Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

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 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

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

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

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

Change management and risk management are among the most important and most commonly discussed topics in the medical device industry today. Yet in spite of that, or perhaps because of that, change management and risk management remain the "root cause" of the most common problems medical device companies experience, often leading to FDA 483 observations, warning letters or worse! Why?

Most medical device development is evolutionary, i.e., design and test a device, get it thru FDA, sell the device… then change the device and repeat. This doesn't often happen in the drug world, but it happens in the medical device world all the time! Medical device companies are "required" to have quality management systems in place with detailed policies and procedures on change management and risk management. But are these components integrated, or to they exist in isolation, and does one talk to the other? Using a case study approach, this webinar will give participants the necessary tools to integrate change management and risk management including:

- How do we integrate change management and risk management?
- How do we assess, implement and validate change in the context of risk?
- Which changes necessitate risk evaluation and which do not?
- How does change management and risk management vary pre-market vs. post-market?
- What if your device is capable of changing (evolving?) by itself (i.e., artificial intelligence)?
- What are the consequences of not integrating change management and risk management?

In this webinar, Dr. Drues uses his unique ***tell don't ask… lead don't follow*** approach to demonstrate how to integrate change management and risk management and will share best practices using case studies from a variety of clinical specialties in this interactive webinar.

What to know more?

Webinar: Best Practices for Change Management: *Don't use FDA as an excuse to hold you back* (Sept, 2017 here

Webinar: Understanding the Conotations of Risk and Consequences of Getting them Wrong (Mar, 2017) here

For more, visit Global Medical Device Podcast (GreenLight.Guru) here, Mike on MedTech (Med Product Outsourcing) here, Med Design & Outsource here, Guerilla Regulatory Strategy (MED Device Online) here and Healthcare Packaging here or LinkedIn here.

Speaker Biography

Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & completive regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, , clinical trial design, reimbursement, clinical acceptance, business development & technology assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted 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 (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com
or via LinkedIn at www.linkedin.com/in/michaeldrues.

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

1

2

GreenLight.Guru Webinar (January 21, 2021)

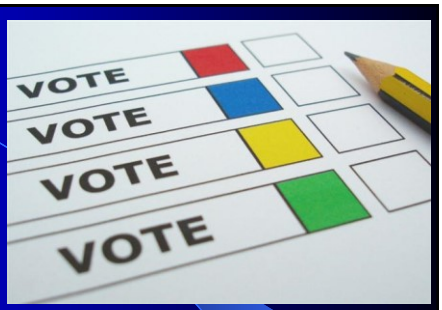
www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

Before we begin…

Polling Question



Do you have change management and risk management systems currently in place? [Y/N]

Do you think those systems work? (How do you know?) ☺ [Y/N]

Are those systems linked together? *i.e., do they "talk" to one another?* [Y/N]

Does changing a medical device → a change in risk? [Y/N]

Does not changing a medical device → no change in risk? [Y/N]

i.e., can you have a change in risk without changing your device?

3

Here's what we'll talk about…

- ✓ How do we integrate change management and risk management?
- ✓ How do we assess, implement and validate change in the context of risk?
- ✓ Which changes necessitate risk evaluation and which do not?
- ✓ How does change management and risk management vary pre-market vs. post-market?
- ✓ What if your device is capable of changing (evolving?) by itself (i.e., artificial intelligence)?
- ✓ What are the consequences of not integrating change management and risk management?
- ✓ Lots more tips and tricks… time permitting!
- ✓ Final thoughts…

4

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

First, an important disclaimer...

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

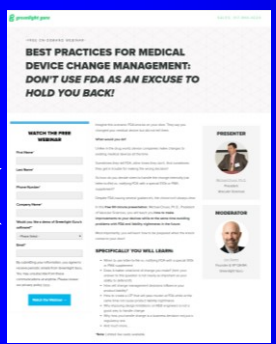
I'm not even going to try but…

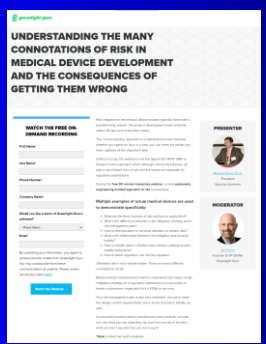
Remember my philosophy of education:

To teach you how to think not what to think!

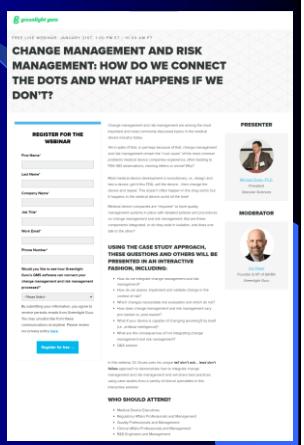
5

Why this topic



(+ 

)<



September, 2017 here March, 2017 here

January, 2021 here

6

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

What are three 'buckets' of risk and how do we apply them?

Short answer:

There are many connotations of risk…

we will focus on the 'big 3 plus one'

7

What is risk

Three buckets of risk:

1. **Probability of direct harm** (usually to patient, sometimes to caregiver)
   a. Most obvious form of risk
   b. Only form considered in risk management plans (i.e., design controls)
2. **Probably of harm of not using**
   a. 510k vs. PMA
3. **Probability of providing the wrong information**
   a. Endemic in *all* diagnostics, i.e., false (+) / false (-)

Bonus Bucket:

4. **Regulatory risk**
   a. Probability of getting *smacked*, i.e., saying something, changing something…
   b. Probability of being unsuccessful selling your regulatory strategy to FDA

Many other forms of risk… not included here.

8

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

Imagine this scenario:

FDA knocks on your door. They say you changed your medical device but did not tell them.

What are the consequences of your decision

Consider:

Regulatory?

Product Liability?

Other?

9

So you want to make a change to your existing medical device, i.e., a device already on the US market…

How to decide when to handle the change internally (via letter-to-file) vs. notifying FDA with a special 510k or PMA supplement

Ask these questions:

Can the proposed change(s) affect safety, efficacy, performance, etc. of the "new" device? What do you do to answer this?

What is the impact on labeling, usability, risk, etc.?

Recommendation:

You need your own process with specific criteria and validate it!

10

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

Question:

Whether you do a L2F or a s510k or PMA supplement…

What should you document

Short answer:

FDA – easy (see guidance)

L2F – totally up to you!

Here's a start:

What is the change, why are you making it, how did you test it, what are the consequences, how will you monitor them, etc. but…

Be very, very careful!

11

What's the relationship between change management and risk management

Metaphor:

Not copy-and-paste… rather copy-and-paste-link!

Note: not limited to only change management & risk management

Question: *Is this required? Should it be? Let's see…*

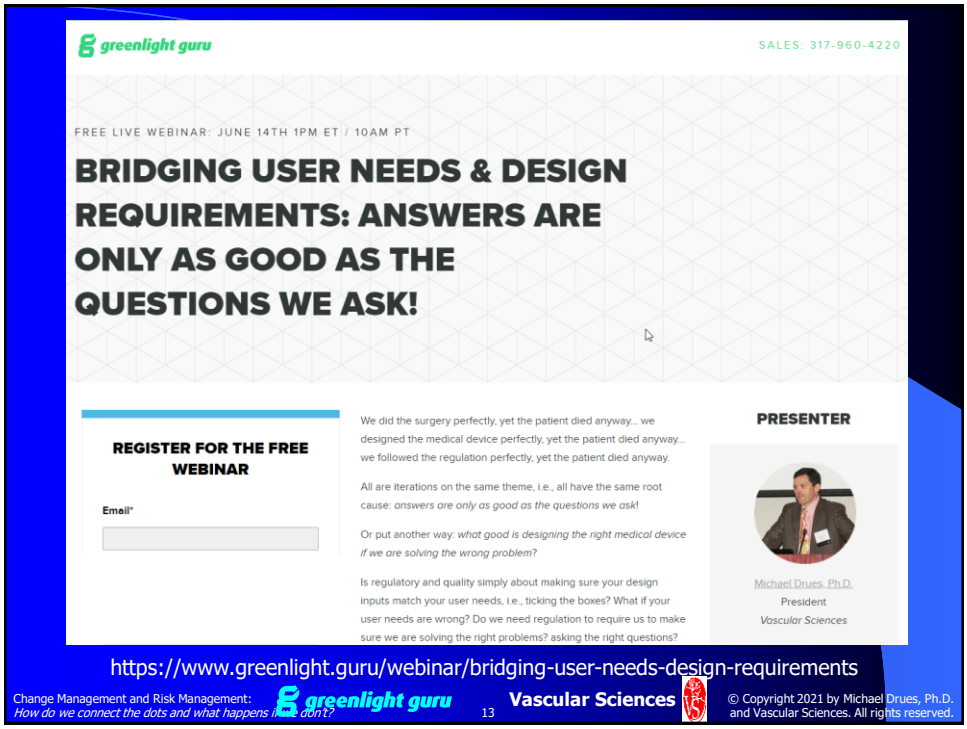
12

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?



13

14

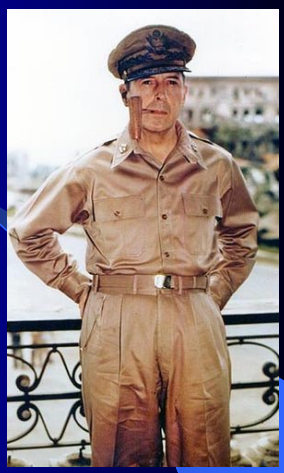
GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

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.

15

What is the true essence of regulation?

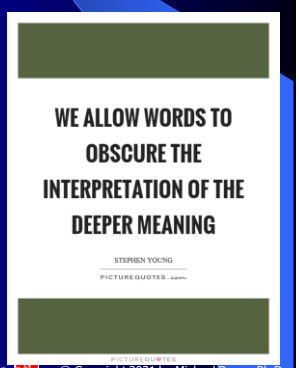
Regulation is all about the interpretation of words…
and your ability to defend your interpretation!

and why assume FDA's interpretation is the only one or the best one???

Happens in regulatory and quality all the time!

Most important…

Understand the spirit of the law
not just the letter of the law



16

GreenLight.Guru Webinar (January 21, 2021)

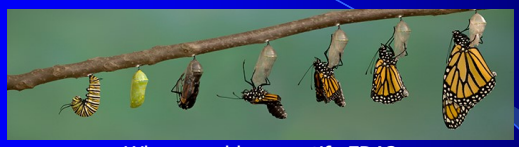
www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

Question:

What are the consequences of incremental changes… i.e.,



When would you notify FDA?

What is change creep
What is risk creep

Short answer:

Similar to predicate creep

Options: *Catch-up Pre-sub vs. Catch-up 510k*

No such thing as either one but that never stopped me! ☺

17

How do we integrate change management and risk management

Recommendation:

Any and all changes <u>automatically</u> necessitate risk re-evaluation…
the only question is to what degree? [think triage!]

Do we really need regulation to tell us this? Isn't it common sense?

Additional Recommendation:

Why focus only on risk (a.k.a. safety)? What about efficacy?

18

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

How do we assess, implement and validate change in the context of risk

Ask the right questions:

What is the change? Why are we making it?

Does it change the risk? ***How do we know?***

Metaphor: consider 510k risk requirements

1. **New Risks:** The subject device cannot pose any new risks compared to the predicate
2. **Known Risks:** The subject device cannot pose an increase level of known risks compared to the predicate, i.e., the known risks subject device ≤ comparable risks in predicate device

We don't need more regulation…

we need people understanding the regulation we already have! ☺

19

Which changes necessitate risk (RE-) evaluation and which do not

Put another way…

Is there any change that does not warrant a risk re-evaluation?

Recommendation:

All changes necessitate risk re-evaluation…

the only question is to what degree?

Further Recommendation: **Do NOT treat all changes the same!** (triage!)

Does this lead to more complicated processes? Yep! Would you want it any other way? ☺

20

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

What are some examples

Change Management vs. Risk Management

Does it matter what kind of change you make? i.e., what if you make a…

- cosmetic change, i.e., a color or font size?
- design change, i.e., the shape or size?
- material change, i.e., swap one material for another or combine two different materials?
- labeling change, i.e., modify an existing claim or add a new one?
- change in manufacturing process, i.e., improving efficiency or reducing rejection rate?
- types of change is endless and unlike drugs, medical device change happens all the time!

21

How does change management and risk management vary pre-market vs. post-market

Pre-Market: *Change management during product development?*

Post-Market: *Where are the changes coming from?*

Users? PMS/RWE? Manufacturer? Competitor? Device itself (AI)? Elsewhere?

22

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

What if your device is capable of changing (evolving?) by itself (i.e., artificial intelligence)

Questions to Consider:

Is AI/ML a drastically *overused* phrase (claims?)

What is true AI?

Is it really as different as many seem to think?

Only in one way: *change management and consequently risk management!*

Why do we dumb-down our technology to fit our regulation?

Is the "locked algorithm" holding us back?

23

What more

April, 2019 here

January, 2021 here

24

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

What are the consequences of not integrating change management and risk management

Simply put:

You may miss something… and probably will!

Consider:

Regulatory concerns, quality concerns and product liability concerns!

25

Final Recommendations

Any and all changes <u>automatically</u> necessitate risk re-evaluation… the only question is to what degree? [think triage!]

Consider ramifications before during and after implementation

Remember,

No change can change risk!

Do we really need regulation to tell us that?
Isn't it common sense? Should it be?

26

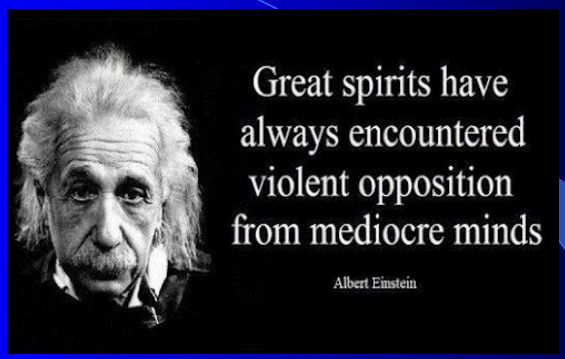
GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection

Change Management and Risk Management:

How do we connect the dots and what happens if we don't?

In which camp do you fall?



As former Apple CEO Steve Jobs famously said

It doesn't make sense to hire smart people and tell them what to do… we hire smart people so they can tell us what to do.

Steve Jobs here

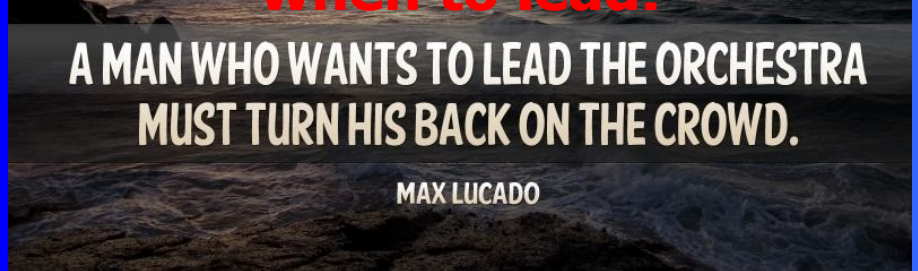
27

There are many regulatory consultants out there…

but there are surprisingly few good ones!

So how do you become a good one?

Learn when to follow and more importantly… when to lead!



28

GreenLight.Guru Webinar (January 21, 2021)

www.greenlight.guru/webinar/change-management-risk-management-connection