

COMPLAINT HANDLING:

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

presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
Carlsbad, California

and

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and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru (October 19, 2023)

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

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COMPLAINT HANDLING:

How to Avoid the Third Most Reason for 483 Observations

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

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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Introductions



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Tips And Tactics

A guest expert series by
Michael Drues, Ph.D., President, Vascular Sciences

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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?

**Guerilla Regulatory Strategy:
Tips And Tactics**

By Michael Drues, Ph.D.
President, Vascular Sciences

"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)

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

Written by: ETIENNE NICHOLS
March 23, 2023



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Medical Device Guru,
Greenlight Guru



MIKE DRUES
President, Vascular
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GLOBAL 

**MEDICAL
DEVICE
PODCAST**

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Why do the same types of problems show up again and again in FDA medical device inspections? In today's episode, Michael Drues, PhD joins the podcast to talk about the FDA's Fiscal Year Report for 2022 inspections and discusses the most common problems found during these inspections.

Recurring guest Michael Drues is the President of Vascular Sciences where he works to educate the industry and offers help to bring medical devices to market in the most effective way possible. Dr. Drues is a medical device professional possessing regulatory expertise who understands the ins and outs of the regulation systems in the medical device industry and is passionate about helping others better understand it as well.

Listen to the episode to learn more about the most common mistakes companies make that result in Form 483s, what companies can do to avoid these mistakes, and how you should be thinking about root cause analysis.

Listen now:



[Like this episode? Subscribe today on iTunes or Spotify.](#)

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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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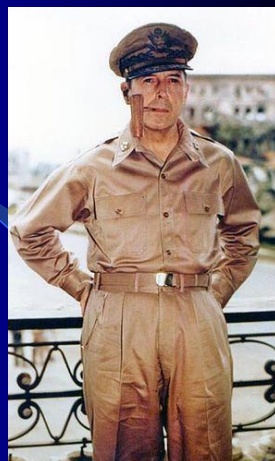
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Don't just follow the rules... think!



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

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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."**

Bridging User Needs & Design Requirements:
Answers are only as good as the questions we ask!"

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What's a Complaint?

There are multiple definitions to "pick" from... and they are all too generic!

(Code of Federal Regulations)

Mike's Recommendation:

Pick it apart... word by word!

Personalize it... what does it mean to you?

here

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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?



Complaint Resolution

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What do you do with complaint information



Mike's Recommendations:

- ✓ welcome it – don't be afraid of it!
- ✓ act on it... don't sit on it!
- ✓ document what you did and did not do with it

Do I really need to tell you that? Apparently I do... ☹

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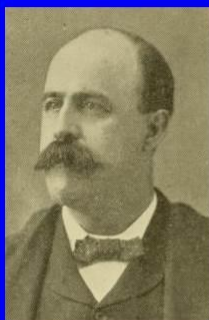
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How should you communicate with FDA?



"Never write if you can speak...

never speak if you can nod...

and never nod if you can wink!"

Martin Lomasney (1859–1933), Massachusetts politician
best remembered for being the ward boss of Boston's Ward Eight

Or put another way...

"Never talk when you can nod...

never nod when you can wink...

and never write an e-mail because it's death.

You're giving prosecutors all the evidence we need!"

Eliot Spitzer (1959–) is a lawyer and former New York Governor (2007–2008)



Communication with FDA: *What do we say and how do we say it?*

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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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How does underreporting impact complaint handling



- "it is evident that *[adverse event] reporting does not occur to a great extent, with the rate of reporting estimated to be as low as 0.5% of all occurrences."*
- "the *FDA estimate of [an adverse event] reporting rate of 0.5%."*
Need for Greater Reporting of Medical Device Incidents (EMJ, Jan, 2019) [here](#).
- There are many similar statistics ☹

Underreporting happens and more than you think!

Remember what Carl Sagan said...


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"The absence of evidence is not evidence of absence."

Dr. Carl Sagan (American Astronomer, Writer and Scientist, 1934-1996)

The Future of Biomaterials

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Michael Drues, Ph.D.

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What are the complaint handling challenges for the future




Can you say 3DP a.k.a. personalized medicine?

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If Time Permits...



BONUS QUESTIONS

AND ANSWERS BELOW

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When should a complaint initiate a CAPA



By the way...

Why do we call it a CAPA instead of a PACA?

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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!**

**A MAN WHO WANTS TO LEAD THE ORCHESTRA
MUST TURN HIS BACK ON THE CROWD.**

MAX LUCADO

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IF YOU CAN THINK IT, WE CAN DO IT.

"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."
Albert Einstein

A Logic B

Imagination

A B

"Logic will get you from A to B. Imagination will take you anywhere."
Albert Einstein

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Questions?
Comments?
Suggestions?
Criticisms?
Complaints?

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