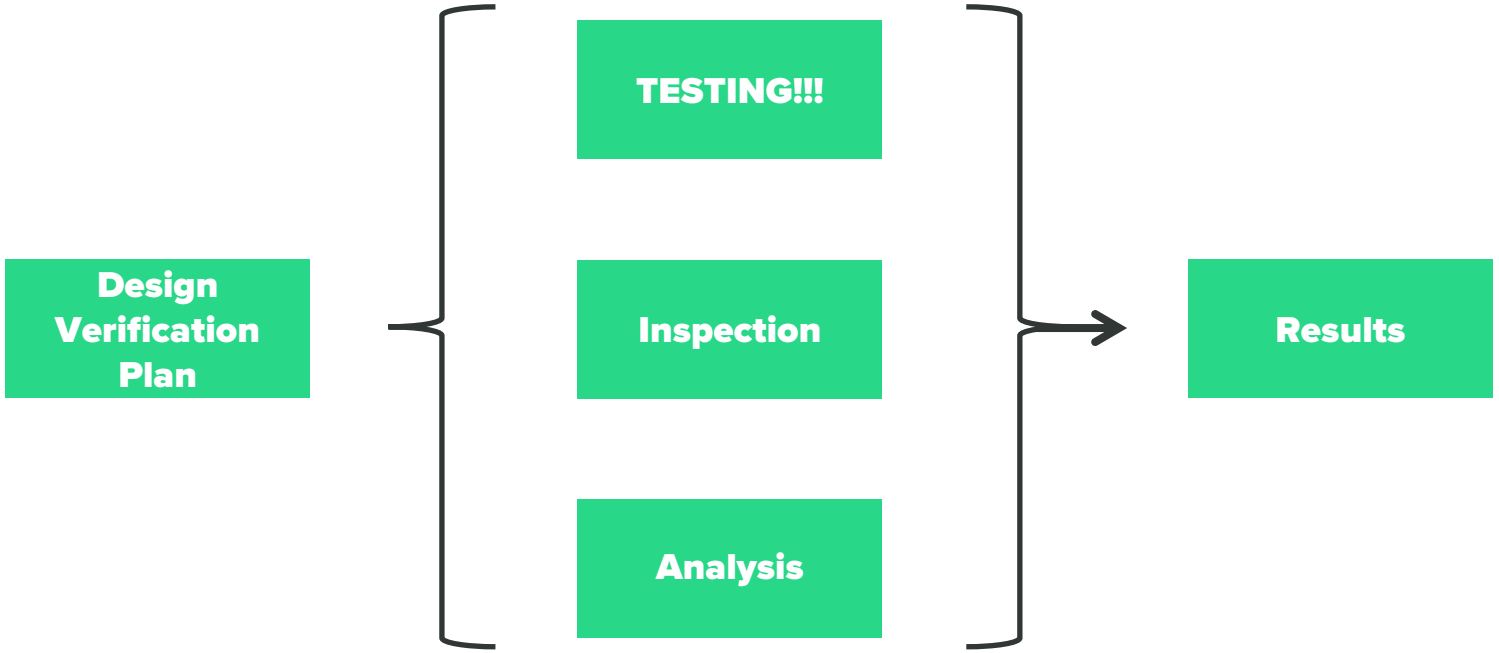
User Needs

Medical Device

Design Validation

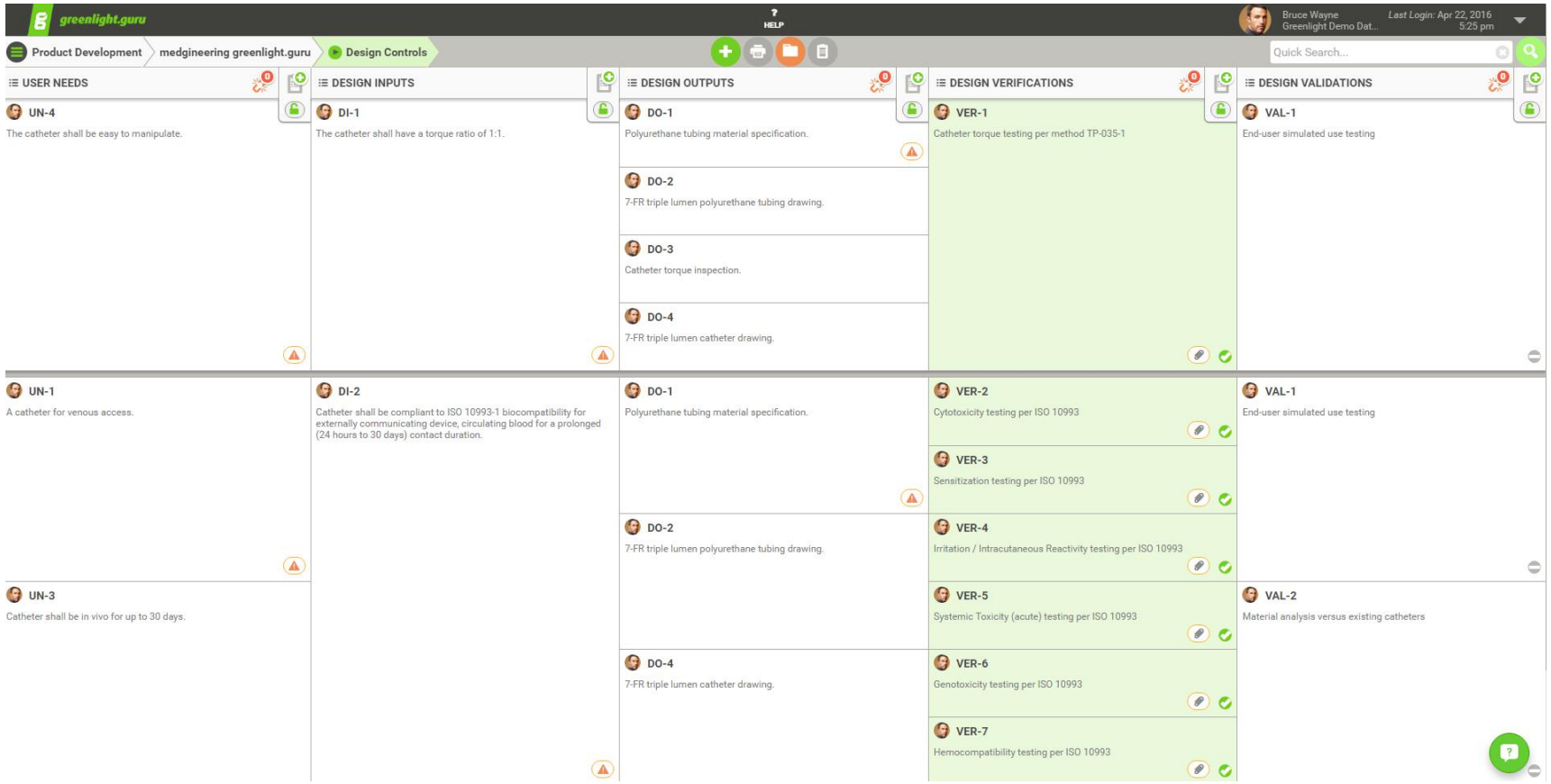
- Plans
- Methods
- Results

DESIGN VALIDATION METHODS



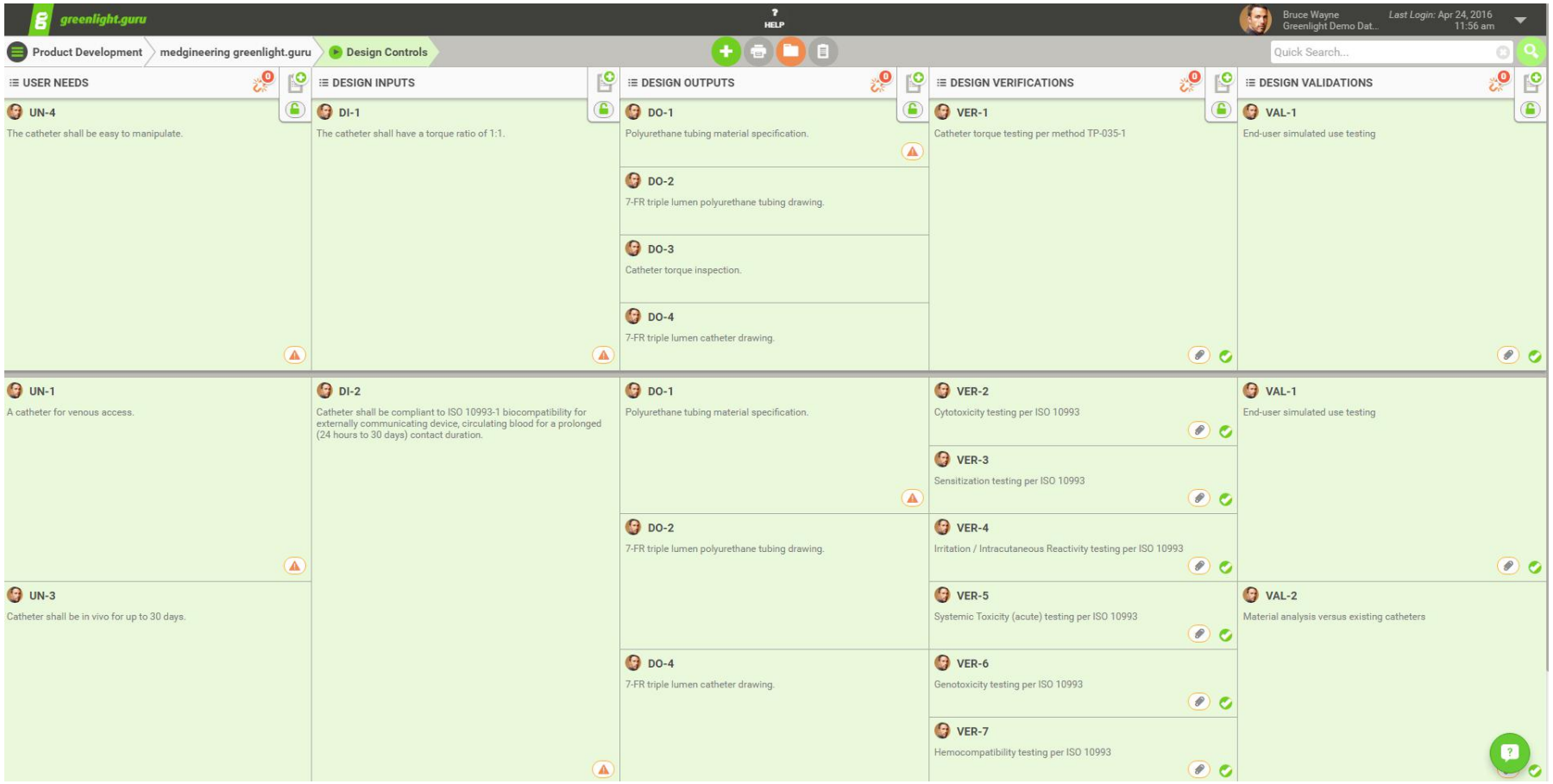
820.30(g) ISO 13485:2016 7.3.7

Design Validation



820.30(g) ISO 13485:2016 7.3.7

Design Validation



DESIGN TRANSFER

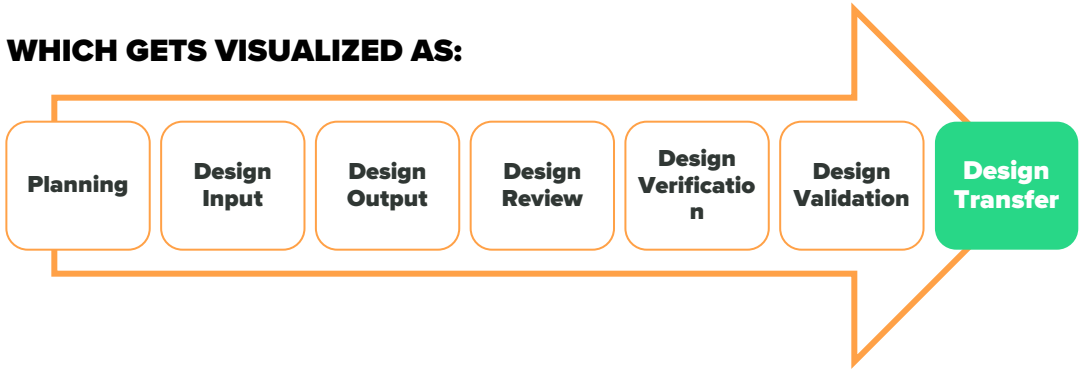
Not an event – but a process!

SOURCE OF MISCONCEPTIONS

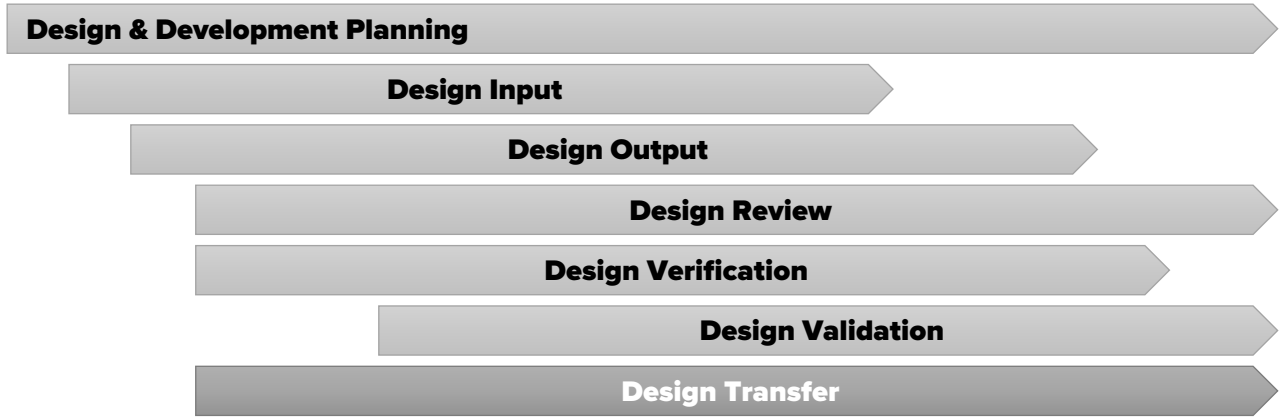
21 CFR PART 820.30 DESIGN CONTROL

a. Design & Development Planning
b. Design Input
c. Design Output
d. Design Review
e. Design Verification
f. Design Validation
g. Design Transfer
h. Design Changes

WHICH GETS VISUALIZED AS:



BUT THE PROCESS REALLY LOOKS MORE LIKE THIS:



DESIGN TRANSFER COMPLETION

- All Device Master Record (DMR) elements reviewed, approved, and production released
- All (DMR) elements are managed under formal change control
- Risk assessments completed and all identified risks appropriately dispositioned
- Defined and implemented test strategy for incoming, in-process, and final acceptance testing
- Plans in place to monitor and/or control features identified as critical to quality
- Process validation complete
- Test methods validated and complete
- Inspection procedures, visual inspections, and workmanship standards are complete
- Installation and servicing procedures are complete
- All equipment identified and calibrated and maintenance procedures are in place
- Manufacturing personnel and inspectors have been trained
- All supplier agreements and qualifications are complete
- Procedures in place to ensure control of device handling, storage and distribution of product
- Procedures in place to ensure identification and traceability of product
- Design verification testing performed and demonstrates design outputs meet design inputs
- Design validation testing performed demonstrates design meets user needs & intended uses
- All elements of the Design Transfer Plan have been completed or otherwise addressed

ABOUT THE PRESENTER

Jon D. Speer
is the founder and VP of QA/RA of greenlight.guru

- **20+ years in medical device industry**
- **Product development engineer, quality manager, regulatory specialist**
- **40+ products to market**
- **Expert at QMS implementations**
- **Dozens of ISO audits & FDA inspections**

greenlight.guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.

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