Beyond Design Controls 101:

Following the Regulation vs. Understanding its Intent

Presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

George Washington University Graduate Dept. of Regulatory Science

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru Webinar (January 9, 2020)

http://blog.greenlight.guru/topic/mike-drues

For questions or more information, call
(508) 887 – 9486 or e-mail mdrues@vascularsci.com

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Beyond Design Controls 101: *Following the Regulation vs. Understanding its Intent*

presented by: ***Michael Drues, Ph.D.***

Since 1990, FDA has required medical device manufacturers to follow design controls. Outside the US, the EU MDR (formerly MDD) include similar requirements as well. Yet, although manufacturers have design control processes in place, they are not always effective as failure to follow design control requirements is commonly cited in FDA 483's and warning letters. Clearly having design controls in place is not enough!

In addition, because design controls must apply to a wide range of devices, they do not specify in detail what manufacturers must do to meet these requirements. Instead, they establish a framework that manufacturers should follow when developing medical devices. This provides manufacturers the flexibility to apply design controls that both comply with the regulation and are appropriate for the Companies devices and development processes.

At a high level, design controls address the design process, i.e., labeling, user needs, design inputs and outputs, design review, verification and validation, etc. But understanding what the regulation says is not enough! We must also understand what design controls are trying to accomplish, i.e., why they exist, in order to avoid problems. At the end of the day, design controls should not be about a hard and fast set of rules… rather, it's about understanding the intent and approaching the process in a logical and systematic fashion. In other words, don't just follow the rules… think!

Using the case study approach, participants will gain a working understanding of:

- What are design controls and why do we have them?
- Who is required to follow design control processes and who is not? What if no design control system?
- How early in the development process do design controls apply?
- How do we control the design process without actually "controlling" it?
- How do we take a holistic approach? i.e., integrate design control, risk management, CAPA, etc.
- What happens if we modify a design or process?
- What does FDA look for in a design control system?
- How do design controls apply to combination products?
- What are the design control challenges for the future, i.e., 3-D printing, etc.?

Upon completion of this webinar, attendees will have an understanding of the design control "framework" and recommendations to effectively meet their requirements. Emphasis will be placed not only on regulatory aspects but on effective design strategy, which is very important to avoid spending unnecessary time and money on an ineffective design control process.

For additional information, check out:

- Column: *Design Controls: Following the Regulation vs. Understanding its Intent* (Med Dev Online, Jan, 2015) available here.
- Podcast: *Do You Make These Design Control Mistakes?* (Med Device Online, December, 2014) available here.
- Webinar: *Why Design Validation is More Than Testing* (June, 2019) here
- Webinar: *Bridging User Needs & Design Requirements* (June, 2018) here
- Webinar: *Medical Device Change Management: Don't use FDA as an excuse to hold you back* (September, 2017) here
- Webinar: *How to Prepare for a Successful Medical Device Design Transfer* (June, 2017) here
- Webinar: *Understanding the Many Connotations of Risk and the Consequences of Getting them Wrong* (March, 2017) here

Additional columns, articles, podcasts and webinars can be found:
Global Medical Device Podcast (GreenLight.Guru) here, Mike on MedTech (Medical Product Outsourcing) here, Medical Design and Outsourcing here, Guerilla Regulatory Strategy (MED Device Online) here and Healthcare Packaging here or LinkedIn here.

Presenter Bio

Michael Drues, Ph.D., is a regulatory strategy consultant specializing in designing novel regulatory strategies to bring new and innovative medical products to market and in developing effective communication strategies between companies and regulatory agencies to minimize time to market and avoid delays.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. He works with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration, Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services and other regulatory and governmental agencies around the world.

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First, an important disclaimer...

I can't make you an expert in a few minutes!

I'm not even going to try but…

Remember my philosophy of education:

To teach you how to think not what to think!

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Is it possible to think regulatory?

"Science is a way of thinking much more than it is a body of knowledge."

Carl Sagan (1934–1996)
American astronomer, author and science journalist

So how about this?

Especially applicable for design controls!

"Regulatory affairs is a way of thinking much more than it is a body of rules and regulations – or at least it should be!"

Michael Drues (1964–)
Regulatory Strategist and Amateur Philosopher ☺
www.meddeviceonline.com/author/michael-drues

Maybe Carl Sagan would be proud!

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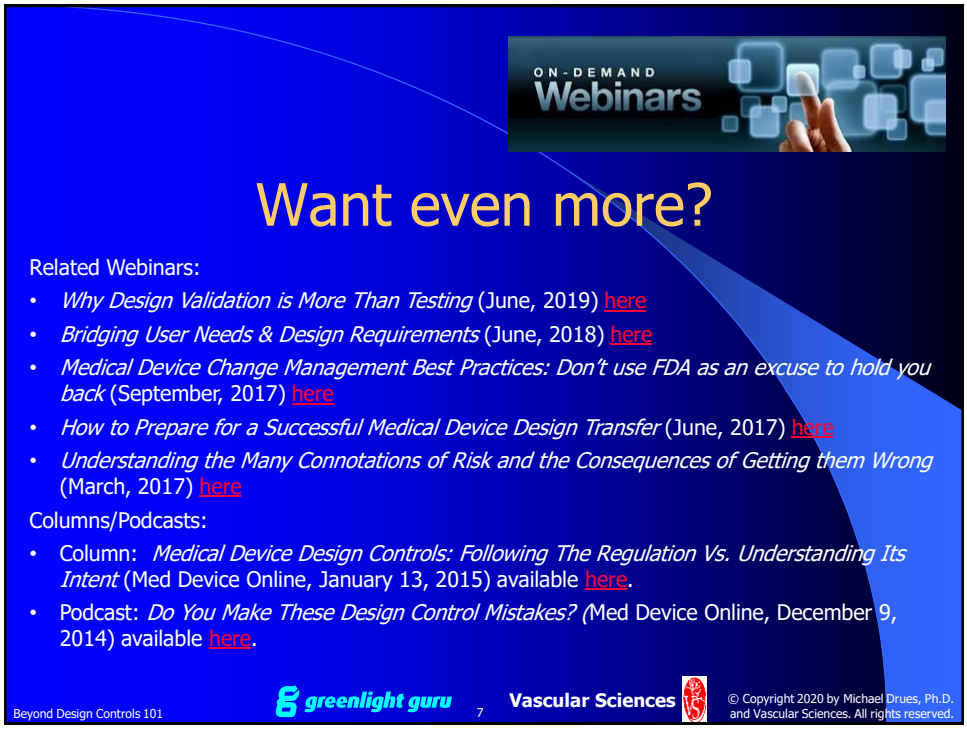

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www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm

Good regulation is neither specific nor rigid… *nor should it be!*

Flexibility of the QS Regulation (Preamble)

"The QS regulation embraces the same "umbrella" approach to the CGMP regulation that was the underpinning of the original CGMP regulation. Because the ***regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device*** according to the current state-of-the-art manufacturing for that specific device.

Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations, 21 CFR 820.5 of the QS regulation. Operating within this flexibility, ***it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective,*** and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. ***The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated.***

FDA has identified in the QS regulation ***the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices."***

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The Philosophy of Design Controls

Design Controls should not be about a hard and fast set of rules… it's about understanding the intent and approaching the process in a logical and systematic fashion.

In other words…

Don't just follow the rules… think!

"Rules are mostly made to be broken and are too often for the lazy to hide behind."

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

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Why do companies get in trouble

Focus on meeting regulatory requirements more than understanding their intent!

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What are design controls

More importantly…

why are design controls important?

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What is Design Control?

What is 

?

What is CONTROL ?

What do we get when we put them together?

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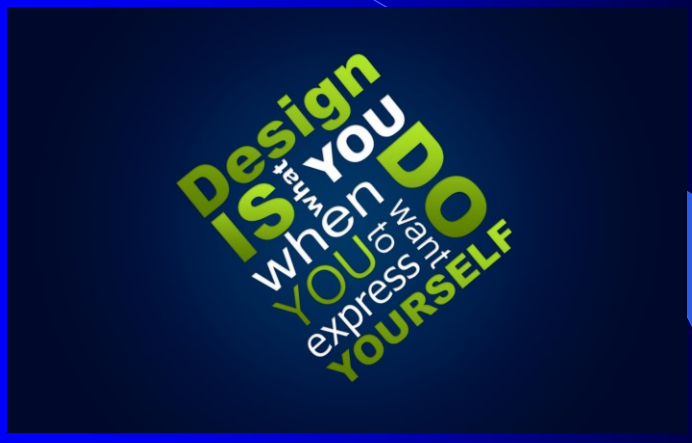
Isn't it ironic?



Do we really want to 'control' it???

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What is Design Control?

Since 1990, the FDA has required that medical device manufacturers that want to market certain categories of medical devices in the US follow Design Control requirements (21 CFR 820.30). At a high level, this regulation requires:

- Design and development planning
- **Design input**, including intended use and user needs (customer attributes)
- **Design output**, including evaluation of conformance to design input requirements through:
  - **Design verification** confirming that the design output meets the design input requirements ("did we design the device right?")
  - **Design validation** ensuring that the devices conform to defined user needs and intended uses ("did we design the right device?")
- **Design review**
- **Design transfer** ensuring that the device design is correctly translated into production specifications
- **Design changes**
- **Design history file**, a demonstration that the design was developed according to the approved design plan and 21 CFR 820.30.

The Medical Devices Directive (MDD 93/42/EEC) similarly lists several requirements regarding the design of a medical device. ISO 13485 is a voluntary standard that contains section 7.3 Design and Development recommending which procedures should be put in place by manufacturers in order to have a quality system that will comply with MDD 93/42/EEC.

The objective of Design Controls is to require that manufacturers follow a methodologically-sound process to develop a medical device with the intent of improving the probability that the device will reach an acceptable level of efficacy and safety.

(Wikipedia, January, 2020)

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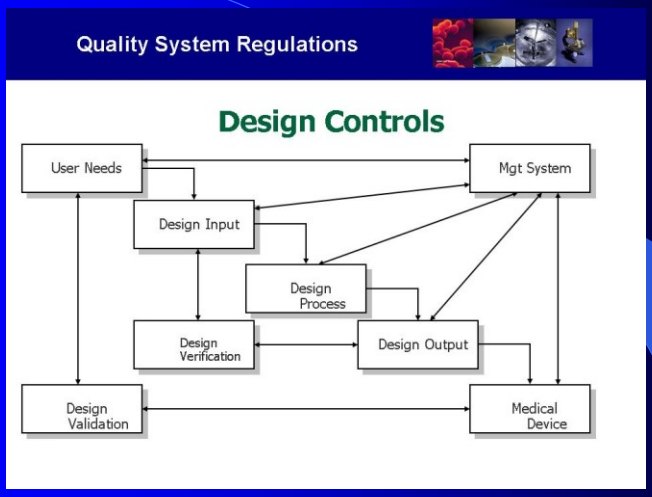
What do Design Control and Physiology share in common?



Everything is connected!

True for development, regulatory, risk, warning letters, CAPA, etc.

Take a wholistic approach!

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How about an example

How would you apply Design Controls to this?

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Case Study: Wound Care Device

Physician: new idea for wound care device (user need)

Question: Why assume user knows what they need?

Engineer + Physician: Need more information!

↓

Engineer: 'translate' → how will it work? i.e., size, properties, materials, etc. (design inputs)

↓

Engineer: design & development (design process)

↓

Engineer: product + process design (design output)

↓

Question: "Did we design the device right?" (design verification)

↓

Question: "Did we design the right device?" (design validation)

↓

Final device

↓

Are we done?

Isn't this just 'prudent engineering' a.k.a. common sense?

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What are the challenges of design control for the future

What is the future of medicine?

Reading the regulation gains you nothing…

but understanding the philosophy buys you a lot!

Recommendation: Apply this to everything you do!

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Case Study: Meet Alex

Do I have your attention yet?

How do Design Controls apply to Personalized Medicine?

Mechanics vs. Intent

Welcome to the world of future of medicine…

and this is just the beginning!

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Why are design controls important?

Textbook answer:

"To ensure that devices meet user needs, intended uses and specified requirements."

Nobel goal but not so simple…

In the US,

"Each manufacturer of any class III or class II device, and [some] class I devices, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met." – *what about wellness devices?*

In the EU,

"In order to distribute a medical device in the EU, a company must demonstrate compliance with the essential requirements of the Medical Device Directives." (MDR)

Your design control system should comply with QSR and ISO13485 but may not look like another!

Remember,

Design controls apply to design of medical devices AND manufacturing processes to make them

Design controls are applicable to new designs as well as modifications of existing designs

Management buy-in is key – not just because it is required… because it is right!

When should design controls start?

Not a simple question!

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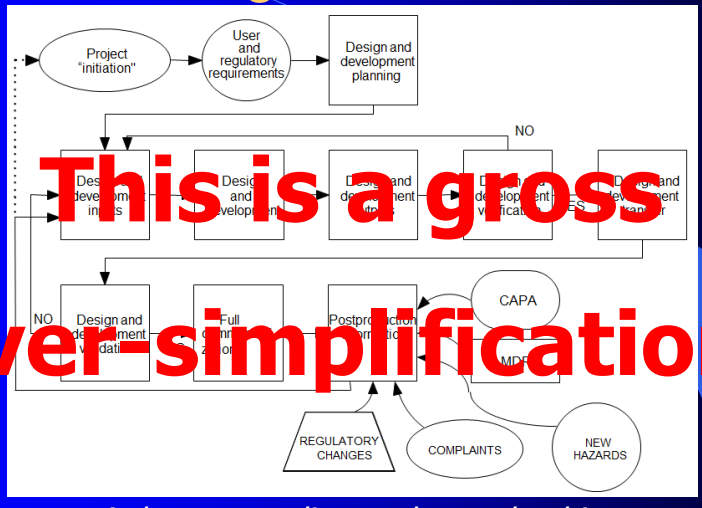
'Ideal' Design Control Process



This is a gross over-simplification!

At least according to the textbook!

Hint: When should DC begin? [hint: where do new devices come from?]

Feasibility/proof-of-concept is not part of design control – *or is it?*

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Basic Terminology and Concepts

- ✓ Design Inputs and Design Outputs
- ✓ Design Verification And Validation
- ✓ Design Freeze
- ✓ Design Review
- ✓ Design Transfer and Scale up
- ✓ Design Changes
- ✓ Design History File (DHF)
- ✓ Device History Record (DHR) & Device Master Record (DMR)

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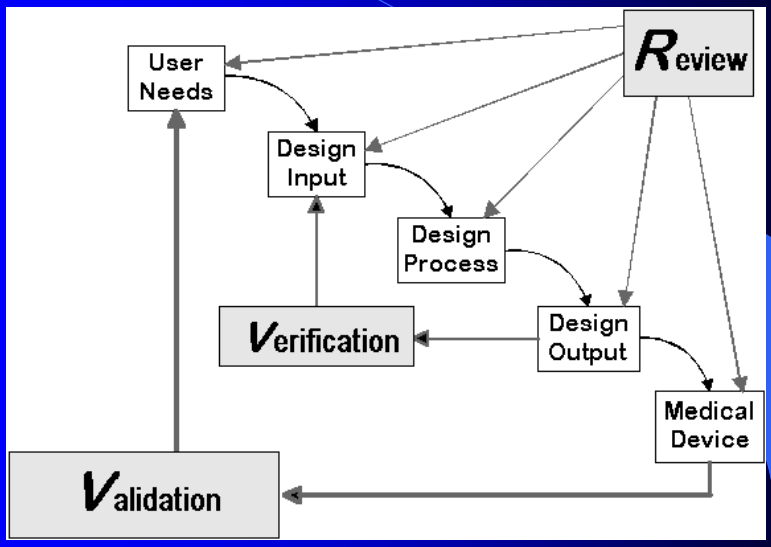
Design Inputs and Design Outputs



Design Control Guidance For Medical Device Manufacturers, March, 1997

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What is a Design Input

"(c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are **appropriate** and address the **intended use** of the device, including the needs of the **user and patient**. The procedures shall include a **mechanism for addressing incomplete, ambiguous, or conflicting requirements**. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented."

21 CFR 820.30(c) here

Much more important…

What does this mean?

Hint: ***Regulation is all about the interpretation of words…***

and your ability to defend your interpretation!

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Design Inputs

Where do they come from?

- External: competitors, customers (physicians), payers, key opinion leaders, subject matter experts, etc.
- Internal: Business Development, Sales and Marketing, R&D, IP, etc.

What are they?

- physical & performance requirements used for device design
- can be quantitative vs. qualitative

One 'key element':

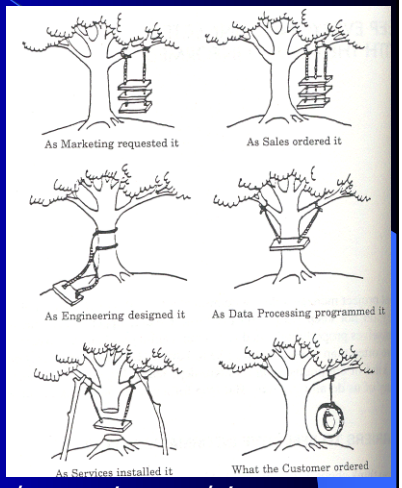
- Address incomplete, ambiguous, or conflicting requirements – *good or bad?*

User Needs → Engineering Design

- i.e., function, performance, interface, safety, regulatory, etc.

Recommendation:

Want to avoid:



Plan for next generations, i.e., label expansions early!

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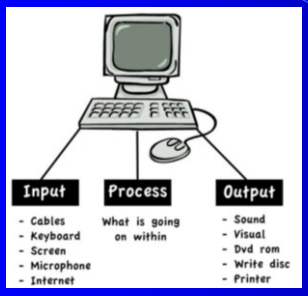
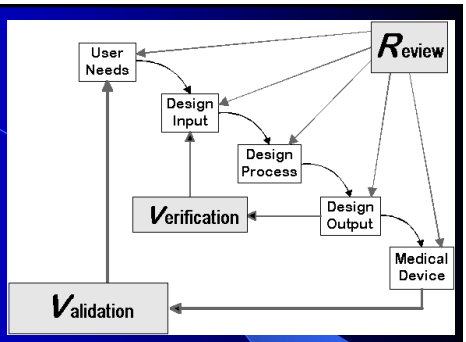
Design Outputs





What are they?

Specifications, drawings, manufacturing procedures, purchasing procedures, service provisions, quality acceptance criteria, software source code, risk analysis, etc.

Where do they go?

Final Product

Design Output → Device Master Record (DMR)

Design output includes device, packaging, labeling and DMR

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What's the relationship between *Design Validation* and *User Needs*

User need is not defined… should it be?

"Design validation shall ensure that devices conform to defined *user needs* and *intended uses*.." and "Design validation means establishing by *objective evidence* that device specifications conform with *user needs* and *intended use(s)*." (CFR: §820.30g)

What does this mean?

Recommendation: *Should not be defined by regulation but by YOU!*

i.e., YOU should define *terms and procedures* in your QMS!

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How about a simple example

Doctor: The device needs to be portable. [User Need]

↓

Engineer: What does that mean?

Maybe the device needs to:

- ✓ lite weight (<5 pounds) – or – on a cart (how big?)?
- ✓ be smaller than a lunch-box (how small is that?)
- ✓ be self-contained (does it need to connect, i.e., power, wi-fi, etc.)?
- ✓ etc., etc., etc.…

All are *design inputs*

Recommendation: Confirm with other users, i.e., ***trust but verify!***

Remember… define *terms and procedures* in your QMS!

Why is all this "required?" [Hint: the designer is not the user!]

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Are there other design inputs

- ✓ Device function
- ✓ Physical characteristics
- ✓ Performance
- ✓ Safety
- ✓ Reliability
- ✓ Standards
- ✓ Regulatory requirements
- ✓ Human factors
- ✓ Labeling & packaging
- ✓ Maintenance
- ✓ Sterilization
- ✓ Compatibility (materials/devices)
- ✓ Environmental
- ✓ Anything else…

Recommendation:

1. Identify as many as possible at the beginning
2. Evaluate/reevaluate throughout design/development process
3. Test at the end of the process, i.e., trust but verify!

Do we really need regulation to tell us this?

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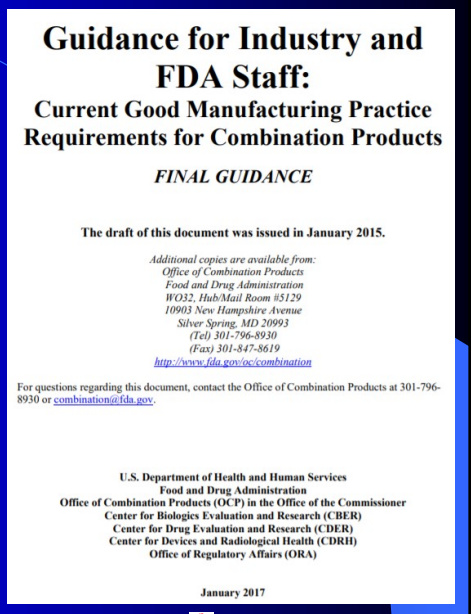
Manufacturing Challenges for Combination Products

Examples of Design Inputs / Design Outputs and Risk Mitigation Tables for a surgical mesh coated with a drug (combination product):

Design Input/User Needs	*Design Output*
Required delivery dose and delivery rate for the drug	Drug formulation and concentration, coating thickness, uniformity of coating, manufacturing process requirements, allowable storage conditions, drug delivery rate
Expected use condition (e.g., anatomical location of use, surgical technique)	Labeling (instructions for use), Material/drug composition to ensure no damage to mesh or coating during surgical placement
Maximum allowable temperature during transportation, handling, and storage for the combination product	Packaging/labeling specifications for the combination product
No unacceptable degradation of the drug over the expected shelf-life	Specifications for the drug-contacting materials, shelf-life labeling
No degradation of the surgical mesh over the expected shelf-life	Specifications for mesh material and drug formulation, shelf-life labeling

Risk	*Mitigation*
Drug concentration in coating not sufficient to treat infection (e.g., due to insufficient thickness, inappropriate delivery rate, or non-uniformity of coating)	In-process acceptance testing, process validation
Mesh erodes or drug degrades during use or storage	Design verification testing (bench), clinical testing, labeling (instructions for use), purchasing controls over drug supplier, specifications and other process controls



Guidance for Industry and FDA Staff:

Current Good Manufacturing Practice Requirements for Combination Products

FINAL GUIDANCE

The draft of this document was issued in January 2015.

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930
(Fax) 301-847-8619
http://www.fda.gov/oc/combination

For questions regarding this document, contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products (OCP) in the Office of the Commissioner
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)
Center for Devices and Radiological Health (CDRH)
Office of Regulatory Affairs (ORA)

January 2017

FDA Guidance, January, 2017 available here.

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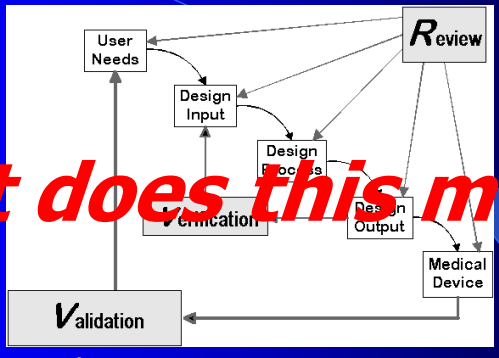
Verification and Validation (V&V)



What does this mean?

Design Control Guidance For Medical Device Manufacturers, March, 1997

Design verification asks

"Did we design the device right?"

Design validation asks

"Did we design the right device?"

Not the same as 'did we solve the right problem?' or 'did we ask the right question?"

Is this not simply 'prudent' engineering?

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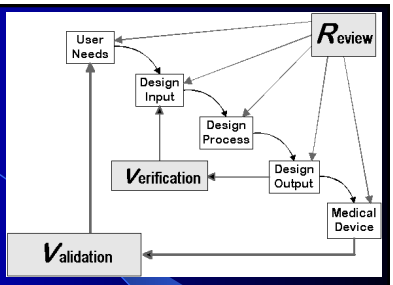
Design Verification



Design verification asks

"Did we design the device right?"

or in more words…

comparing the output of each design process step with the input to that step in order to demonstrate that the results are consistent with the goals

but…

Do we have the right goals? i.e.,

Are we asking the right questions?

Are we solving the right problems?

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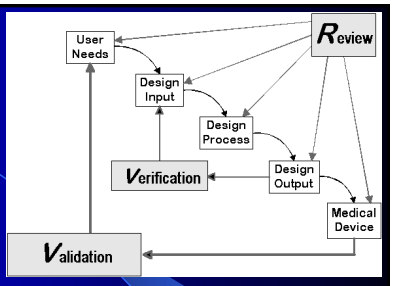
Design Validation



Design validation asks

"Did we design the right device?"

or in more words…

test device against requirements (after verification)

Important reminder:

use devices as close to 'final product' as possible,

i.e., 'manufactured' using the same methods and procedures expected to be used for production

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Beyond Design Controls 101:

Following the Regulation vs. Understanding its Intent

Questions and Answers

Remember,

Answers are only as good as the questions we ask!

What good is designing the 'right' device...

if we're solving the wrong problem?

What good is getting the 'right' answer...

if we're asking the wrong question?

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What does "validation" *really* mean

Is it about ticking boxes on a form?

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Are we required to "validate" we are solving the right problem

Should we be?

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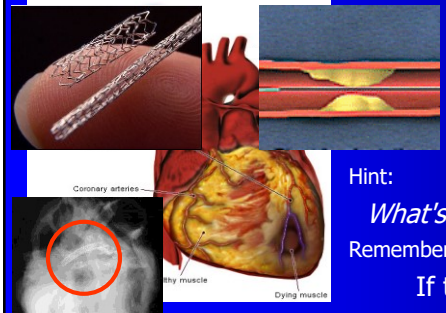
Case Study: *Bare Metal Coronary Stent*



Some *reverse engineering…*

What's the user need?

How does user need → design input?

Does this influence / limit / bias design?

Answers are only as good as the questions we ask!

Hint:

What's the biological problem (i.e., root cause)?

Remember…

If the only tool you have is a hammer…

all of your problems look like _____ ?

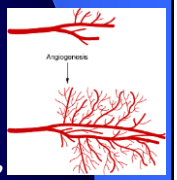
How does that apply here? Hint: What solutions do we ***not*** have & why?

LOTS!

Transmyocardial Revascularization (TMR/pTMR)

a.k.a. *mechanical angiogenesis*

True Angiogenesis



Why is this important? *Can you say disruptive technology?*

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What's the real sham?

Background:

- >500K patients/yr (WW) have stents inserted to *relieve chest pain* at cost $11K – $41K (US hospitals)

Method:

- 200 patients treated 6 weeks with drugs →
- procedure: "real or fake" insertion of stent

"This is one of the few studies in cardiology in which a sham procedure was given to controls who were then compared to patients receiving the actual treatment."

"In both groups, doctors threaded catheter through the groin or wrist and, with X-ray guidance, up to the blocked artery. Once the catheter reached the blockage, the doctor inserted a stent or, if the patient was getting the sham procedure, simply pulled the catheter out."

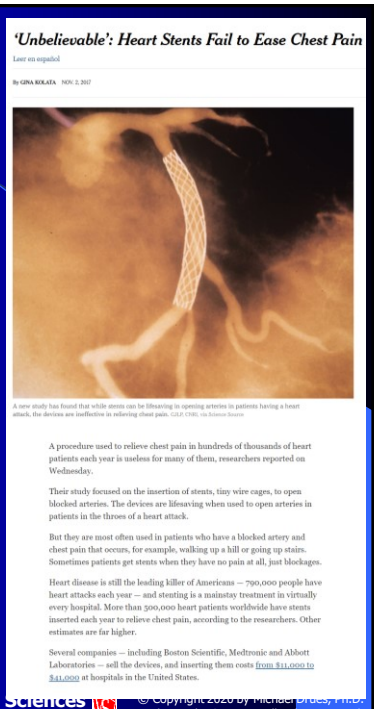
Conclusion:

"**A procedure used to relieve chest pain in hundreds of thousands of patients/year is useless for many of them.**"

Is this a sham procedure or a sham device?

What do you think?

'Unbelievable': Heart Stents Fail to Ease Chest Pain (New York Times, Nov. 2, 2017) here



'Unbelievable': Heart Stents Fail to Ease Chest Pain

Laser en español

By GINA KOLATA NOV. 2, 2017

A new study has found that while stents can be lifesaving in opening arteries in patients having a heart attack, the devices are ineffective in relieving chest pain. GALIT CHEN, via Science Source

A procedure used to relieve chest pain in hundreds of thousands of heart patients each year is useless for many of them, researchers reported on Wednesday.

Their study focused on the insertion of stents, tiny wire cages, to open blocked arteries. The devices are lifesaving when used to open arteries in patients in the throes of a heart attack.

But they are most often used in patients who have a blocked artery and chest pain that occurs, for example, walking up a hill or going up stairs. Sometimes patients get stents when they have no pain at all, just blockages.

Heart disease is still the leading killer of Americans — 790,000 people have heart attacks each year — and stenting is a mainstay treatment in virtually every hospital. More than 500,000 heart patients worldwide have stents inserted each year to relieve chest pain, according to the researchers. Other estimates are far higher.

Several companies — including Boston Scientific, Medtronic and Abbott Laboratories — sell the devices, and inserting them costs from $11,000 to $41,000 at hospitals in the United States.

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Always question the status quo!

BusinessWeek

Medical Guesswork

From heart surgery to prostate care, the medical industry knows little about which treatments really work

BY JOHN CAREY (P. 72)

DRUGS PSYCHIATRY CHIROPRACTIC ASPIRIN REST WATCH & WAIT YOGA SURGERY PHYSICAL

BusinessWeek, May 29, 2006

"Treatments are based largely on rules and traditions, not scientific evidence."

COVER STORY

something called "evidence-based medicine"

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Beyond Design Controls 101:

Following the Regulation vs. Understanding its Intent

Product Validation vs. Process Validation

Design/Product Validation

- conforming to user and patient needs, i.e.

'Does the device work right?'

Process Validation:

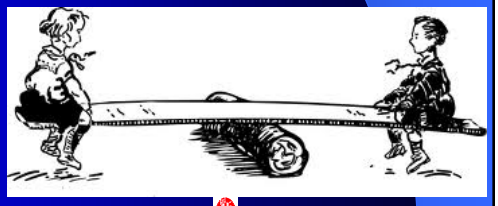
- manufacturing process meets predetermined specifications

Remember,

Design/Product Validation ≠ Process Validation

Regulation requires both – *individually!*

Should not separate them…
both are important!



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How early in the development process should we think about validation

It's never to early!

Start with validating that we are solving the right problem!

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How do we "validate" what we don't validate

Validating what we don't do is just as important (if not more) than validating what we do!

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When (not if) we change our device while on the market, when and how do we revalidate

Welcome to the world of change management… s510k vs. L2F

Reminder:

Most common cause of warning letters and 483's!

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Design Changes and Process Changes

Very common source of problems down the road…

Most of which could be mitigated if not entirely avoided!

Reasons for Change:

- New/Improved features
- Fixing Problems
- New safety/regulatory/purchasing/etc. requirements
- Greater efficiency, i.e., cost reduction
- Lots of others…

Please…

Don't use regulatory burden as a design criterion…
this practice is really holding us back!

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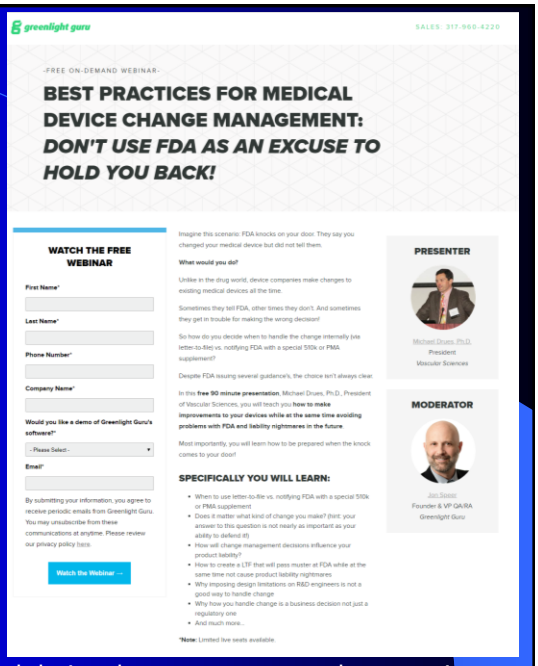
Check out



www.greenlight.guru/webinar/medical-device-change-management-best-practices

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Design Transfer and Scale-Up

Remember Design-for-Manufacturing concept

- recommendation: involve manufacturing early (beginning!)
- design controls 'remind us' of what Socrates taught
  what we know and what we don't and the difference!
- future of manufacturing i.e., 3-D printing (personalized medicine)

Challenges of Scale-Up

- Less concern for devices & drugs – big challenge for biologics!
- Especially combination products!

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Design Review

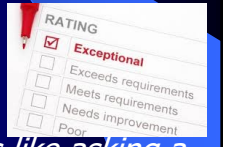
Design Review:

- Objective: meet objectives, prevent problems
  Market (CMS + Customers) provides 'ultimate' design review!
- Recommendation: start early – conduct frequently!
- Documented and included in design history file
  Desirable from regulatory but not product liability!

Recommendation: regulation does not require frequency or detail!

Independent Design Review

Is this desirable?



- Why?

Asking an engineer to critique their own design is like asking a parent to critique their own child… it's inherently biased!

- Required but what does it really mean – how do we achieve it?
  i.e., who should do it?

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DHF vs. DMR vs. DHR

Nomenclature is confusing… *focus on what they contain and why!*

To market device in US, must comply with QSR which requires:

Design History File (DHF)

- contains *design history* of finished device

Device History Record (DHR)

- contains *production history* of finished device

Device Master Record (DMR)

- contains *procedures and specifications* for finished device

Refer to guidance and CFR for definitions but very vague!

Does not mean all records must be there…

just that they must be referenced

Recommendation: *don't let this*  *slow you down!*

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Beyond design controls… what else is related

Don't think of design controls in isolation…

think wholistically!

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Corrective and Preventive Action

CAPA simplified →

Gotten pretty good at CA…
PA not so much! ☹

What is the ideal number of CAPA's?
Is it zero?

Can we have a PA without a CA?
Absolutely… how so?

Relationship to Design Controls?

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What about risk

Risk have many connotations….
Risk Management Strategy *vs.* Risk Management Plan
On- *vs.* Off-Label Use

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What about risk

Risk Migration Strategy *vs.* Risk Management Plan

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When does risk management end?

Risk management never ends…

At least in theory!

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Beyond Design Controls 101:

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The Philosophy of Risk Management

Risk Management should not be about a hard and fast set of rules… it's about understanding the intent and approaching the process in a logical and systematic fashion.

In other words…

Don't just follow the rules… think!

"Rules are mostly made to be broken and are too often for the lazy to hide behind."

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

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Bottom Line:

When it comes to risk analysis and planning:

- Should be utilized early and throughout design and development process
- Often generates new information to feed back into design and development process (→ current/future devices)
- No amount of planning can eliminate all hazards and risks…

but we can mitigate many of them!

Following the design control philosophies automatically mitigates risk!

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What does FDA look for in a design control system

or at least what they should be looking for!

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What does FDA look for?

- ✓ Design procedures and plan established?
- ✓ Design inputs and requirements identified?
- ✓ Design outputs and specifications identified?
- ✓ Design verification and validation conducted?
- ✓ Process validation completed (including software if applicable)?
- ✓ Risk analysis conducted (on-going, mechanism for review/update)?
- ✓ Design review(s) conducted (independent review?)?
- ✓ Design transfer to manufacturing completed successfully?

Consider this:

Is what FDA looks for >, < or = to what your organization looks for?

Remember what the Design Controls are trying to accomplish!

Isn't this simply "good engineering" a.k.a. common sense?

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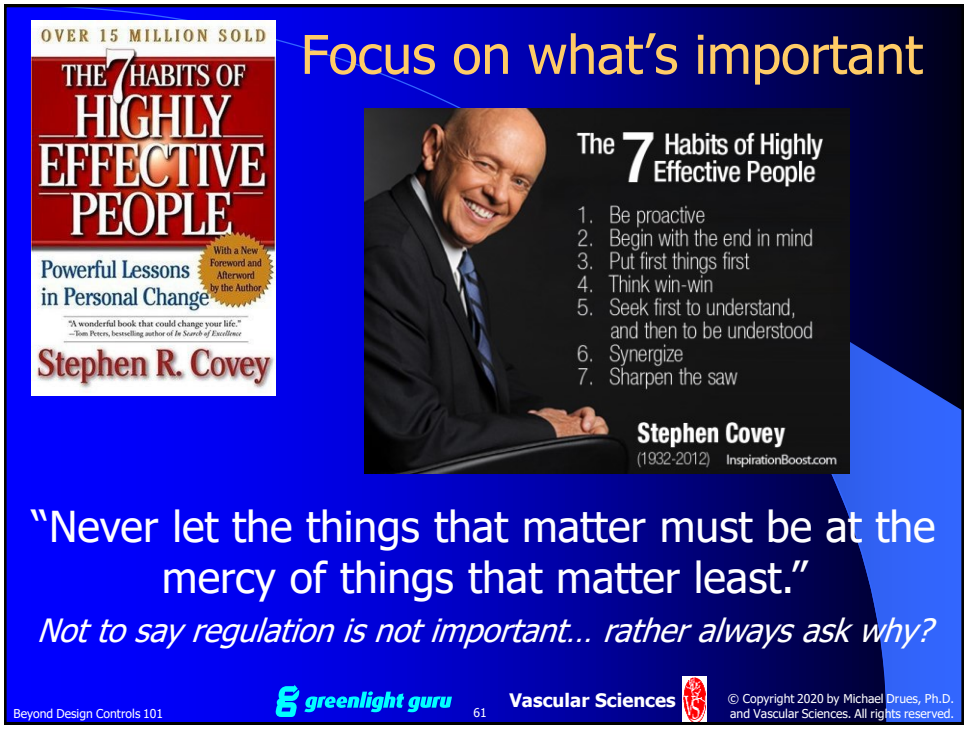

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What if no design control system?

- ✓ Why no design control system?
- ✓ Common scenarios:
  - ✓ Acquisition of company/technology? i.e., entrepreneurs/R&D engineers don't like red tape!
  - ✓ Research → Development i.e., internal transition, when does design control kick in?
  - ✓ Inadequate system – is any system adequate?
  - ✓ Reclassification (I→II) of existing device and/or next-generation device?
- ✓ Learn requirements and use terminology

Regulators like to know you now know… or at least act like you do! ☺

- ✓ Document formal training
- ✓ Start a CAPA
- ✓ Create *retrospective* DHF – don't pretend!
- ✓ Recommendation: validate you systems

Not 'required' but highly recommended!

Bottom line: *view this as an opportunity… but act quickly!*

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What are the challenges for the future

Or put another way…

What's one of the most significant limitations of the Design Controls?

Fundamental tenant: ***meet the needs of your user!*** But…

Why assume the user knows what they <u>really</u> need?!?!?

Evolutionary vs. Revolutionary Product Development

horse → car, candle → lightbulb, etc.

How about a medical device example…

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