Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru (November 17, 2022)

www.greenlight.guru/webinar/regulatory-due-diligence-why-pay-for-information-you-can-get-for-free

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

Regulatory Due Diligence: *Why pay for information you can get for free?*

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

It's staggering to see how many companies (and the people in them) embarrass themselves when going to FDA unprepared, i.e., not knowing the most basic information. Not only is this unprofessional, but it does not instill a high degree of confidence that the company and the people in it know what they are doing. And when it comes to developing medical devices, this is not an image you want to present to the FDA! Being well prepared, i.e., doing your homework a.k.a. regulatory due diligence, is the best way to mitigate or even eliminate this risk. It's also your responsibility as a medical device professional!

But what is regulatory due diligence and how do you do it? More importantly, how do you use it to your strategic advantage? You can pay a regulatory consultant to do it for you but why do that when, with the right skills, you can do it yourself – and use the money you saved for more important things like to develop your regulatory strategy instead!

In his signature style, Dr. Michael Drues will use actual devices as case studies to discuss:

- What is regulatory due diligence? Why is it important?
- What tools are available and how do you use them?
- How can you use regulatory due diligence to your competitive advantage?

Regulatory due diligence is like a scalpel: when used in the hands of a skilled surgeon, it can be a very useful tool. But when used by someone who doesn't know what they are doing, it can cause a lot of damage. So which group would you like to be in?

About the Presenter

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, Product Development, Combination Products and Pathophysiology.

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.

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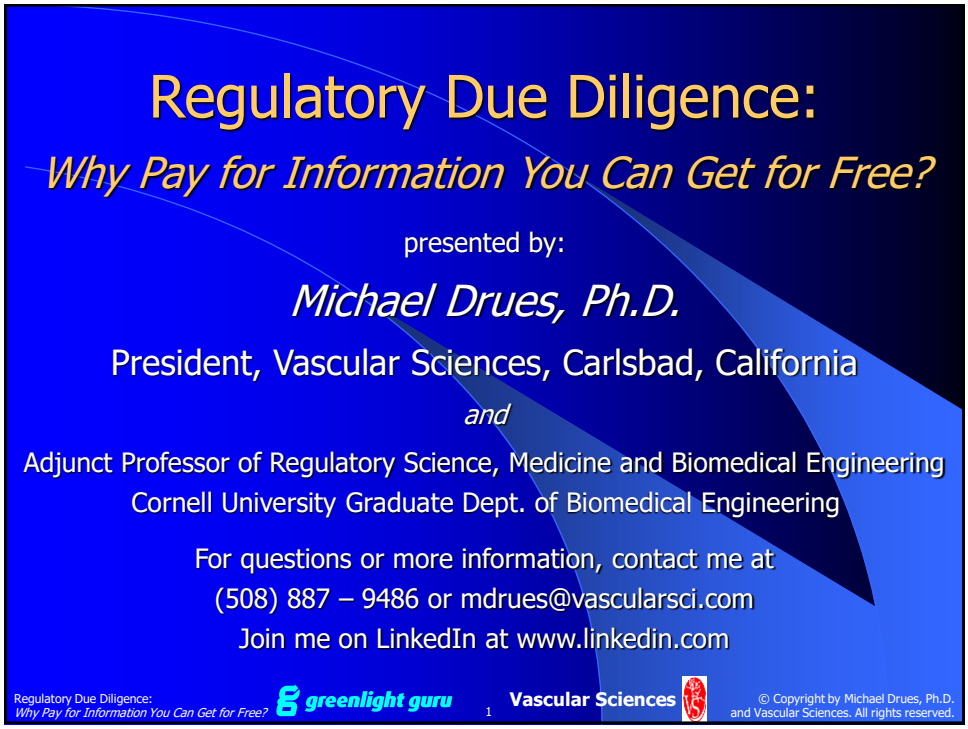

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Regulatory Due Diligence:

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Additional Resources

https://www.greenlight.guru/blog/what-is-regulatory-due-diligence-for-medical-devices

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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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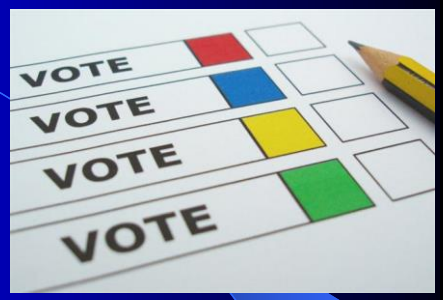
Before we begin…

Polling Question



I always do my homework prior to meeting with FDA? [y/n]

I've been asked a question by FDA that I didn't anticipate/expect? [y/n]

I know everything there is to know about regulatory due diligence and there is nothing new I need to learn. [y/n]

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Here's what we'll talk about…

- ✓ What is regulatory due diligence? Why is it important?
- ✓ What tools are available and how do I use them?
- ✓ How can you use regulatory due diligence to your competitive advantage?
- ✓ Case studies and bonus questions… time permitting
- ✓ Lots more tips and tricks… time permitting!
- ✓ Final thoughts…

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What is regulatory due diligence

Simple answer:

Being a responsible medical device professional, i.e., doing your homework!

In other words…

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Why is regulatory due diligence important

Put another way…

How will you use this information?

Within your Company: Developing your regulatory strategy

vs.

Dealing with FDA: Demonstrating you know what you're doing

vs.

Something else? (selling to investors, senior management, etc.)

Mike's Recommendation:

Do your homework and be prepared!

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How else can I use regulatory due diligence

How about to create a *regulatory strategy executive summary?*

See podcast: How to Construct an Effective Regulatory Strategy (May, 2020)

How about to design an effective international regulatory strategy (Aug, 2022)?

There are many ways to use this information!

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Additional Resources

https://www.greenlight.guru/blog/how-to-construct-an-effective-regulatory-strategy

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Additional Resources

https://regulations.greenlight.guru/talks/designing-an-international-regulatory-strategy/

Video here (https://greenlight.wistia.com/medias/j1i40hh5a6?

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What tools are available and how do I use them?

There are many to choose from!

Remember,

Any tool is only as good as the person using it!

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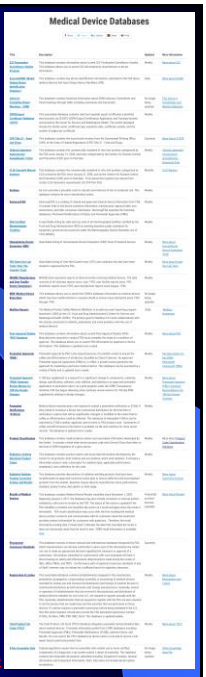
Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

CDRH Databases

- ✓ 27 CDRH Databases
- ✓ Does not include other centers, i.e., CDER, CBER, etc.
- ✓ Does not include general FDA databases, i.e., guidance docs
- ✓ Some overlap but need to search multiple databases
- ✓ Each database serves a different purpose, i.e.,
  - ➢ Regulatory vs. Quality
- ✓ Maybe we need AI-based tool for "intelligent" searching! ☺

Let's highlight some of the more important / useful ones…



CDRH Database List here

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CDRH Databases

Title	Description	Updated	More Information
522 Postmarket Surveillance Studies Program	This database contains information about current 522 Postmarket Surveillance Studies. This database allows you to search 522 information by manufacturer or device information.	Weekly	More about 522
AccessGUDID (Global Unique Device Identification Database)	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	More about GUDID
Advisory Committee/Panel Meetings - CDRH	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	FDA Advisory Committees and Meeting Materials
CDRH Export Certificate Validation (CECV)	This searchable database contains valid (not expired) export certificates submitted electronically via CECATS (CDRH Export Certification Application and Tracking System) and issued by the Center for Devices and Radiological Health. The results displayed include the facility name, certificate type, expiration date, certificate number, and the number of pages per certificate.	Weekly	
CFR Title 21 - Food and Drugs	This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.	Quarterly	More About 21CFR
Clinical Laboratory Improvement Amendments (CLIA)	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000, and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.	Weekly	Clinical Laboratory Improvement Amendments - Download Data
CLIA Currently Waived Analytes	This database contains the commercially marketed in vitro test systems categorized as CLIA waived by the FDA since January 31, 2000, and by the Centers for Disease Control and Prevention (CDC) prior to that date. CLIA waived test systems are waived from certain CLIA laboratory requirements (42 CFR Part 493).	Monthly	CLIA Waivers

CDRH Database List here

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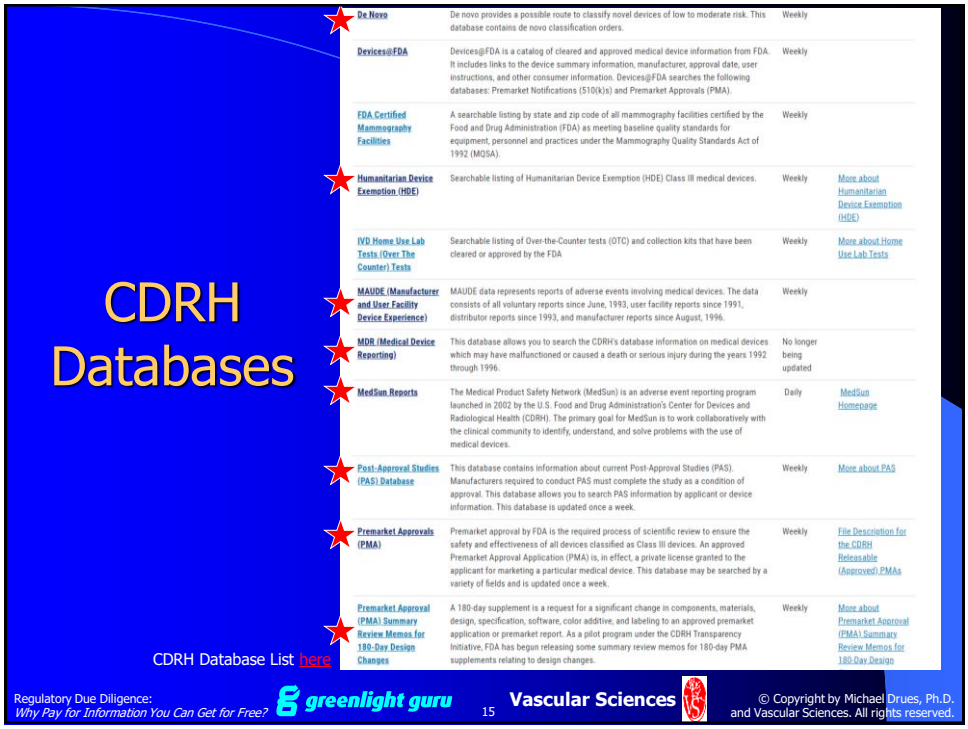

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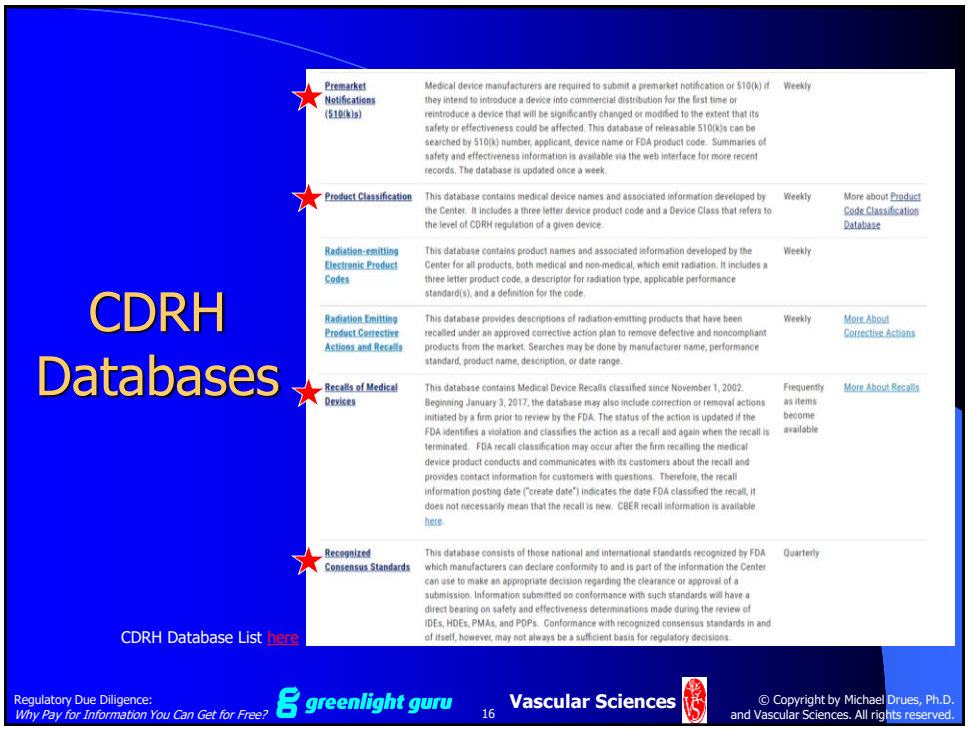

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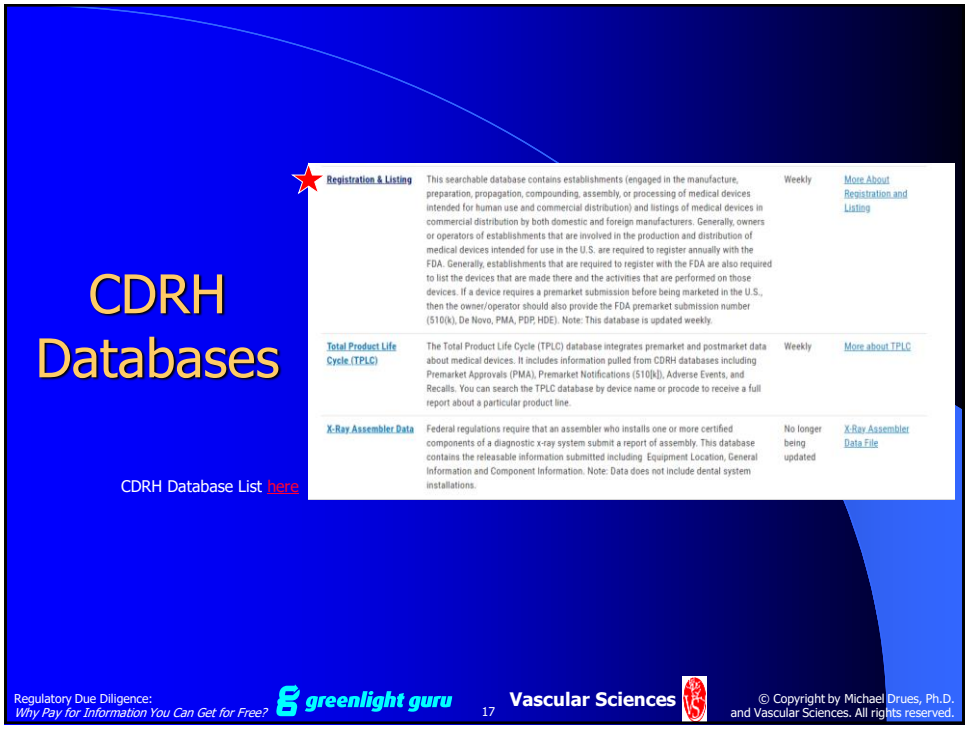

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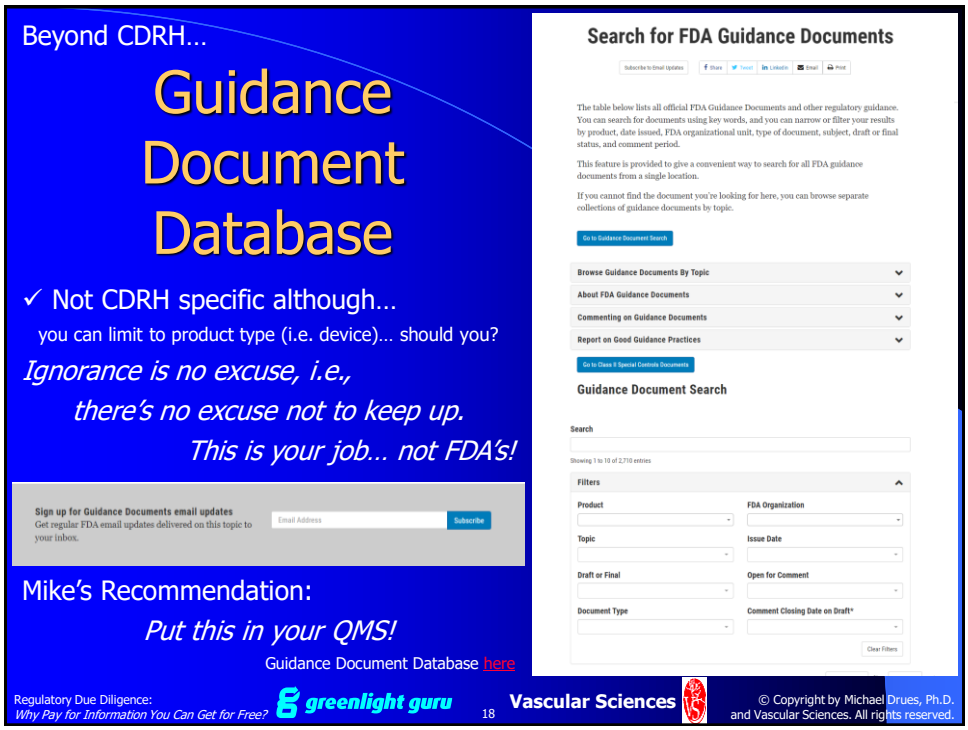

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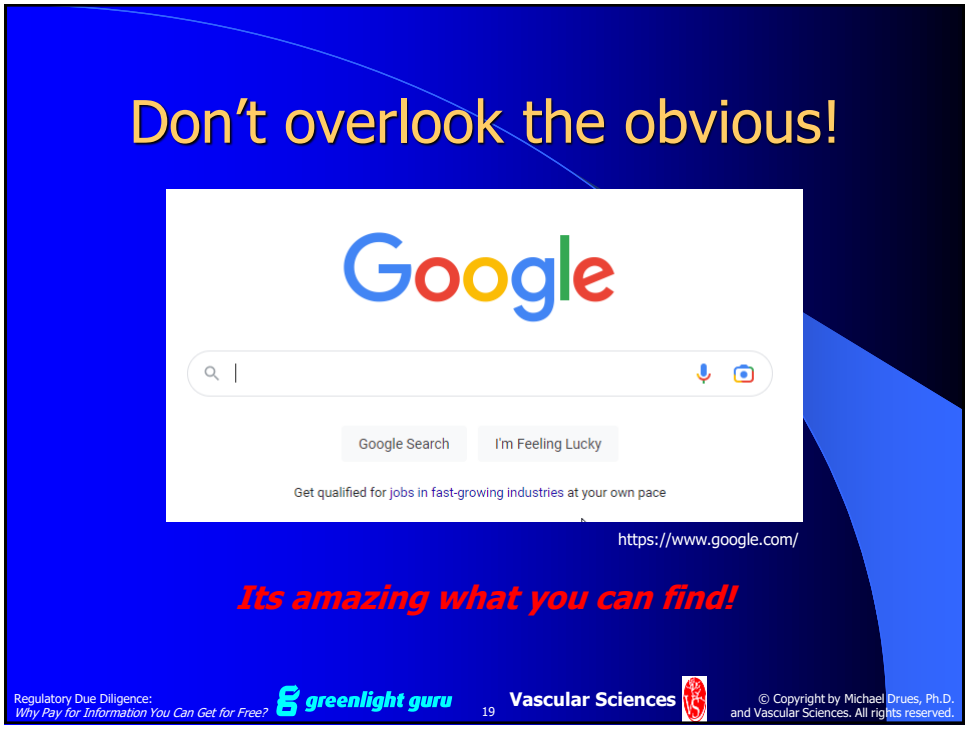

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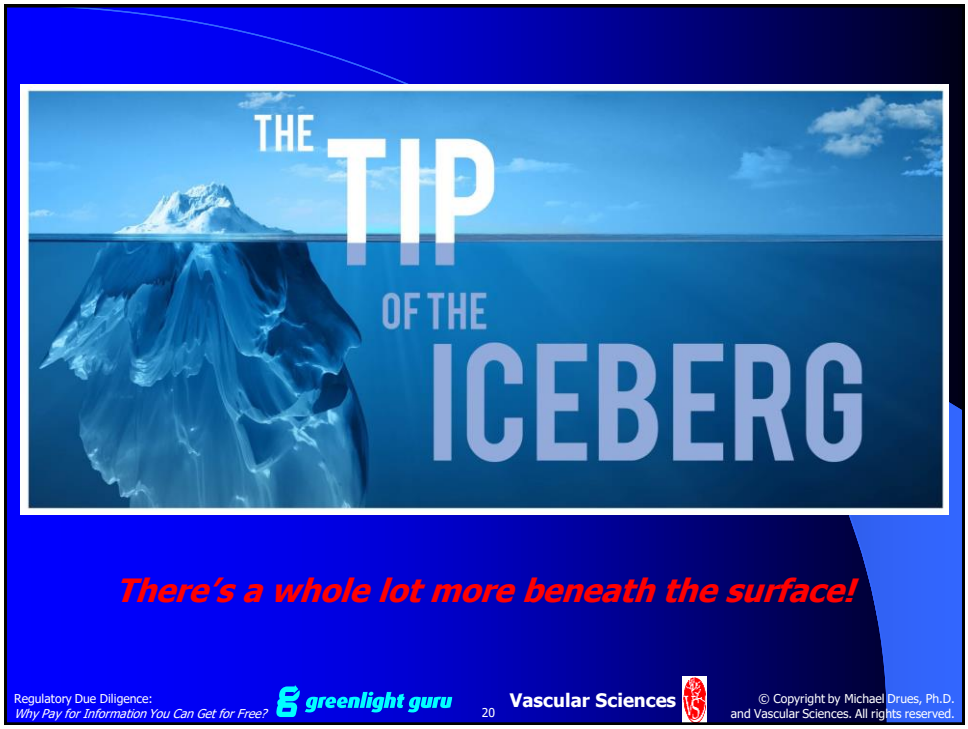

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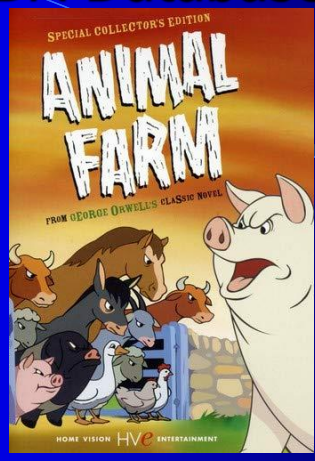
FDA Databases



Let's apply a little George Orwell…

All animals are equal… but some animals are more equal than others.

Applied here:

All databases are important… but some databases are more important than others.

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New Project – Where to start?

Mike's Recommendations:

From the "master list" of CDRH Medical Device Databases is here, start with:

Basic Regulatory Due Diligence:

- All devices: Product Code Database here
- Class I / II Non-Exempt Devices: 510k database here / De novo database here
- Class III Devices: PMA database here / HDE database here
- All Devices: Estab Reg & Device Listing database here (especially Class I / II Exempt)

Engineering/Technical Due Diligence:

- CDRH Recognized Consensus Standards Database here

Problems with Similar / Existing Devices Due Diligence:

- MAUDE (Manufacturer and User Facility Device Experience) here
- MDR (Medical Device Reporting) here
- MedSun Reports here

Guidance Due Diligence

- Guidance Document Database here

Wellness Devices:

- There is no wellness device database ***– but there should be!***

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Regulatory Due Diligence:

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How about some

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Case Study: Nystagmograph

What is a nystagmograph?
Where do I begin?
…after the biology and engineering of course!

Video: Vestibular Tests (1 min) here

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Regulatory Due Diligence:

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Start with the Product Code but

What's an FDA Product Code

Short answer: *Think of a pie!*

Each slice has a three-character name

Note:

CDRH Product Codes ≠ CMS Reimbursement codes!

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Case Study: Nystagmograph

Google (or bookmark) FDA product code database

Product Code Classification Database

The Product Classification Database contains medical device names and associated information developed by the Center for Devices and Radiological Health (CD[illegible] support of its mission. This database contains device names and their associat codes. The name and product code identify the generic category of a device for Product Code assigned to a device is based upon the medical device product cl designated under 21 CFR Parts 862-892.

These files are updated every Sunday.

- Search the on-line product code database
- Information on how to classify a device
- Download Product Code files

Information on Devices Regulated by other Centers

- Devices regulated by CBER (Center for Biologics Evaluation and Researc
- Intercenter Agreements which are working agreements developed betwe Centers, outline certain categories of products and how these products ha regulated by the FDA.

CDRH Product Code Database here

Product Classification

FDA Home > Medical Devices > Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

learn more...

Search Database Help Download Files

Device: Nystagmograph

Review Panel | Product Code | Regulation Number | Submission Type | Third Party Eligible | Implanted Device | Life-Sustain/Support Device | Device Class | Summary Malfunction Reporting

Go to Quick Search | Clear Form | search

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Regulatory Due Diligence:

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Case Study: Nystagmograph

Product Classification

FDA Home • Medical Devices • Databases

New Search | Back to Search Results

Device	Nystagmograph
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	GWN
Premarket Review	Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A) Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)
Submission Type	510(k)
Regulation Number	882.1460
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Recognized Consensus Standard
- 4-185 ANSI ASA S3.45-2009 (Reaffirmed 2019)
  American National Standard Procedures for Testing Basic Vestibular Function

Third Party Review
- Eligible for *510(k) Third Party Review Program*

Accredited Persons
- Beanstock Ventures
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

Product code GWN

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Case Study: Copper Fit Energy Socks

Is this a regulated medical device?

Why or why not?

CFR Definition of Medical Device here

If not a regulated device, *could it be?*

Hint: *what would we have to change?*

If a regulated device, what are the options?

Wellness → Class I Exempt → Class II (510k or de novo) → higher?

Copper Fit Energy Socks video available here.

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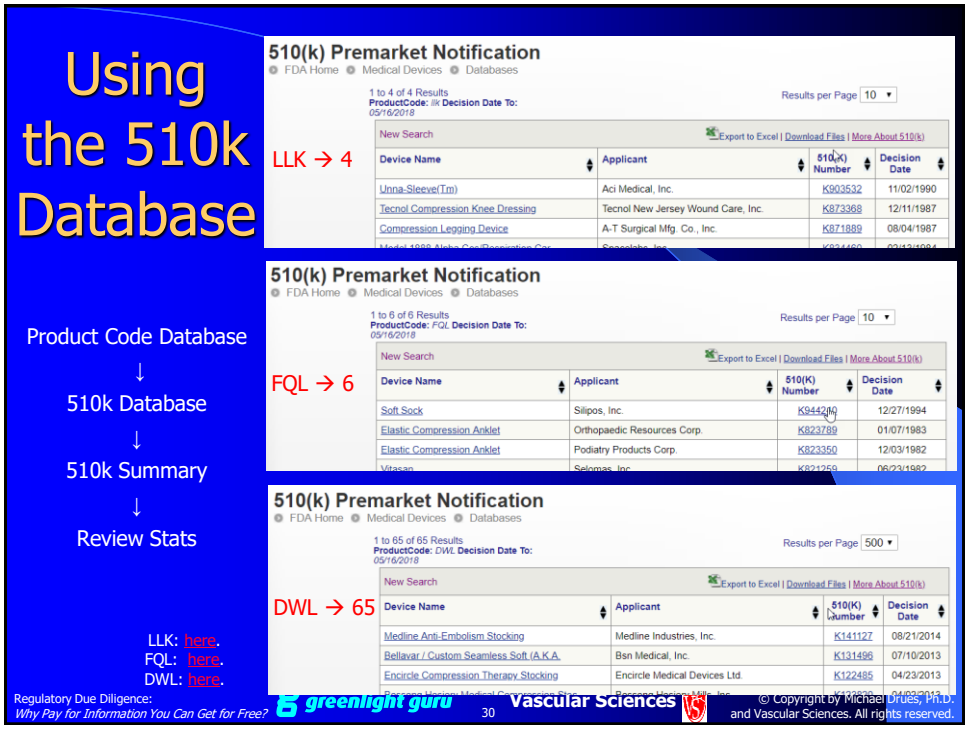

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An example from

Remember

It's all about the claims!

Shark Tank: Apolla Socks (S13/E18) here

[watch from 30:40 → 41:45]

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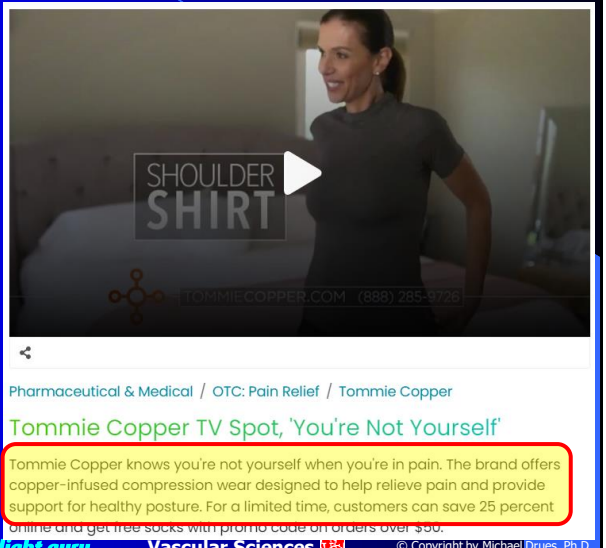
Beyond socks?

Other wearables with "similar" i.e., substantially equivalent claims? – *pun intended!*



Video here (2 min)

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Take a lesson from Hill Street Blues

Hill Street Blues is an American television series that aired on NBC from 1981 until 1987.

Michael Conrad Video: here (5 sec)

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When making claims…

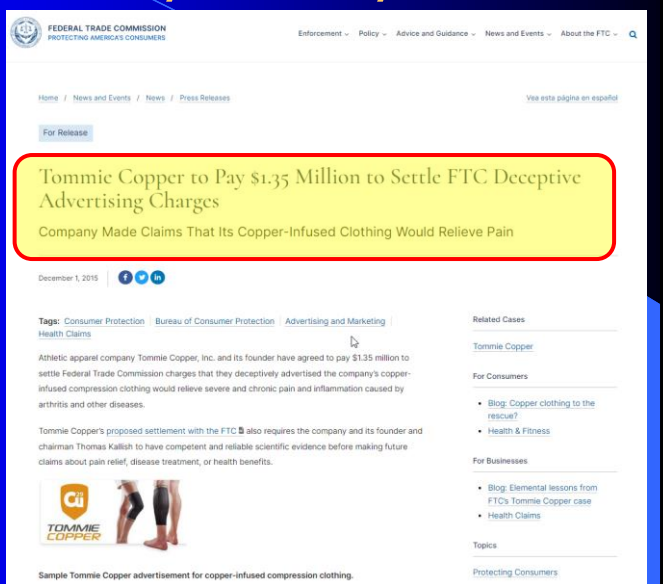
FDA may not be your only concern!

Regulatory 101:

You can say (i.e., claim) anything you want…

as long as you can support it!

FTC Press Release (Dec, 2015) here.


FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Tommie Copper to Pay $1.35 Million to Settle FTC Deceptive Advertising Charges

Company Made Claims That Its Copper-Infused Clothing Would Relieve Pain

December 1, 2015

Tags: Consumer Protection | Bureau of Consumer Protection | Advertising and Marketing | Health Claims

Athletic apparel company Tommie Copper, Inc. and its founder have agreed to pay $1.35 million to settle Federal Trade Commission charges that they deceptively advertised the company's copper-infused compression clothing would relieve severe and chronic pain and inflammation caused by arthritis and other diseases.

Tommie Copper's proposed settlement with the FTC also requires the company and its founder and chairman Thomas Kalfish to have competent and reliable scientific evidence before making future claims about pain relief, disease treatment, or health benefits.

Related Cases
Tommie Copper

For Consumers
- Blog: Copper clothing to the rescue?
- Health & Fitness

For Businesses
- Blog: Elemental lessons from FTC's Tommie Copper case
- Health Claims

Topics
Protecting Consumers

Sample Tommie Copper advertisement for copper-infused compression clothing.

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Sometimes lessons learn can be expensive!

Tommie Copper Settles, Bringing Bill to $2 Million

Baker & Hostetler LLP

BakerHostetler

USA | March 16 2018

Keep Reaching for the Stars

According to George Potzner's class action complaint, Tommie Copper was making a lot of unsubstantiated ...

body and is a natural, permanent antibacterial agent with skin benefits.

The company also touted speedy joint and muscle recovery, pain relief and, in what might perhaps be more puffery than a measurable claim, helping people "overcome obstacles and achieve their dreams." Sounds kind of great, right?

Not only are these problems preventable…

they are predictable!

Lexology (Mar, 2018) here.

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Is underwear a regulated medical device?

What matters more… what it does or what it says?

Hint: *this is a trick question!*

Don't think so… how do you explain this?

Question:

How would you bring this to market?

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For additional information, www.linkedin.com/in/michaeldrues, call (508) 887-9486 or e-mail mdrues@vascularsci.com

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Case Study: Underwear

K212928 (April, 2022)

Device	Barrier, Std, Oral Sex
Regulation Medical Specialty	Obstetrics/Gynecology
Review Panel	Obstetrics/Gynecology
Product Code	MSC
Premarket Review	GastroRenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	510(k)
Regulation Number	884.5300
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standard	• 9-88 ISO 29942 First edition 2011-07-01 Prophylatic dams -- Requirements and test methods
Third Party Review	• Eligible for *510(k) Third Party Review Program*
Accredited Persons	• Center For Measurement Standards Of Industrial • Global Quality And Regulatory Services • Regulatory Technology Services, Llc • Third Party Review Group, Llc

Product Code MSC

Device Classification Name	barrier, std, oral sex
510(k) Number	K212928
Device Name	Lorals
Applicant	Brazen Goods Inc. Dba Lorals 106 1/2 Judge John Aiso St. #305 Los Angeles, CA 90012
Applicant Contact	Melanie Cristol
Correspondent	AcKnowledge Regulatory Strategies LLC 2251 San Diego Ave, B-257 San Diego, CA 92110
Correspondent Contact	Erin Gontang
Regulation Number	884.5300
Classification Product Code	MSC
Date Received	09/14/2021
Decision Date	04/22/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Obstetrics/Gynecology
510k Review Panel	Obstetrics/Gynecology
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

First time FDA has cleared an underwear product as a medical device!

Note: *Not class I exempt... class II non-exempt – why??*

510k Summary here / FDA Gets Down with Vanilla-Flavored STI Undies (MDDI, May, 2022) here

Question:

What's your predicate? What's your product code?

Is underwear substantially equivalent to a condom? [Hint: Product Code MSC]

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Product Code and CFR

CFR - Code of Federal Regulations Title 21

FDA Home • Medical Devices • Databases

⚠ **The information on this page is current as of Mar 29, 2022.**

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).

New Search — Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR884.5300]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 884 -- OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart F - Obstetrical and Gynecological Therapeutic Devices

Sec. 884.5300 Condom.

(a) *Identification.* A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility.

(b) *Classification.* (1) Class II (special controls) for condoms made of materials other than natural rubber latex, including natural membrane (skin) or synthetic.

(2) Class II (special controls) for natural rubber latex condoms. The guidance document entitled "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300" will serve as the special control. See § 884.1(e) for the availability of this guidance document.

[73 FR 66538, Nov. 10, 2008]

Product Code MSC
↓
↓
CFR 884.5300 here

Note:
Label reduction!

Why Class II? *Special controls!* [see special controls webinar here]

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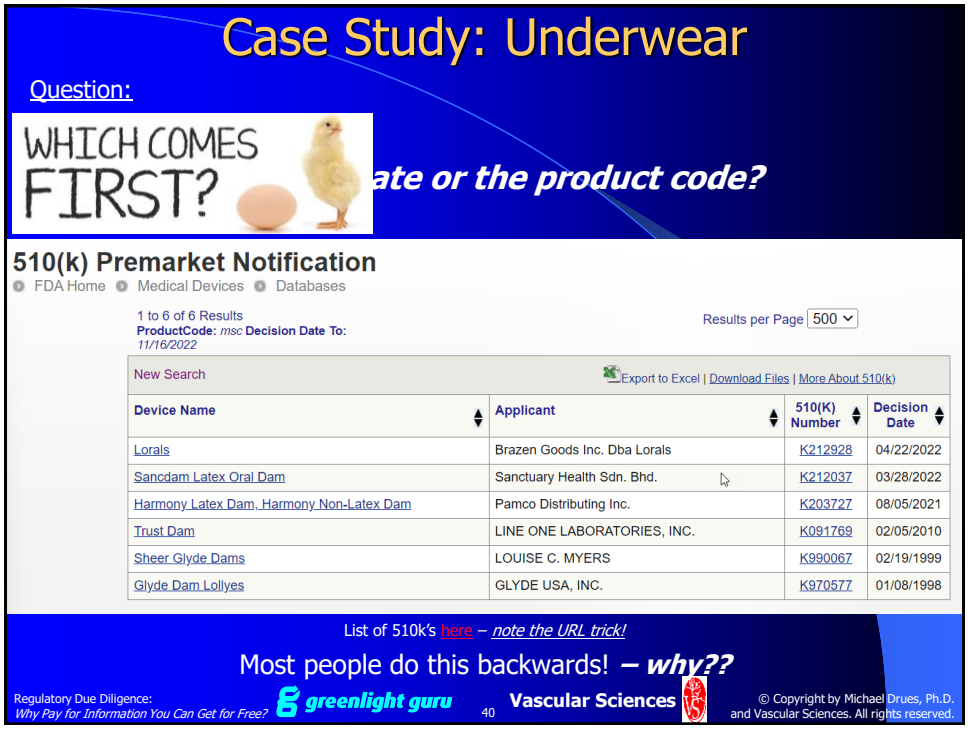

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GreenLight.Guru Webinar (November 17, 2022)

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Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

Would this be a 510k or De novo

Short answer:

Take your pick! ☺

Slightly longer answer… *Governing Equation of the 510k:*

510k = (Labeling$_{SE}$ + Technology$_{SE}$) + Risk

see webinar: The 510k and Substantial Equivalence: *Why do so many get it wrong?* here.

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Labeling

What are the claims?

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212928

Device Name
Lorals

Indications for Use *(Describe)*
Lorals are used as a barrier when engaging in oral/vaginal and oral/anal sex to help reduce the transmission of bodily fluids, harmful pathogens, and sexually transmitted infections.

from K212928 510k Summary here

Question:

Is underwear substantially equivalent to a condom?

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Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

Why are 510k's more "challenging" today than in the past

Consider this:

Is a  substantially equivalent to a  ????

CT: MOA = X-ray

MRI: MOA = Magnet

In the past, absolutely… today, good luck!

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How can I use regulatory due diligence to my competitive advantage?

Short answer:

Think *competitive regulatory strategy!*

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Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

Check it out!

Competitive Regulatory Strategy – using regulation to your tactical advantage

Journal of Medical Device Regulation (August, 2015)

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Competitive Regulatory Strategy

Article:

Competitive Regulatory Strategy: *Using regulation to your tactical advantage*

Journal of Medical Device Regulation, August, 2015 available here. JMDR abstract here.

Podcast:

Selecting The Best Regulatory Path For Your Medical Device here

Column:

Is Your Boring Regulatory Strategy Costing You Business. available here.

Podcast:

An Introduction To Competitive Regulatory Strategy available here.

Article:

"How to Sharpen Your Regulatory Sword"

MDDI (February, 2014) available here.

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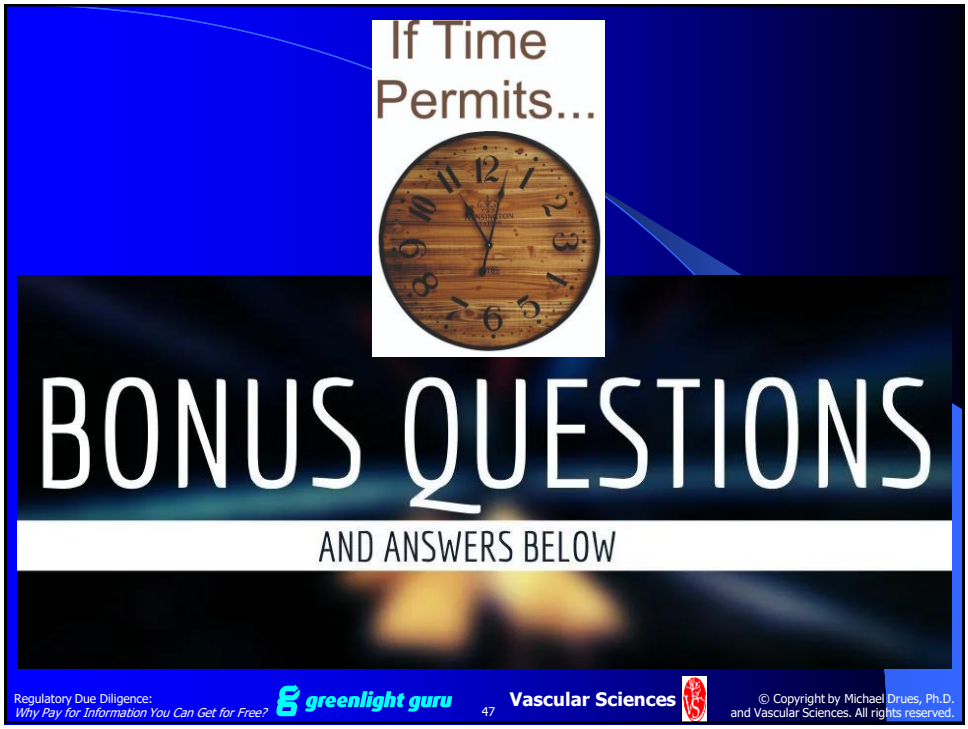

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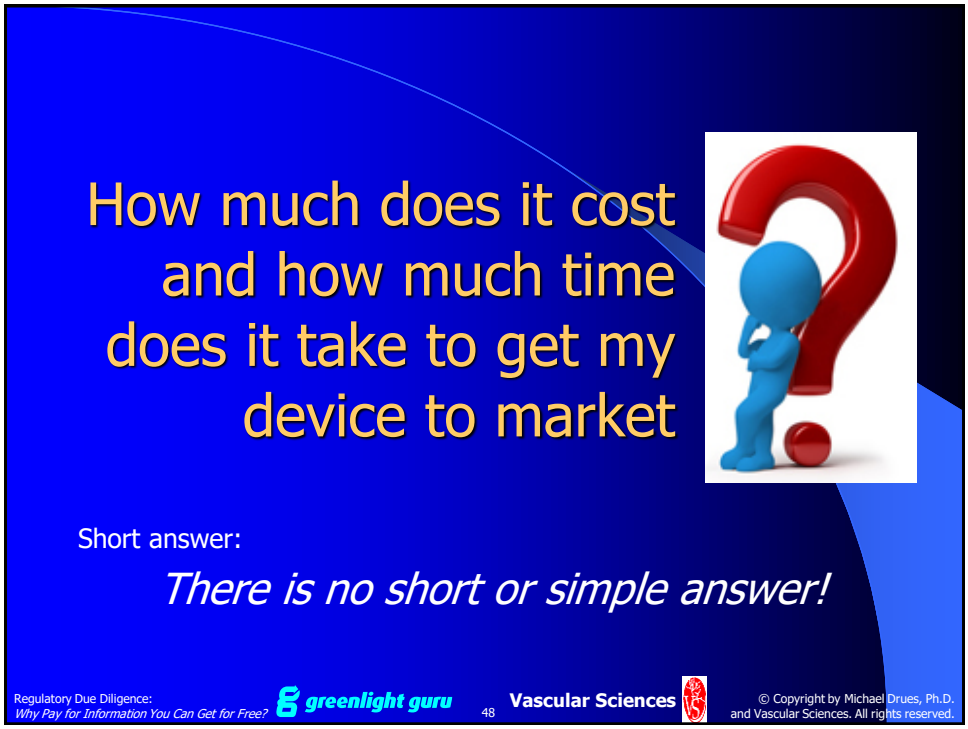

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For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

Average Time & Cost to Market: 510k & De novo

FDA 510(k) Average Cost: Concept → Clearance

Average = $6.1M [Range: $200K → $41M

Half clearances $1.2M → $6.8M [Median = $3.1M]

FDA 510(k) Average Clearance Times: Concept → Clearance

Average = 33 months [Range: 2 months → 132 months (11 years)

Half clearances 18 → 43 months [Median = 31 months]

FDA De Novo Cost: Concept → Granting

Average = $17.8M [Range = $800K → $90M]

Half Granted $2M → $21M [Median = $5M]

FDA De Novo Time: Concept → Granting

Average = 80 months [Range: 18 months to 240 months (20 years)

Half Granted 45 → 99 months [Median = 66 months]

from *How much time and money does it take for FDA 510(k) clearance versus De Novo classification?* (Med Design and Outsourcing (March 21, 2022) here

Important caveat:

Be VERY careful interpreting these statistics…

they can be very misleading if not deceptive!

MDUFA Performance Reports here. 510k Database here. De novo Database here

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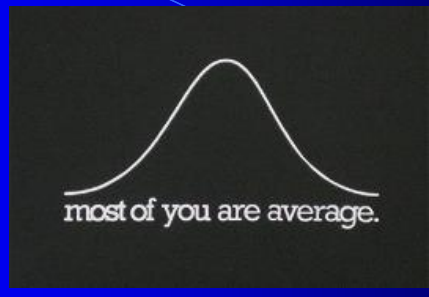
The problem with being average…



Remember,

If you're average… than 50% of the world is better than you!

Think about it this way:

Average folks do average things to keep averagely running!

This is a very low place to set the bar… would you agree?

Video: *OK Surgeon - just OK isn't OK* (30 sec)

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Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

MDUFA Statistics Deceptive if not Meaningless

Useful but non-specific!

MDUFA Reports

Share Tweet LinkedIn Email Print

The FDA provides annual and quarterly reports on its progress towards meeting performance goals and commitments set under MDUFMA to its stakeholders and Congress.

The FDA also provides an annual financial report to Congress to help ensure transparency and accountability of its use of the additional resources provided by MDUFMA.

MDUFA Annual Reports

- MDUFA Performance Reports
- MDUFA Financial Reports

MDUFA Quarterly Performance Reports

Each report includes the agenda for the quarterly meeting and the quarterly performance data.

MDUFA IV

- September 7, 2022 MDUFA IV Performance Report
- June 2, 2022 MDUFA IV Performance Report
- February 25, 2022 MDUFA IV Performance Report
- November 16, 2021 MDUFA IV Performance Report
- August 3, 2021 MDUFA IV Performance Report

MDUFA Statistics here

MDUFA User Fees here

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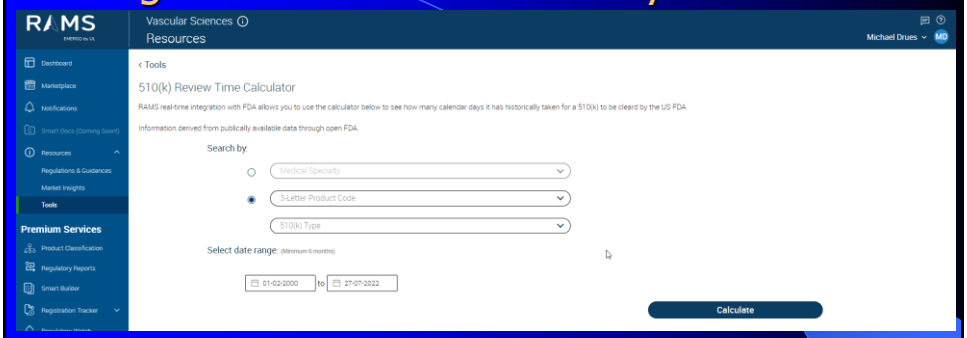
What is a better i.e., more specific approach?

Average 510k Clearance Time by Product Code



Emergo Group "510k Calculator" here

Mechanics:

After signing up for an account (free), click on:

1. RESOURCES (left side of home page) then
2. TOOLS (under resources) then
3. GET STARTED (under 510 (K) Review Time Calculator) then
4. Click on the SEARCH BY 3-LETTER PRODUCT CODE button

Note: You can also change the date range to search over a particular period of time.

Important Points to Remember:

- ✓ Uses publicly available information → saves doing the arithmetic yourself!
- ✓ Much more specific (i.e., realistic) estimates of clearance times!

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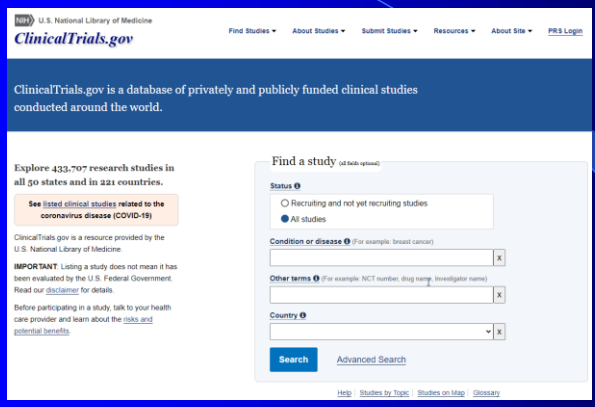
Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

How do I find out about clinical trials



https://clinicaltrials.gov/

How can I use this information?

- ✓ Clinical trial design and justification – *valuable but obvious!*
- ✓ Reverse engineer your competitions regulatory strategy – *my favorite!* ☺

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What is the true essence of regulation?

Regulation is all about the interpretation of words…

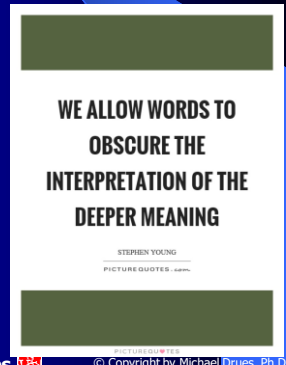
and your ability to defend your interpretation!

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



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Regulatory Due Diligence:

Why Pay for Information You Can Get for Free?

Why is this important?

Updated Definitions of Face-to-Face Format for Formal Meetings with FDA

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The PDUFA VII and BsUFA III commitment letters provide an update to the definition of face-to-face formal meetings with Industry. This update clarifies that a face-to-face meeting "includes in-person meetings and virtual meetings on IT platforms that allow for both audio and visual communication."[1] In other words, a face-to-face meeting between FDA and Industry is defined as either in-person or virtual with cameras on. FDA is in the process of updating our formal meetings guidance documents to reflect this revised definition. In the interim, we are highlighting this change on our public website to help reduce uncertainties on this point.

We note that while the revised face-to-face definition includes either in-person or virtual meetings, FDA is not currently holding in-person meetings, as communicated in our guidance *Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications—Questions and Answers*. **This means face-to-face meetings will only be virtual at this time.** Once FDA returns to in-person meetings, sponsors/applicants will be notified of that option for a face-to-face meeting.

As a reminder, sponsors/applicants may still request a teleconference. When a meeting is granted as a teleconference, regardless of the platform (e.g., Zoom) on which the teleconference is held, the meeting is audio only (i.e., no cameras on) and thus is not considered a face-to-face meeting.

Strongly NOT Recommended!

Updated Definitions of Face-to-Face Format for Formal Meetings with FDA (10/27/22) here

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What's the

- ✓ Do your homework and be prepared!
- ✓ Begin early and update/revise/reevaluate often
- ✓ Know the right tool(s) to use for the right job
- ✓ Continue to expand your toolbox and keep your tools sharp

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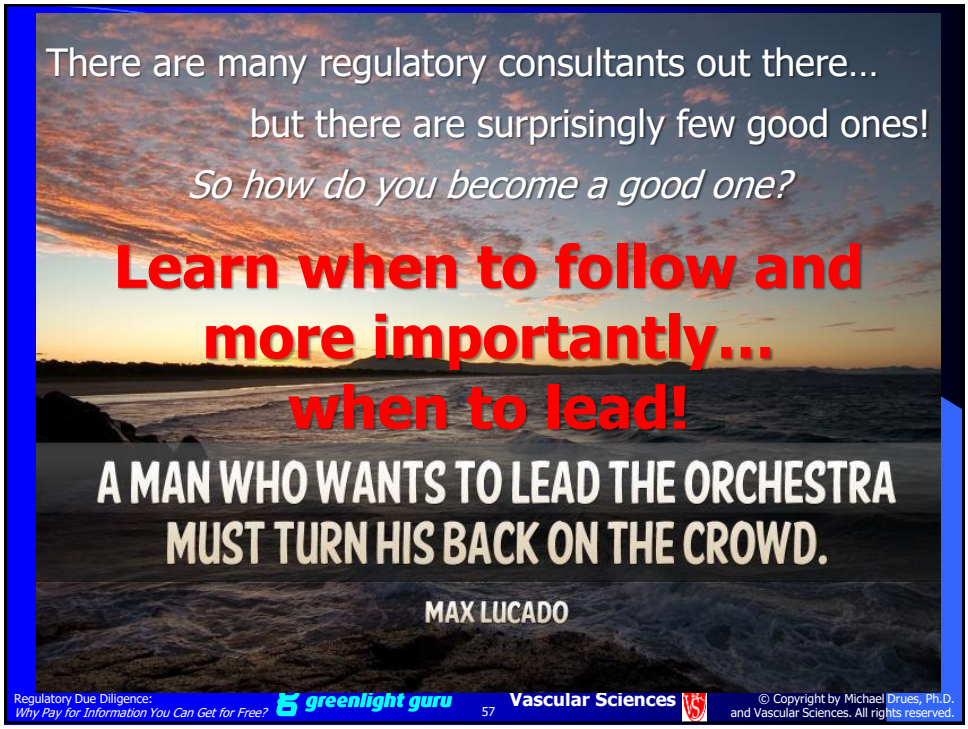

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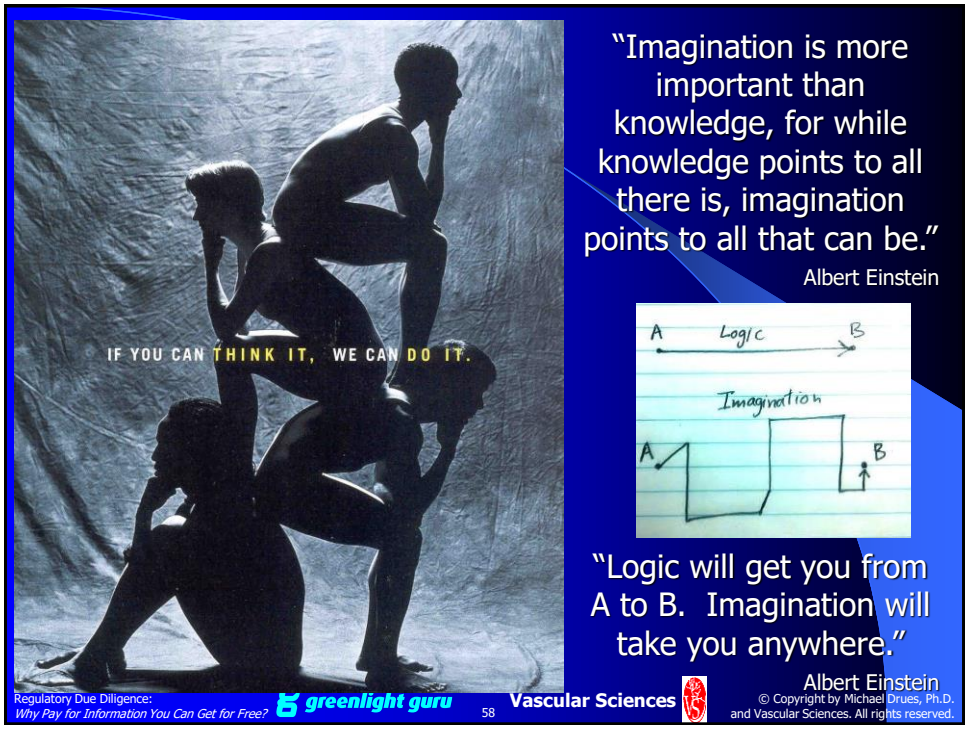

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Regulatory Due Diligence:

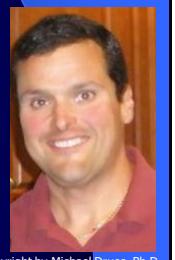
Why Pay for Information You Can Get for Free?

Taking inspiration from one of best…

"Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo. You can quote them, disagree with them, glorify or vilify them. About the only thing you can't do is ignore them. Because they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do."

Steve Jobs (1955 – 2011), entrepreneur, marketer and inventor, the co-founder of Apple Inc. and widely recognized as a pioneer of the personal computer revolution.

Steve Jobs Heres To The Crazy Ones (1 min)



More importantly…

"Imagine where we could be if discontent for the status quo was the norm rather than the exception."

Can you guess who said this?

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Questions?

Comments?

Suggestions?

Criticisms?

Complaints?

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