COMPLAINT HANDLING:

How to Avoid the Third Most Common Reason for FDA 483 Observations

presented by:

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and

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GreenLight.Guru (October 19, 2023)

https://www.greenlight.guru/webinar/complaint-handling-how-to-avoid-483-observations

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Improper complaint handling lead to 11% of 483 observations by FDA in medical device company inspections is 2022 (here). Even more depressing: this statistic has remained the same for 16 of the last 17 years!

Common causes of complaint-related 483 observations include: not documenting procedures, not maintaining files, complaints of failures not investigated, complaints not evaluated to determine if an investigation was necessary or lacked rationale for not conducting an investigation, complaints deemed reportable were not promptly investigated, complaint records did not contain required information, etc., etc.

So why do companies get so many 483 observations and why do they keep getting them? Are we fulfilling Einstein's definition of insanity, i.e. *doing the same thing over and over and expecting different results?* Common sense dictates if we don't identify the *root cause* of a problem, any solution will be a Band-Aid at best! In other words, practice does *not* make perfect… rather, *perfect practice makes perfect!*

Having an effective complaint handling system is important from both a regulatory and quality perspective. But can we assume if our complaint handling system meets the regulatory and quality requirements, that its effective? that its working? Absolutely not! This presentation will use the case study approach to take a broad look at medical device complaint handling including:

- What constitutes a complaint?
- What do you do with complaint information?
- How does the broad problem of device under-reporting impact complaint handling?
- How do you properly and adequately investigate complaints to avoid 483's?
- Can complaints be positive?
- What are the complaint handling challenges for the future?

Using the case study approach, participants will learn best practices to avoid timely and costly mistakes as well as creative ways to use complaint handling to their advantage!

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.

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 FDA, Health Canada, the US and European Patent Offices, CMS and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Regulatory Affairs, Medicine and Biomedical Engineering at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Medical Device Regulatory Affairs and Product Development, Combination Products and Pathophysiology.

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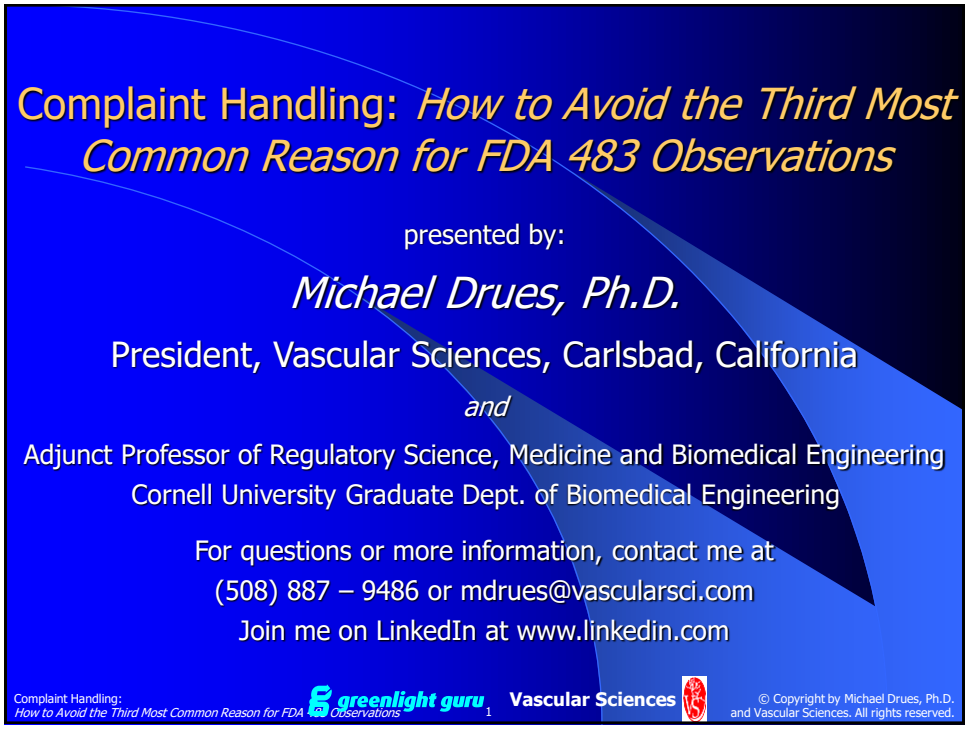

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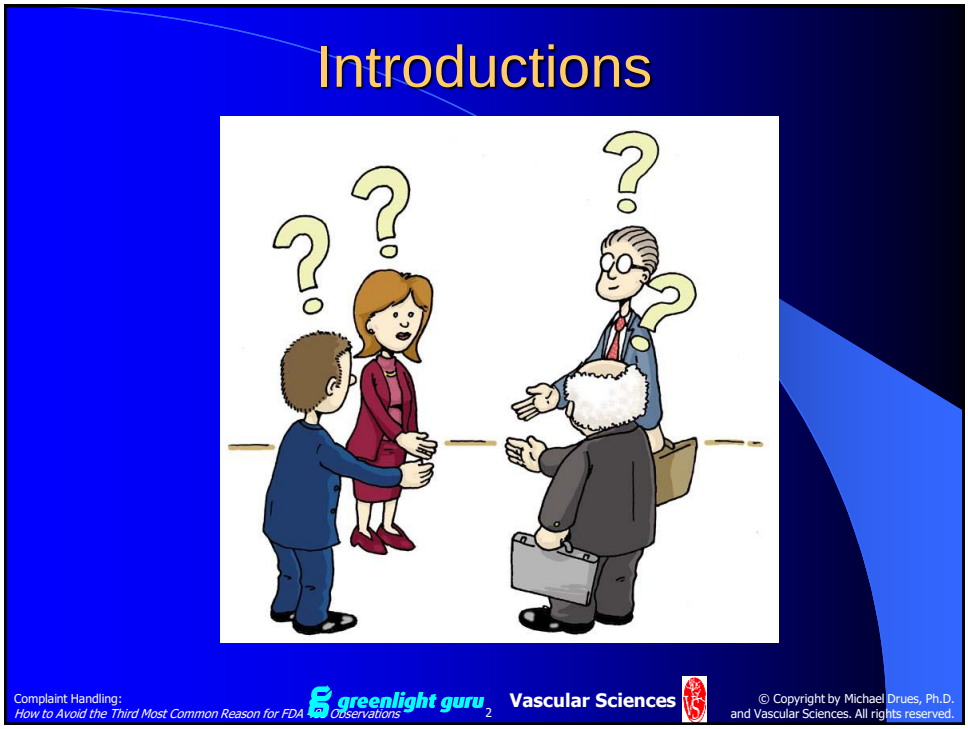

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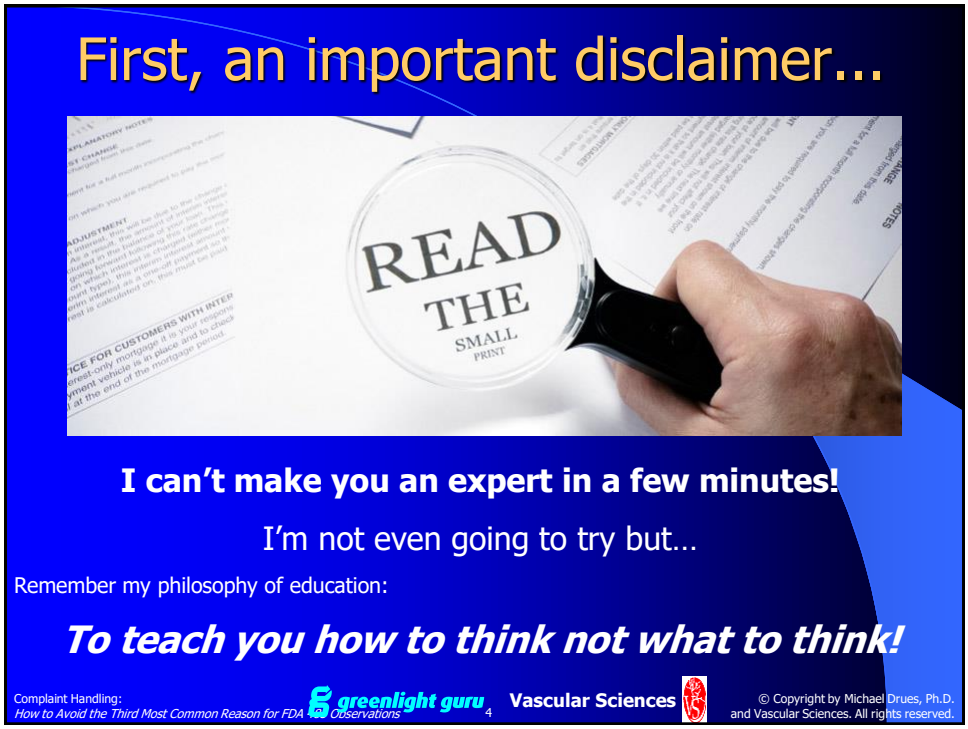

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Is it possible to think regulatory?

"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?

"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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Here's what we'll talk about…

- ✓ What constitutes a complaint?
- ✓ What do you do with complaint information?
- ✓ How does the broad problem of device under-reporting impact complaint handling?
- ✓ How do you properly and adequately investigate complaints to avoid 483's?
- ✓ Can complaints be positive?
- ✓ What are the complaint handling challenges for the future?
- ✓ Bonus: When should a complaint initiate a CAPA?
- ✓ Lots more tips and tricks… time permitting!
- ✓ Final thoughts…

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What's the inspiration?

Complaint Handling

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Top Ten Reasons for 483 Observations

- CAPA (820.100) 12.42%
- Design Controls (820.30) 12.32%
- **Complaints (820.198) 10.61%**

35% of all clauses cited in medical device 483s issued in FY2022!

- Purchasing Controls (820.50)
- Process Validation (820.75)
- Medical Device Reporting (803)
- Nonconforming Product (820.90)
- Production and Process Controls (820.70)
- Acceptance Activities (820.80)
- Quality Audit (820.22)


Life Science Leader

The Top 10 Most Cited QSR Clauses In FDA FY2022 Medical Device Inspections

The Top 10 Most Cited QSR Clauses In FDA FY2022 Medical Device Inspections (Jan, 2023) here.

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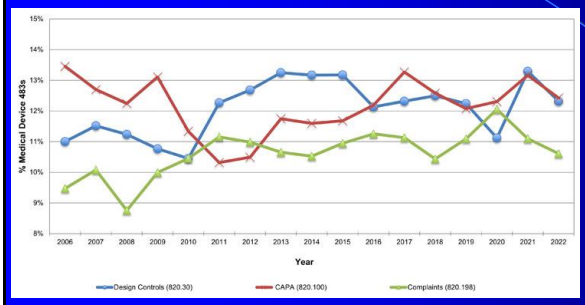
Is this a new trend?



- ~ 1/3 of all medical device 483 citations last 13 years are:
  - Design Controls
  - CAPA
  - Complaints
- Same for 16 of last 17 years!

The Top 10 Most Cited QSR Clauses In FDA FY2022 Medical Device Inspections (Jan, 2023) here.

Regrettably,

Absolutely not

Note the irony (hypocrisy?) in "trend analysis"

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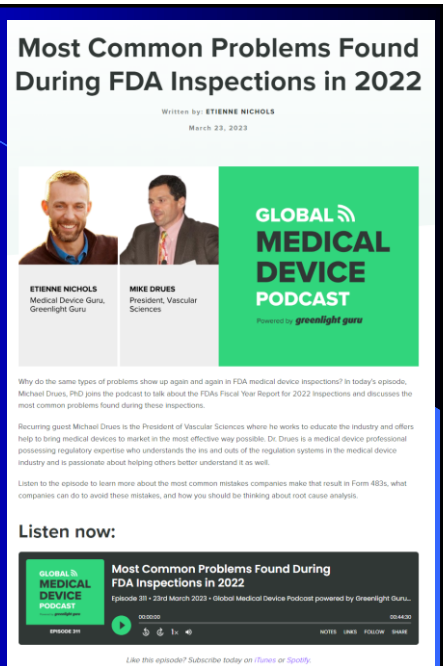
Want more?

Most Common Problems Found During FDA Inspections in 2022 (March, 2023) here

Top 3 Most Cited Issues in Device Inspections from FDA FY2020 (June 14, 2021) here

Top 483s of 2020—Mike on Medtech (MPO, June, 2021) here



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Most Common Reasons for *Complaint-Related* 483 Observations

Real (not hypothetical) examples of complaint-related 483's:

- Manufacturers ***did not document their procedures*** (820.198(a), cited 138 times)
- Manufacturers ***did not maintain their complaint files*** (820.198(a), cited 19 times)
- ***Complaints of device failures were not investigated*** (820.198(e), cited 24 times)
- ***Complaints were not reviewed and evaluated to determine if an investigation was necessary*** (7 times) ***or lacked rationale for not conducting an investigation*** (3 times) (820.198(b), cited 10 times)
- ***Complaints that were deemed reportable were not promptly investigated*** (820.198(d), cited 9 times)
- ***Complaint records did not contain required information*** (4 times) or were not maintained by the formally designated unit (1 time) (820.198(e), cited 5 times).

The Top 10 Most Cited QSR Clauses In FDA FY2022 Medical Device Inspections (Jan, 2023) here.

Question:

How can we explain / rationalize / justify any of these?

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What is the "root cause" of most complaints, recalls and warning letters, etc.

Following rules without thinking!

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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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What is a complaint

Mike's Recommendations:

- ✓ create your *<u>own</u>* definition (specific examples are nice)
- ✓ test (i.e., validate) it
- ✓ continue to retest (i.e., validate) it
- ✓ interpret it consistently *<u>and</u>* validate that you do!

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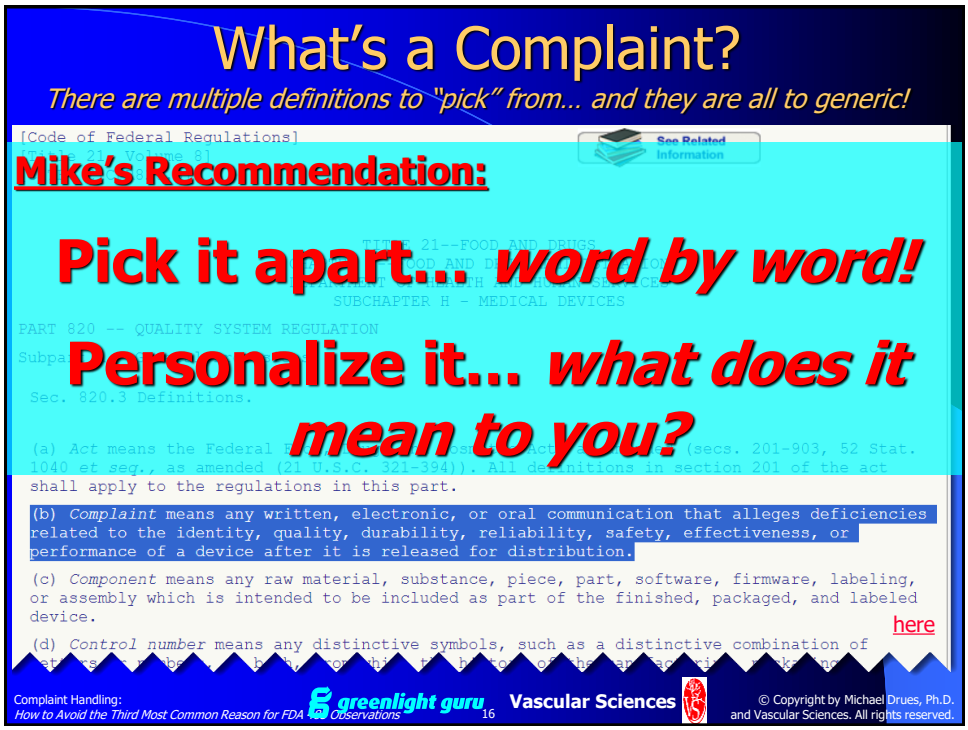

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What's a Complaint?

21 CFR Part 820.3 (b) (here):

*"Complaint means **any** written, electronic, or oral **communication that alleges deficiencies** related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution."*

Here's another [very different] (21 CFR Part 803, Medical Device Reporting (MDR):

*"A complaint is any indication of the **failure** of a device **to meet customer or user expectations** for quality **or to meet performance specifications.**"*

There are others… which definition to use?

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What is a Device-Related Complaint?

FDA "recommends" using QSR definition of a complaint:

> ***Any* written, electronic, or oral communication that *alleges deficiencies* related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution** [21CFR 820.3(b) Complaint Definition].

Mike's Recommendation: *Don't use above… its to generic / broad / general / non-specific!*

Also,

> **[Manufacturers] are *required* to review and evaluate *all* device-related complaints to determine whether the complaint represents an MDR reportable event** [21CFR803.18(e) Medical Device Reporting and 21CFR820.198 Complaint Files].
>
> ***– what does "review and evaluate" mean?***

CDRH Guidance *Medical Device Reporting for Manufacturers* (Nov, 2016) here

Remember,

Not "sufficiently" investigating complaints or not investigating complaints at all is one of the most common reasons why companies get warning letters from FDA.

The Top 10 Most Cited QSR Clauses In FDA FY2022 Medical Device Inspections (Jan, 2023) here.

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Complaint Handling

Definition Key Items:

1. Any communication
2. Alleged deficiency
3. After release

Example:

Device X has been on the market for 3 years

Hospital user calls & says:

"I went to use a new model X & the handle came off – I think it was broken when it arrived."

Is this a complaint?

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Complaint Handling Example: Device X

- Is it a communication?
  YES – phone call
- Does it allege deficiency?
  YES – "*I think it was broken*"
- Is it after release?
  YES – been on the market for 3 years

This "appears" to meet the definition of a complaint but…

Does it meet your definition?

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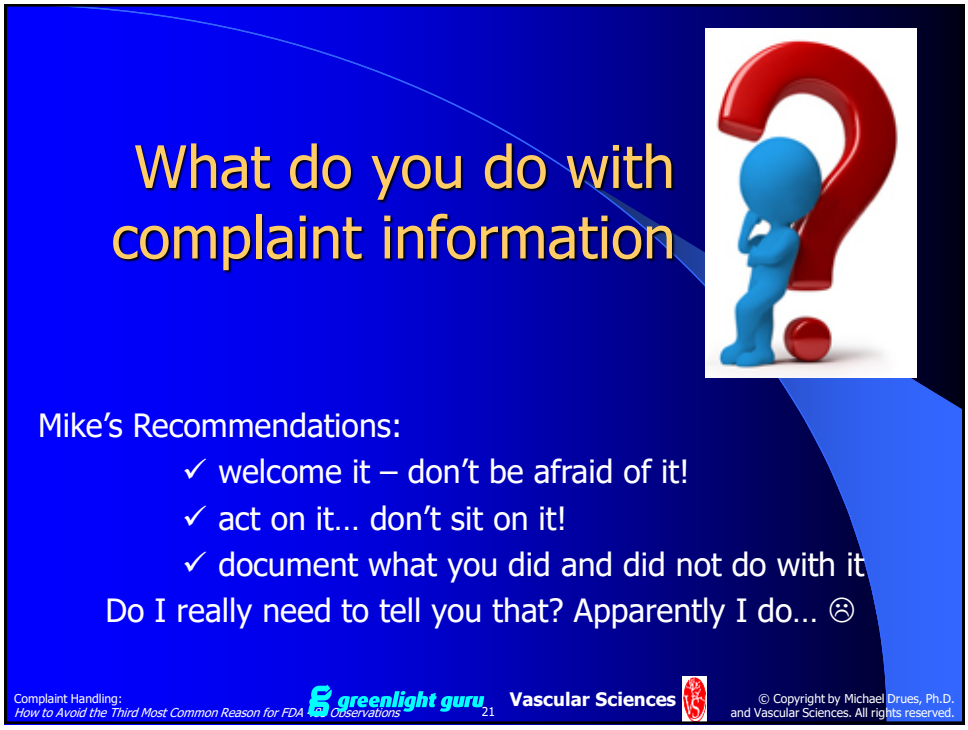

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How do you "properly and adequately" investigate complaints

Simply put:

1. Have you identified the *root cause* of the problem?
2. How do you know it's the *root cause*?

If you cannot answer and defend your answers…

You have not "properly and adequately" investigated the complaint so… check your mailbox for a

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Can complaints be positive

Short answer:

Absolutely… so why do we call them *complaints?*

Inherently biased, i.e., negative! ☹

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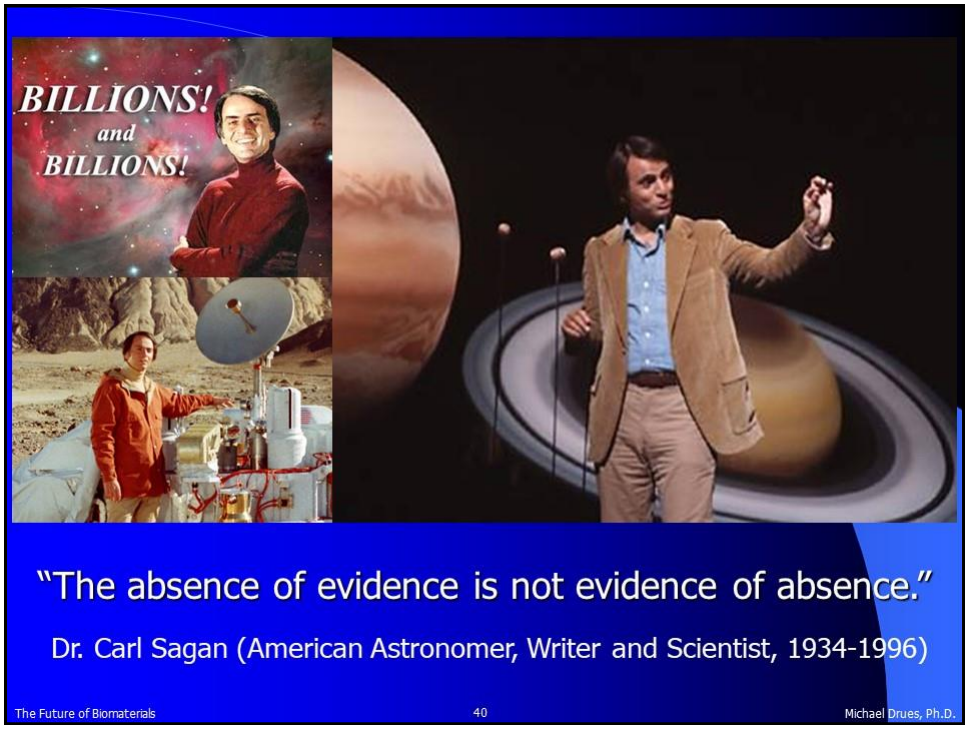

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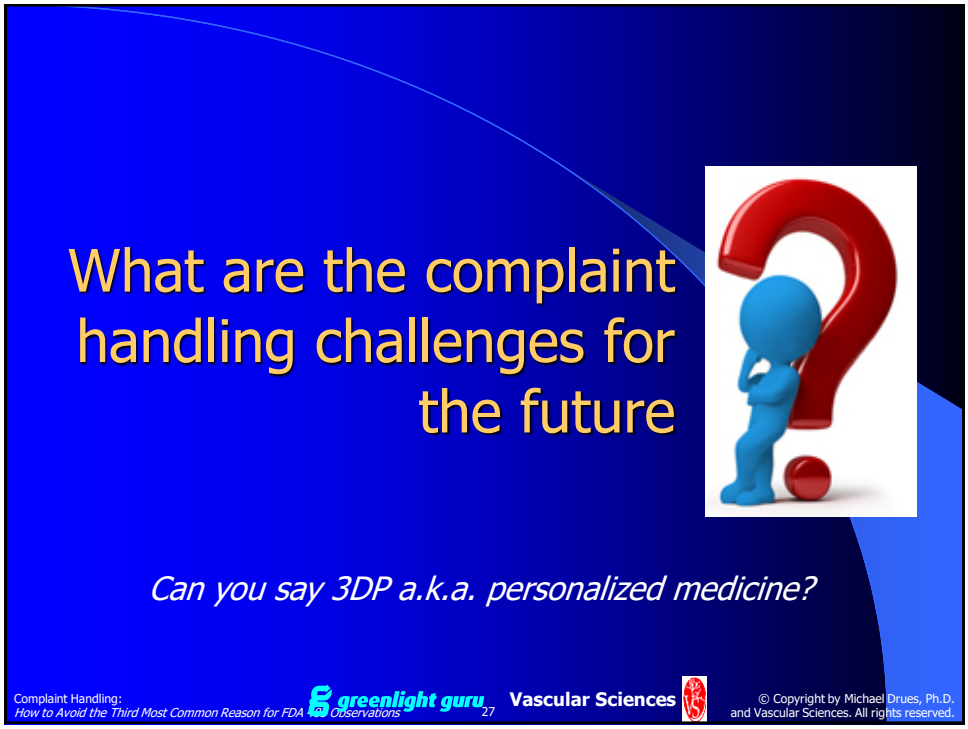

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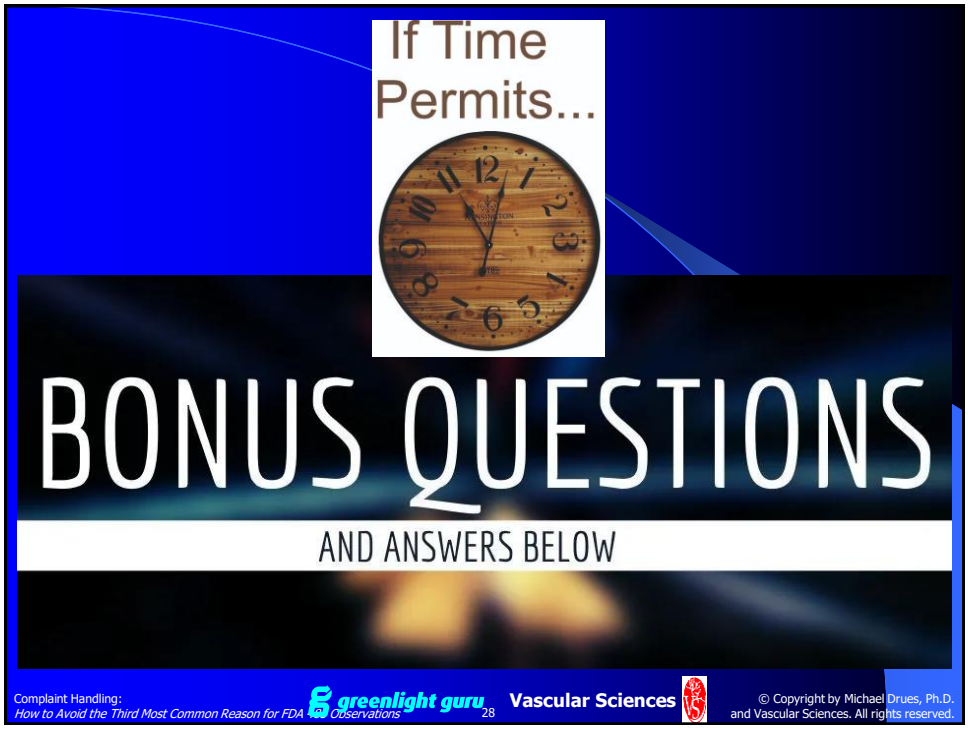

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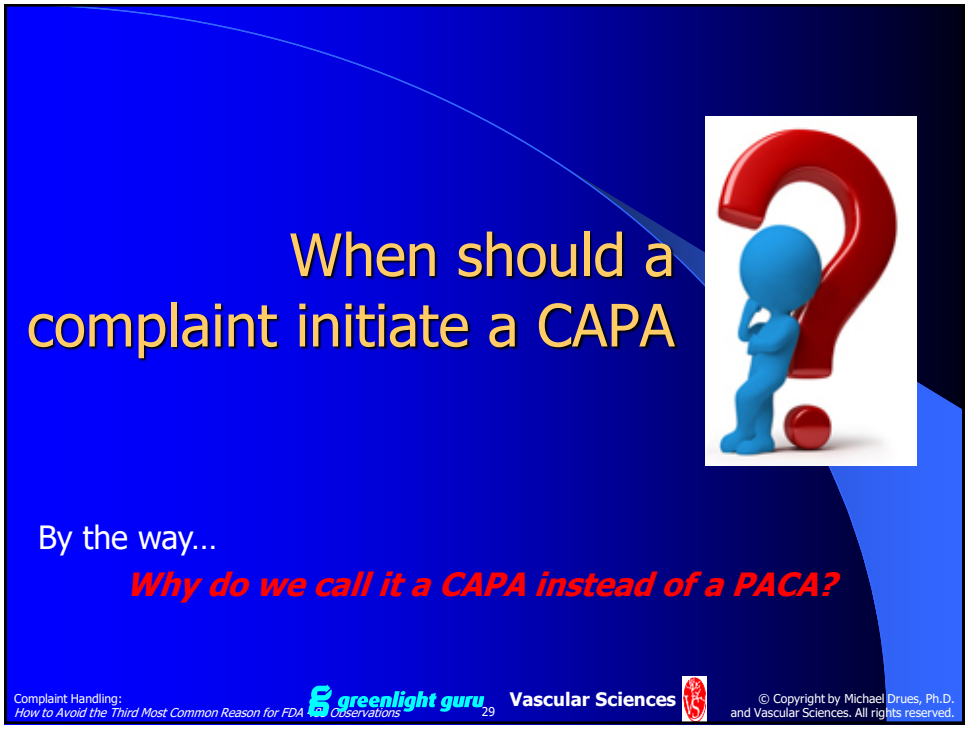

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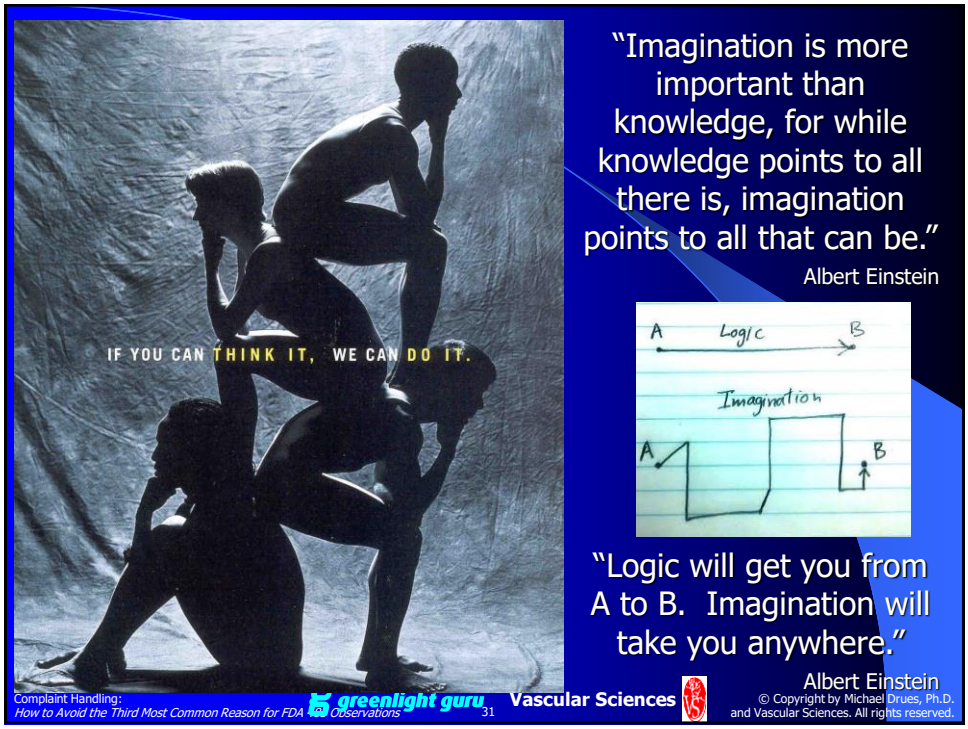

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