

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

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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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Hosted by: greenlightguru.com

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 **LinkedIn**

 **Guerilla Regulatory Strategy**
Tips And Tactics
A guest expert series by Michael Drues, Ph.D., President, Vascular Sciences

 **Medical Design & OUTSOURCING**
A MassDevice Resource

 **Healthcare PACKAGING**

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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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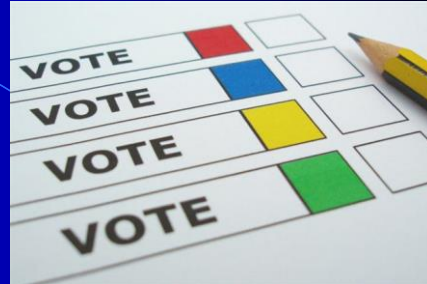
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Before we begin...

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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Regulatory Due Diligence:



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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

How to Construct an Effective Regulatory Strategy
Written by: **NICK TIPPMANN**
May 27, 2020



JON SPEER
Founder & VP of
QA/RA
Greenlight Guru

MICHAEL DRUES, PH.D.
President
Vascular Sciences

GLOBAL MEDICAL DEVICE PODCAST
Powered by **greenlight guru**

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

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MICHAEL DRUES PHD
President
Vascular Sciences



ETIENNE NICHOLAS
Medical Device Guru
Greenlight Guru

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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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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

CDRH Database List [here](#)

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 Analyses	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

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CDRH Databases

★ De Novo	De novo provides a possible route to classify novel devices of low to moderate risk. This database contains de novo classification orders.	Weekly	
★ Devices@FDA	Devices@FDA is a catalog of cleared and approved medical device information from FDA. It includes links to the device summary information, manufacturer, approval date, user instructions, and other consumer information. Devices@FDA searches the following databases: Premarket Notifications (510(k)s) and Premarket Approvals (PMA).	Weekly	
★ FDA Certified Mammography Facilities	A searchable listing by state and zip code of all mammography facilities certified by the Food and Drug Administration (FDA) as meeting baseline quality standards for equipment, personnel and practices under the Mammography Quality Standards Act of 1992 (MQSA).	Weekly	
★ Humanitarian Device Exemption (HDE)	Searchable listing of Humanitarian Device Exemption (HDE) Class III medical devices.	Weekly	More about Humanitarian Device Exemption (HDE)
★ IVD Home Use Lab Tests (Over-The-Counter) Tests	Searchable listing of Over-the-Counter tests (OTC) and collection kits that have been cleared or approved by the FDA.	Weekly	More about Home Use Lab Tests
★ MAUDE (Manufacturer and User Facility Device Experience)	MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.	Weekly	
★ MDR (Medical Device Reporting)	This database allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.	No longer being updated	
★ MedSun Reports	The Medical Product Safety Network (MedSun) is an adverse event reporting program launched in 2002 by the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices.	Daily	MedSun Homepage
★ Post-Approval Studies (PAS) Database	This database contains information about current Post Approval Studies (PAS). Manufacturers required to conduct PAS must complete the study as a condition of approval. This database allows you to search PAS information by applicant or device information. This database is updated once a week.	Weekly	More about PAS
★ Premarket Approvals (PMA)	Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of all devices classified as Class III devices. An approved Premarket Approval Application (PMA) is, in effect, a private license granted to the applicant for marketing a particular medical device. This database may be searched by a variety of fields and is updated once a week.	Weekly	File Description for the CDRH Releasable (Approved) PMAs
★ Premarket Approval (PMA) Summary Review Memos for 180-Day Design Changes	A 180-day supplement is a request for a significant change in components, materials, design, specification, software, color additive, and labeling to an approved premarket application or premarket report. As a pilot program under the CDRH Transparency Initiative, FDA has begun releasing some summary review memos for 180-day PMA supplements relating to design changes.	Weekly	More about Premarket Approval (PMA) Summary Review Memos for 180-Day Design

CDRH Database List [here](#)

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CDRH Databases

★ Premarket Notifications (510(k)s)	Medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. This database of releasable 510(k)s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information is available via the web interface for more recent records. The database is updated once a week.	Weekly	
★ Product Classification	This database contains medical device names and associated information developed by the Center. It includes a three letter device product code and a Device Class that refers to the level of CDRH regulation of a given device.	Weekly	More about Product Code Classification Database
★ Radiation-emitting Electronic Product Codes	This database contains product names and associated information developed by the Center for all products, both medical and non-medical, which emit radiation. It includes a three letter product code, a descriptor for radiation type, applicable performance standard(s), and a definition for the code.	Weekly	
★ Radiation Emitting Product Corrective Actions and Recalls	This database provides descriptions of radiation-emitting products that have been recalled under an approved corrective action plan to remove defective and noncompliant products from the market. Searches may be done by manufacturer name, performance standard, product name, description, or date range.	Weekly	More About Corrective Actions
★ Recalls of Medical Devices	This database contains Medical Device Recalls classified since November 1, 2002. Beginning January 3, 2017, the database may also include correction or removal actions initiated by a firm prior to review by the FDA. The status of the action is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall and provides contact information for customers with questions. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. CBER recall information is available here .	Frequently as items become available	More About Recalls
★ Recognized Consensus Standards	This database consists of those national and international standards recognized by FDA which manufacturers can declare conformity to and is part of the information the Center can use to make an appropriate decision regarding the clearance or approval of a submission. Information submitted on conformance with such standards will have a direct bearing on safety and effectiveness determinations made during the review of IDEs, HDEs, PMAs, and PDPs. Conformance with recognized consensus standards in and of itself, however, may not always be a sufficient basis for regulatory decisions.	Quarterly	

CDRH Database List [here](#)

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CDRH Databases

CDRH Database List [here](#)

Registration & Listing

This searchable database contains establishments (engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution) and listings of medical devices in commercial distribution by both domestic and foreign manufacturers. Generally, owners or operators of establishments that are involved in the production and distribution of medical devices intended for use in the U.S. are required to register annually with the FDA. Generally, establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires a premarket submission before being marketed in the U.S., then the owner/operator should also provide the FDA premarket submission number (510(k), De Novo, PMA, PDR, HDE). Note: This database is updated weekly.

Weekly

[More About Registration and Listing](#)

Total Product Life Cycle (TPLC)

The Total Product Life Cycle (TPLC) database integrates premarket and postmarket data about medical devices. It includes information pulled from CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510(k)), Adverse Events, and Recalls. You can search the TPLC database by device name or procode to receive a full report about a particular product line.

Weekly

[More about TPLC](#)

X-Ray Assembler Data

Federal regulations require that an assembler who installs one or more certified components of a diagnostic x-ray system submit a report of assembly. This database contains the releasable information submitted including Equipment Location, General Information and Component Information. Note: Data does not include dental system installations.

No longer being updated

[X-Ray Assembler Data File](#)

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Beyond CDRH...

Guidance Document Database

✓ Not CDRH specific although...
you can limit to product type (i.e. device)... should you?

*Ignorance is no excuse, i.e.,
there's no excuse not to keep up.
This is your job... not FDA's!*

Sign up for Guidance Documents email updates
Get regular FDA email updates delivered on this topic to your inbox.

Mike's Recommendation:
Put this in your QMS!
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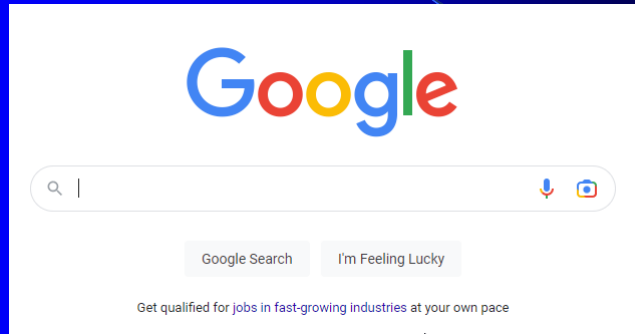
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Don't overlook the obvious!



<https://www.google.com/>

Its amazing what you can find!

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There's a whole lot more beneath the surface!

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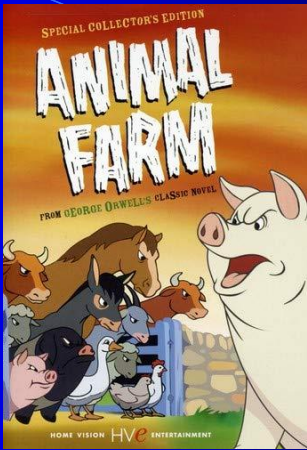
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FDA Databases





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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How about some



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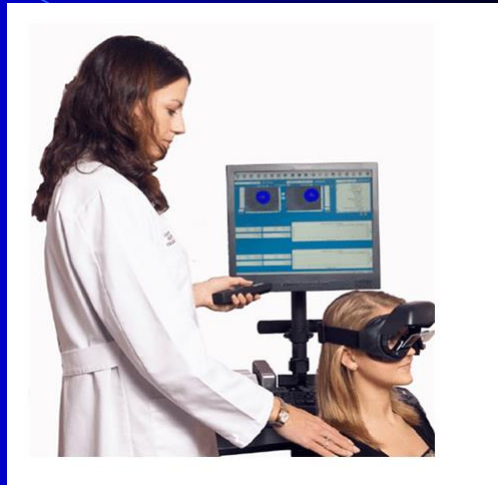
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Case Study: Nystagmograph

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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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 \neq 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 (CDRH) support of its mission. This database contains device names and their associated 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 code 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 Biological Evaluation and Research)
- [Intercenter Agreements](#) which are working agreements developed between Centers, outline certain categories of products and how these products are regulated by the FDA.

Product Classification

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

Device: Product Code:

Review Panel:

Submission Type:

Implanted Device: Life-Sustain/Support Device:


Summary Malfunction Reporting:

Go to Quick Search

Clear Form search

CDRH Product Code Database [here](#)

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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	BeaStock 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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Its all about what you say!

Why do I have to choose... Can you say label expansion?

Pathway options:
Wellness
↓
Class I Exempt
↓
Class II (510k or de novo)
↓
higher?
CFR 880.5780 [here](#)
Product Codes [here](#)

Why do I have to choose... Can you say label expansion?

(a) Medical support stocking to prevent the pooling of blood in the legs --(1) Identification. A medical support stocking to prevent the pooling of blood in the legs is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for use in the prevention of pooling of blood in the leg.

(2) Classification. Class II (performance standards). **or**

(b) Medical support stocking for general medical purposes --(1) Identification. A medical support stocking for general medical purposes is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for medical purposes other than the prevention of pooling of blood in the leg.

(2) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

Product Classification
FDA Home Medical Devices Databases
1 to 3 of 3 Results
880.5780
Results per Page 5

[New Search](#) [Export to Excel](#) [Help](#)

Product Code	Device	Regulation Number	Device Class
LLK	Legging, Compression, Non-Inflatable	880.5780	2
FQL	Stocking, Medical Support (For General Medical Pur...)	880.5780	1
DWL	Stocking, Medical Support (To Prevent Pooling Of B...	880.5780	2

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Using the 510k Database

Product Code Database
↓
510k Database
↓
510k Summary
↓
Review Stats

LLK → 4

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 4 of 4 Results
Product Code: LLK Decision Date To: 09/16/2018
Results per Page 10

Device Name	Applicant	510(k) Number	Decision Date
Unna-Sleeve(TM)	Ac Medical, Inc.	K903532	11/02/1990
Tecno Compression Knee Dressing	Tecno New Jersey Wound Care, Inc.	K873368	12/11/1987
Compression Legging Device	A-T Surgical Mfg. Co., Inc.	K871889	08/04/1987

FQL → 6

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 6 of 6 Results
Product Code: FQL Decision Date To: 09/16/2018
Results per Page 10

Device Name	Applicant	510(k) Number	Decision Date
Soft Sock	Silpos, Inc.	K944280	12/27/1994
Elastic Compression Ankle	Orthopaedic Resources Corp.	K823789	01/07/1983
Elastic Compression Ankle	Podiatry Products Corp.	K823350	12/03/1982
Medson	Silpos, Inc.	K921250	06/23/1992

DWL → 65

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 65 of 65 Results
Product Code: DWL Decision Date To: 09/16/2018
Results per Page 500

Device Name	Applicant	510(k) Number	Decision Date
Medline Anti-Embolism Stocking	Medline Industries, Inc.	K141127	08/21/2014
Bellivar / Custom Seamless Soft (A.K.A.)	Bsn Medical, Inc.	K131498	07/10/2013
Encircle Compression Therapy Stocking	Encircle Medical Devices Ltd.	K122485	04/23/2013

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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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APOLL α
ATTITUDE • PERFORMANCE • ART

THE INFINITE

THE INFINITE'S HIGHLY ENGINEERED DESIGN HAS MOISTURE WICKING & ANTI-MICROBIAL PROPERTIES ALONG WITH THE FOLLOWING INNOVATIVE PERFORMANCE FEATURES:

1. FITTED CALF OPENING RESTS COMFORTABLY THROUGHOUT MOVEMENT AND ACTIVITY
2. ATHLETIC GRADUATED COMPRESSION PROMOTES OPTIMAL CIRCULATION AND MUSCLE RECOVERY
3. TARGETED COMPRESSION ZONES FOR REVOLUTIONARY ARCH SUPPORT THAT LIFTS AND STABILIZES THE ARCH
4. KNOT-IN ENERGY ABSORPTION IN THE HEEL FOR MAXIMUM COMFORT
5. STRETCH FABRIC ENABLES TOES TO SPREAD AND WEARERS TO FEEL THE FLOOR
6. KNOT-IN ENERGY ABSORPTION PAD AVAILABLE WITH OR WITHOUT INVISIBLE TRACTION
- 7.

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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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SHOULDER SHIRT

Pharmaceutical & Medical / OTC: Pain Relief / Tommie Copper

Tommie Copper TV Spot, 'You're Not Yourself'

Tommie Copper knows you're not yourself when you're in pain. The brand offers copper-infused compression wear designed to help relieve pain and provide support for healthy posture. For a limited time, customers can save 25 percent online and get free socks with promo code on orders over \$50.

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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.



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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](#).

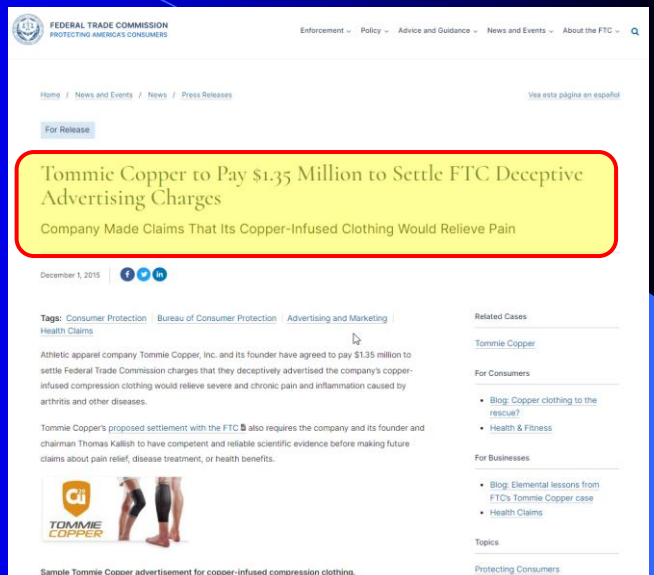
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Sometimes lessons learn can be expensive!

Tommie Copper Settles, Bringing Bill to \$2 Million

Baker & Hostetler LLP



BakerHostetler

USA | March 16 2018

Tommy Cooper Settles, Bringing Bill to \$2 Million

Problems Plevel

Keep Reaching for the Stars

they are predictable!

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?

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 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!*



Question:

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

How would you bring this to market?

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Case Study: Underwear

[K212928](#) (April, 2022)

Product Code [MSC](#)

Device	Barrier, Std, Oral Sex	Device Classification Name	barrier_std_oral_sex
Regulation Medical Specialty	Obstetrics/Gynecology	510(k) Number	K212928
Review Panel	Obstetrics/Gynecology	Device Name	Lorals
Product Code	MSC	Applicant	Brazen Goods Inc. Dba Lorals 106 1/2 Judge John Also St. #305 Los Angeles, CA 90012
Premarket Review	GastroRenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)	Applicant Contact	Melanie Cristol
Submission Type	510(k)	Correspondent	Acknowledge Regulatory Strategies LLC 2251 San Diego Ave, B-257 San Diego, CA 92110
Regulation Number	884.5300	Correspondent Contact	Erin Gontang
Device Class	2	Regulation Number	884.5300
Total Product Life Cycle (TPLC)	TPLC Product Code Report	Classification Product Code	MSC
GMP Exempt?	No	Date Received	09/14/2021
Summary Malfunction Reporting	Eligible	Decision Date	04/22/2022
Implanted Device?	No	Decision	Substantially Equivalent (SESE)
Life-Sustain/Support Device?	No	Regulation Medical Specialty	Obstetrics/Gynecology
Recognized Consensus Standard	9-88 ISO 20942 First edition 2011-07-01 Prophylactic dams -- Requirements and test methods	510k Review Panel	Obstetrics/Gynecology
Third Party Review	Eligible for 510(k) Third Party Review Program	Summary	Summary
Accredited Persons	Center For Measurement Standards Of Industrial Global Quality And Regulatory Services Regulatory Technology Services, Llc Third Party Review Group, Llc	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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May 19th @
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Presenter

MIKE DRUES
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JON SPEER
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<https://www.greenlight.guru/webinar/advantages-of-special-controls>

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Case Study: Underwear

Question:

WHICH COMES FIRST?

Device or the product code?

510(k) Premarket Notification

● FDA Home ● Medical Devices ● Databases

1 to 6 of 6 Results
ProductCode: msc Decision Date To: 11/16/2022

Results per Page 500 ▾

New Search [Export to Excel](#) | [Download Files](#) | [More About 510\(k\)](#)

Device Name	Applicant	510(K) Number	Decision Date
Lorals	Brazen Goods Inc. Dba Lorals	K212928	04/22/2022
Sancdam Latex Oral Dam	Sanctuary Health Sdn. Bhd.	K212037	03/28/2022
Harmony Latex Dam_Harmony Non-Latex Dam	Pamco Distributing Inc.	K203727	08/05/2021
Trust Dam	LINE ONE LABORATORIES, INC.	K091769	02/05/2010
Sheer Glyde Dams	LOUISE C. MYERS	K990067	02/19/1999
Glyde Dam Lollyes	GLYDE USA, INC.	K970577	01/08/1998

List of 510k's [here](#) – *note the URL trick!*

Most people do this backwards! – why??

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Would this be a 510k or De novo



Short answer:

Take your pick! 😊

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

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

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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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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Check it out!

Competitive Regulatory Strategy – using regulation to your tactical advantage

Journal of Medical Device Regulation
(August, 2015)

JOURNAL of MEDICAL DEVICE REGULATION

AUGUST 2015 VOLUME 12 (3)

In this issue:

- **Guest Editorial: Competitive regulatory strategy – using regulation to your tactical advantage**
- What is the potential impact of the new General Data Protection Regulation (GDPR) on clinical research in the medical device sector?
- Implementing a robust complaint handling system for a corporate company group
- Is the framework for the regulation of medical devices in Europe fundamentally flawed?
- News updates from Europe, North America, Central & South America, Asia, Africa & the Middle East, and global interest
- Country overview: Turkey

ISSN 1759-148X

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


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call (508) 887-9486 or e-mail mdrues@vascularsci.com

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Regulatory Due Diligence:

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If Time Permits...

BONUS QUESTIONS

AND ANSWERS BELOW

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How much does it cost
and how much time
does it take to get my
device to market



Short answer:
There is no short or simple answer!

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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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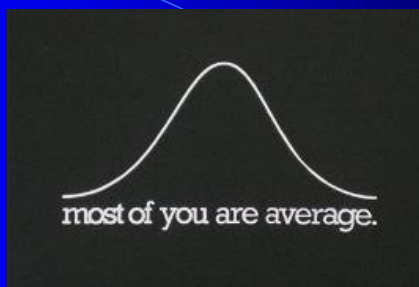
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The problem with being average...



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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MDUFA Statistics Deceptive if not Meaningless

Useful but non-specific!

MDUFA Statistics [here](#)
MDUFA User Fees [here](#)

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](#)

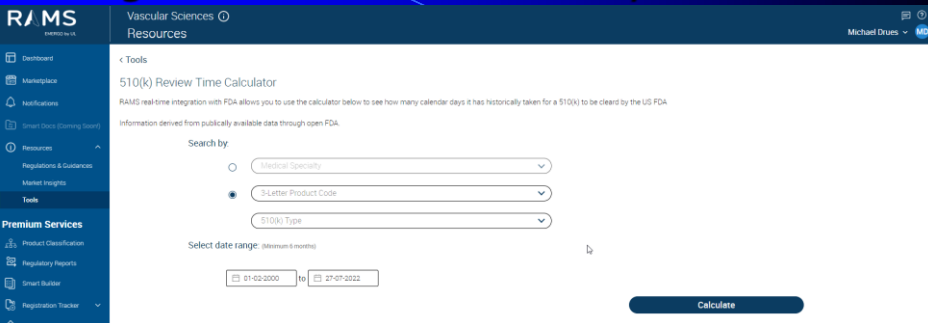
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What is a better i.e., more specific approach?

Average 510k Clearance Time by Product Code



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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How do I find out about clinical trials



U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies • About Studies • Submit Studies • Resources • About Site • PHS Login

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 433,707 research studies in all 50 states and in 221 countries.

See [listed clinical studies related to the coronavirus disease \(COVID-19\)](#)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (optional)

Status

☐ Recruiting and not yet recruiting studies

☒ All studies

Condition or disease (for example: breast cancer)

Other terms (for example: NCT number; drug name; investigator name)

Country

Search [Advanced Search](#)

[Help](#) • [Studies by Topic](#) • [Studies on Map](#) • [Disclaimer](#)

<https://clinicaltrials.gov/>

How can I use this information?

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

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What is the true essence of regulation?

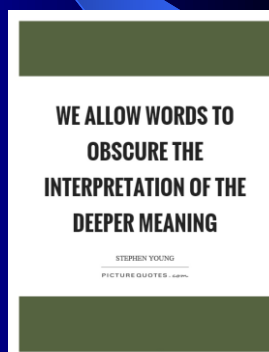
***Regulation is all about the interpretation of words...
and your ability to defend your interpretation!***

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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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."³ 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.


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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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.**

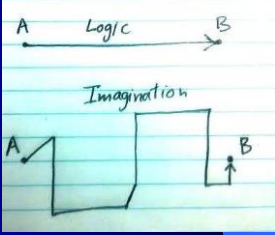
MAX LUCADO

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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



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

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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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