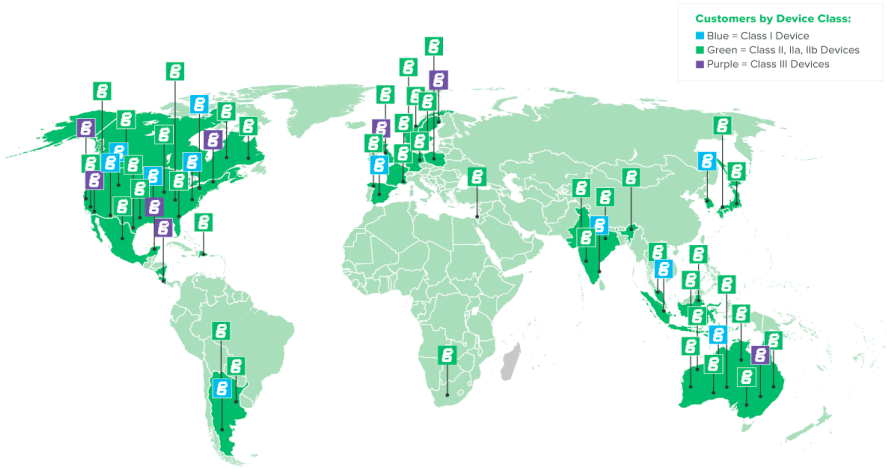
WHEN DESIGN INPUT REQUIREMENTS GO WRONG

February 7th, 2019

Presented by: **Jon Speer**
Founder & VP QA/RA of Greenlight Guru

TRUSTED BY LEADING MEDICAL DEVICE COMPANIES IN MORE THAN 50 COUNTRIES



abcam
COOK MEDICAL
COMPUMEDICS
invendo medical
THE FUTURE OF ENDOSCOPY
sigilon therapeutics
GCMI GLOBAL CENTER FOR MEDICAL INNOVATION
infinite biomedical technologies
RECOVERY FORCE
PHAGENESIS
MR Coils
SONAVEX SURGICAL
RR Mechatronics Masters of Measurement

Greg Sommer, CEO & Co-founder
Sandstone Diagnostics, Inc.

"Greenlight Guru has enabled us to implement our quality system across the company and accelerate product development"

Ryan Shelton, CEO
PhotoniCare

"We've been using Greenlight Guru for the better part of a year now and it really simplifies quality management."

Linda Cox, Senior Vice President QA
Solius

"I was actually a little nervous going into the audit, because it seemed too effortless. I've worked in QA at a Fortune 500 company with a custom solution. Your flow is better."

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

125k
podcast listeners

#1
blog and podcast in the industry

68k
look to us for the latest in quality

FEATURED IN

MedTech Intelligence
Inc.
THE VERGE
MDDI
TechCrunch
TNW THE NEXT WEB
Forbes
MED DEVICE ONLINE

G2 CROWD ★★★★½

"Great eQMS Software..."

"The software is easy to use with little to no customization needed. It has been a great tool for developing our device through design control. The post-market additions have been amazing as well as tasks. After using multiple types of eQMS software over the years this is the best by far!"

★★★★★
"My QMS is world class"

★★★★★
"Design controls lifesaver"

★★★★★
"One-stop shop"

★★★★★
"Fantastic product, even better team"

THE PLATFORM FOR MEDICAL DEVICE COMPANIES

PREMARKET

Multi-Level Design Controls

Risk Management

Advanced Document Management

POSTMARKET

Audit Management

Complaint Management

CAPA Management

Nonconformance Management

Change Management

Training Management

QA/RA SERVICES

Medical Device Industry Expertise

QMS Software Support

Strategic Partnership

Customer Success

WE'LL BE DISCUSSING...

- Common Design Mistakes
- Regulatory Requirements
- Art of Defining Design Inputs
- Sources for Design Inputs
- Best Practices for Becoming a Design Input Artist
- Real-life Example Case Study
- Q&A Session

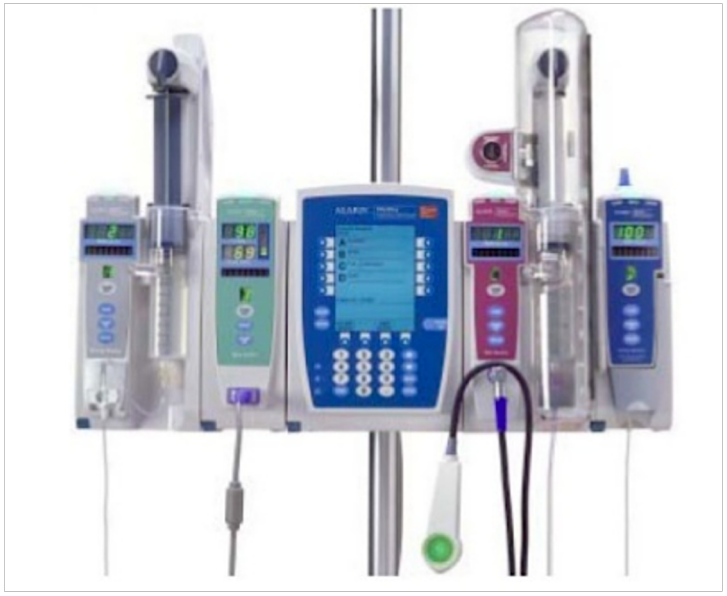

ONE OF US WILL HAVE TO READ THIS GIGANTIC PRODUCT REQUIREMENTS DOCUMENT.
www.dilbert.com scottadams@aol.com
UNLESS IT GETS DESTROYED IN A FREAK ACCIDENT.
© 1999 United Feature Syndicate, Inc.
IT'S LIKE WATCHING THOMAS EDISON WORK.
I HAVE SOME OILY RAGS IN MY CUBE.

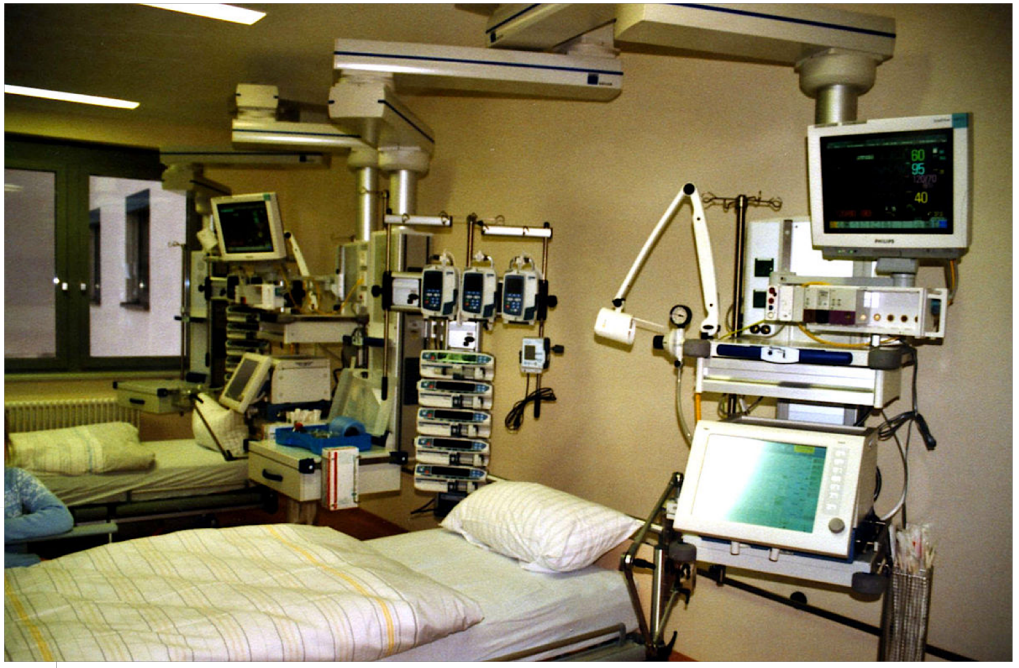
WHEN DESIGNS GO WRONG

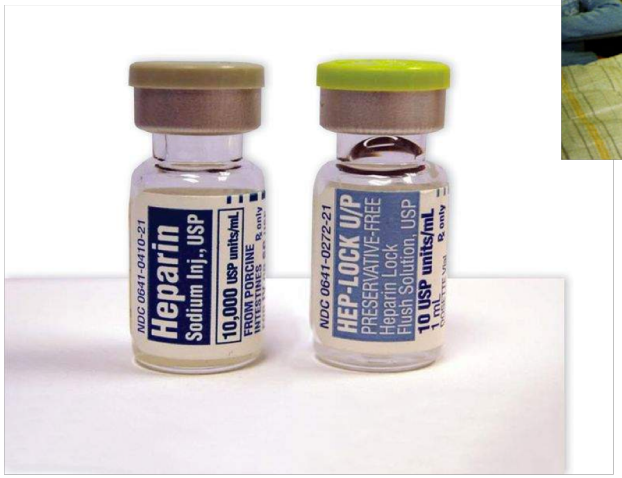

Black & Gold
Fly & Insect Killer
300g NET
Black & Gold
Canola Cooking Spray
400g NET


FOUR ARMS
THREE ARMRESTS


PUSH
PUSH






NDC 0641-0410-21
Heparin
Sodium Inj., USP
10,000 USP units/mL
FROM PORCINE
NDC 0641-0272-21
HEP-LOCK U/P
PRESERVATIVE-FREE
Heparin Lock
Flush Solution, USP
10 USP units/mL

THE ART OF DEFINING DESIGN INPUTS

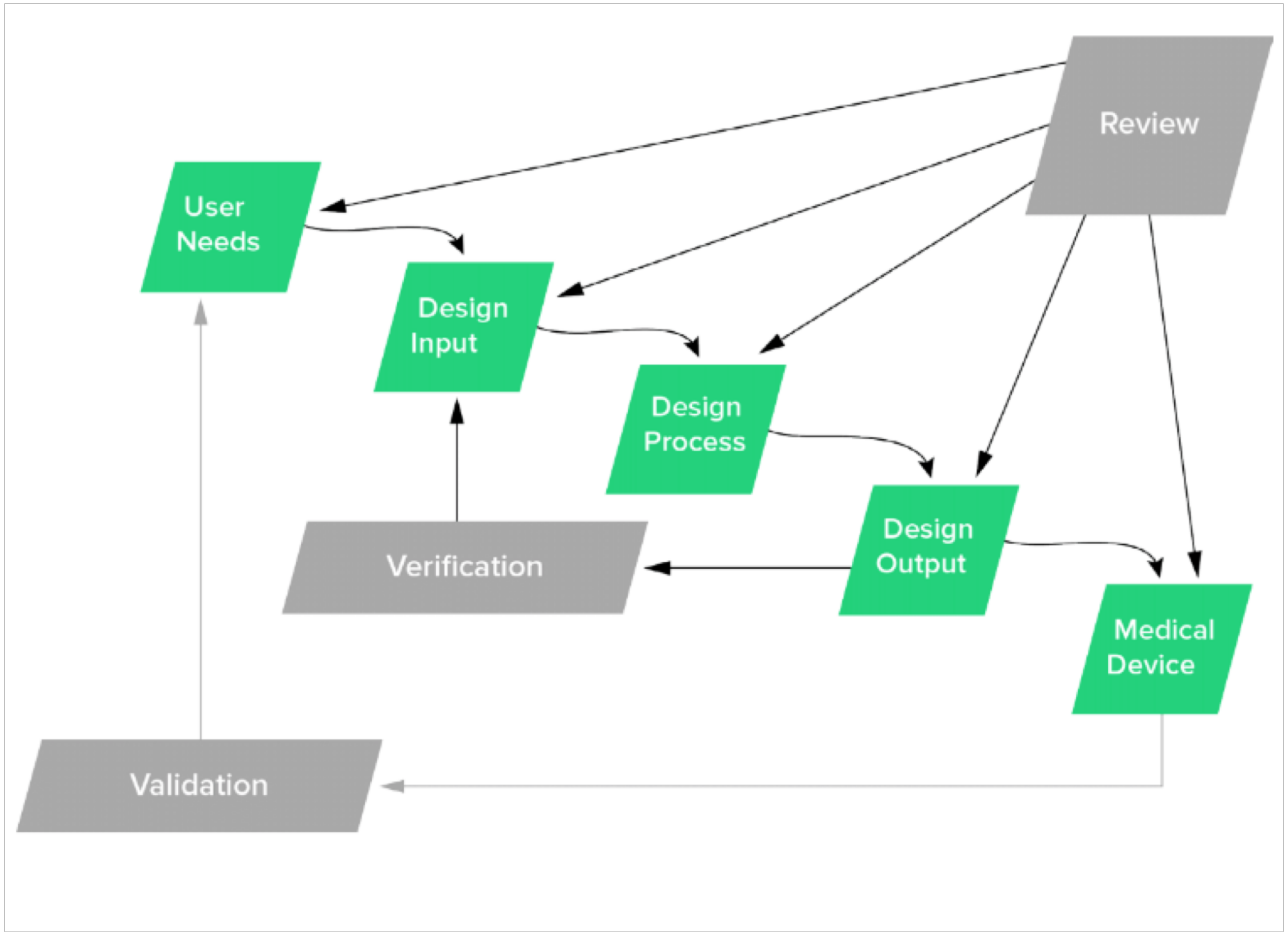
DESIGN INPUTS

also known as...

- Design & Development Inputs
- Design Input Requirements
- Requirements
- Design Requirements
- Product Requirements
- Requirements Specifications

WHY ARE DESIGN INPUTS IMPORTANT?

- **Design Inputs** are widely regarded as the most important design control element (FDA says so too in their guidance document).
- **Design Inputs** drive product development.
- **Design Inputs** have first degree relationships to User Needs, Design Outputs, and Design Verification.


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

DEFINING DESIGN INPUTS

- Expect it to be an iterative process.
- First iteration will likely be ambiguous and vague.
- It is your job to figure out how to define these so that all are clear and objective.

TIP : A good practice is to make a prototype and to do some informal bench testing to help make design inputs clear and objective.

GOALS TO CONSIDER WHEN APPROACHING DESIGN INPUTS

- Capture all functional, performance, safety, and regulatory requirements
- Build upon user needs and intended use
- Make them clear and objective
- State them in a way that allows you to prove or disprove them

DESIGN INPUT REQUIREMENTS FOR FDA 21 CFR 820 & ISO 13485:2016

FDA 21 CFR 820.30(c)

(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.

ISO 13485:2016 SECTION 7.3.3

7.3.3 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.5).

These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use;

b) applicable regulatory requirements and standards;

c) applicable output(s) of risk management;

d) as appropriate, information derived from previous similar designs;

e) other requirements essential for design and development of the product and processes.

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

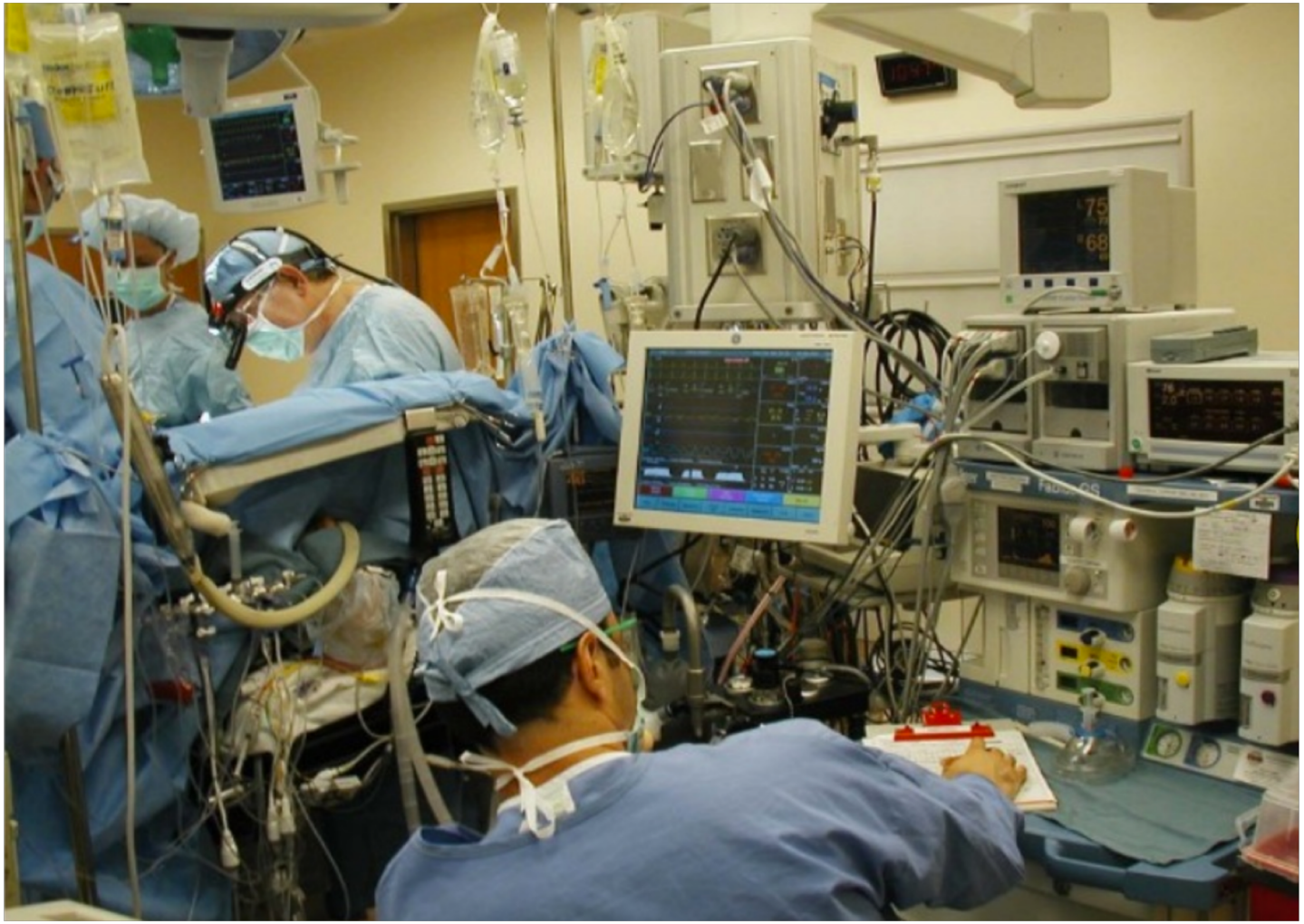
NOTE Further information can be found in IEC 62366-1.

QUTOES FROM FDA DESIGN CONTROLS GUIDANCE

"Risk management begins with the development of the design input requirements. As the design evolves, new risks may become evident. To systematically identify and, when necessary, reduce these risks, the risk management process is integrated into the design process. In this way, unacceptable risks can be identified and managed earlier in the design process when changes are easier to make and less costly." (page 5)

"Design input is the starting point for product design. The requirements which form the design input establish a basis for performing subsequent design tasks and validating the design. Therefore, development of a solid foundation of requirements is the single most important design control activity." (page 13)

30%



SOURCES FOR DESIGN INPUTS

PRIMARY SOURCE:
PREVIOUSLY DEFINED USER NEEDS

ADDITIONAL SOURCES TO CONSIDER WHILE DEFINING DESIGN INPUTS:

- Industry standards
- Regulations
- Previous projects or products
- Competitor products
- End users
- Prototypes

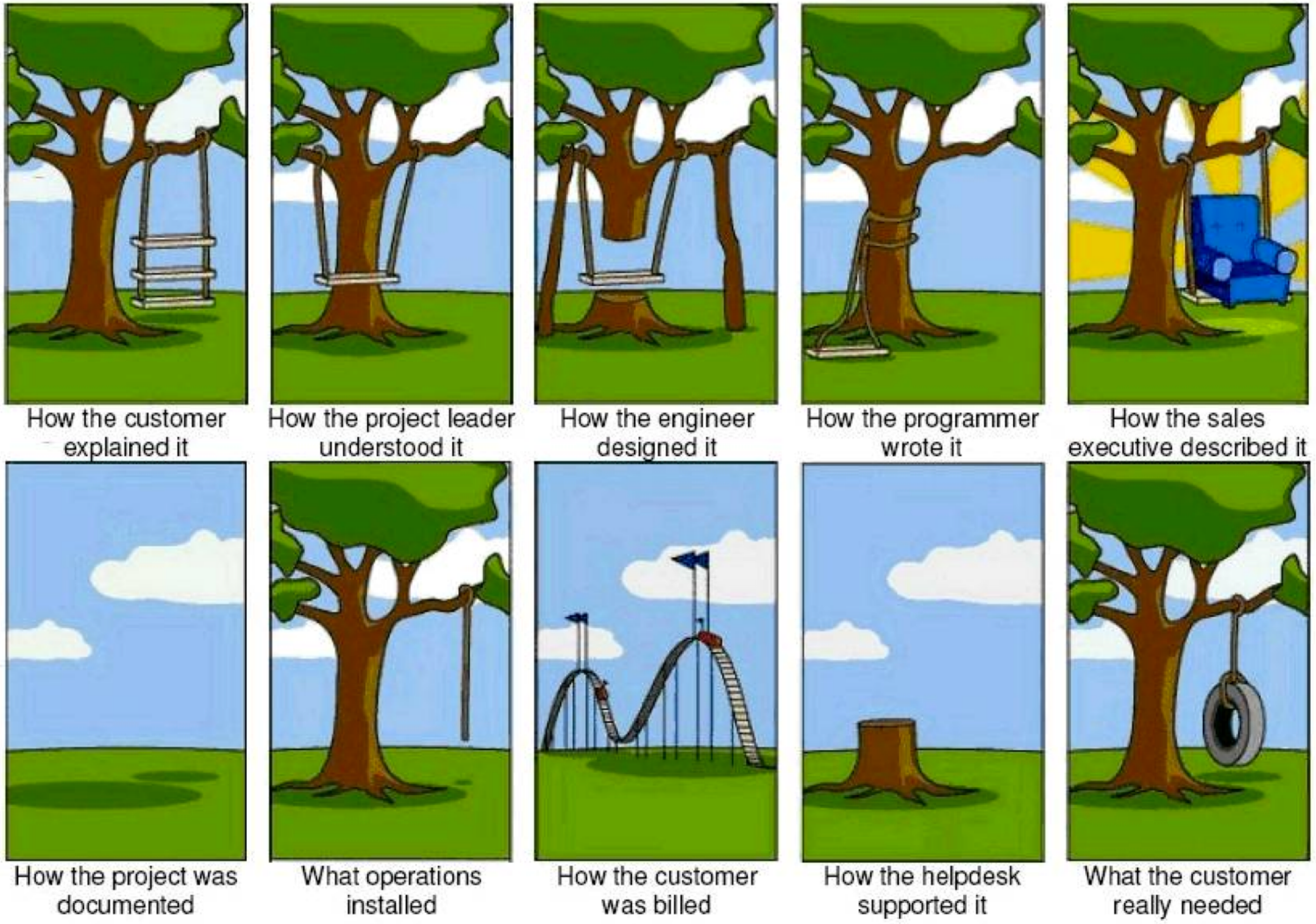
BEST PRACTICES FOR BECOMING A DESIGN INPUT ARTIST

WHO'S INVOLVED IN THE PROCESS?

- There is not a *single person* who should be solely responsible for design inputs.
- When a team is involved, everyone should contribute–it will make the effort that much stronger.

GOALS OF DESIGN INPUTS

- ✓ To be clear and objective
- ✓ To be stated in a measurable way so that you can prove or disprove them later during design verification
- ✓ To be comprised of your user needs and intended use
- ✓ To capture all performance, regulatory, functional, and safety requirements


How the customer explained it
How the project leader understood it
How the engineer designed it
How the programmer wrote it
How the sales executive described it
How the project was documented
What operations installed
How the customer was billed
How the helpdesk supported it
What the customer really needed

REAL-LIFE CASE STUDY EXAMPLE


END

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FDA News Release

FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release March 31, 2017

Release

Español

The U.S. Food and Drug Administration is alerting consumers to Meridian Medical Technologies' voluntary recall of 13 lots of Mylan's EpiPen and EpiPen Jr (epinephrine injection) Auto-Injector products used for emergency treatment of severe allergic reactions. This recall is due to the potential that these devices may contain a defective part that may result in the devices' failure to activate. The recalled product was manufactured by Meridian Medical Technologies and distributed by Mylan Specialty.

While the number of reported failures is small, EpiPen products that potentially contain a defective part are being recalled because of the potential for life-threatening risk if a severe allergic reaction goes untreated. Consumers should keep and use their current EpiPens if needed until they get a replacement. Consumers should contact Stericycle at 877-650-3494.

As stated on the product label, consumers should always seek emergency medical help right away after using their EpiPens, particularly if the device did not activate.

Inquiries

Media

Theresa Eisenman
301-796-2969

Consumers

888-INFO-FDA

Follow FDA

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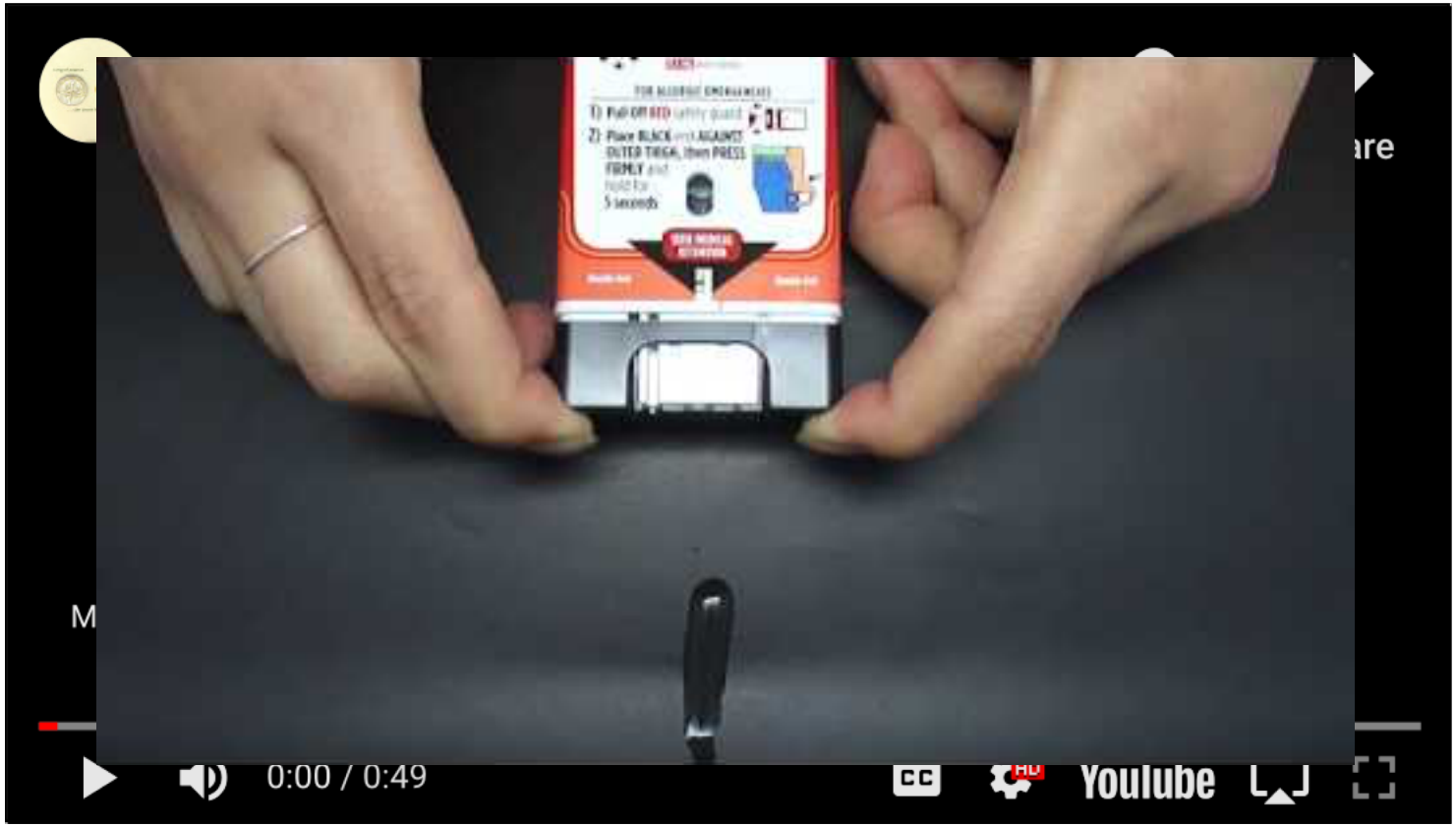
Follow FDA
Follow @FDAmedia

DID DESIGN INPUT REQUIREMENTS GO WRONG?


Auvi-Q
epinephrine injection, USP
0.15 mg auto-injector
NDC 0024-5831-02
Rx Only
Pull device from this case
Auvi-Q
epinephrine injection, USP
0.15 mg auto-injector
For single-use injection. Refill prescription after use.
FOR ALLERGIC EMERGENCIES
in patients weighing 33 lb–66 lb
Instructions for use found inside on device
FRONT


Auvi-Q
epinephrine injection, USP
0.3 mg auto-injector
NDC 0024-5833-02
Rx Only
Pull device from this case
Auvi-Q
epinephrine injection, USP
0.3 mg auto-injector
For single-use injection. Refill prescription after use.
FOR ALLERGIC EMERGENCIES
in patients weighing over 66 lb
Instructions for use found inside on device
FRONT

CLICK HERE TO VIEW VIDEO



WHICH DEVICE MAKES MORE SENSE?

greenlight guru

QUESTIONS?

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