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Is Regulation Necessary for Quality?

How To Improve Your Product & Bottom Line With Compliance & A QMS

March 10th, 2022

1– 2 pm ET

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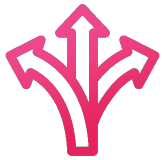
Topics covered in this webinar:



- The difference between laws, regulations, guidances, and standards

- How and why these things come to be

- Specifics of FDA regulations that govern quality

- FDA and ISO 13485

- FDA's Transition to ISO 13485

Laws, regulations, guidances, and standards are not the same things but are related.

Laws

Products of written statutes passed by congress.

Regulations

Set of rules adopted by administrations, such as FDA, that govern how the laws will be enforced

Guidances

FDA's interpretation of their policy on a regulation

Standards

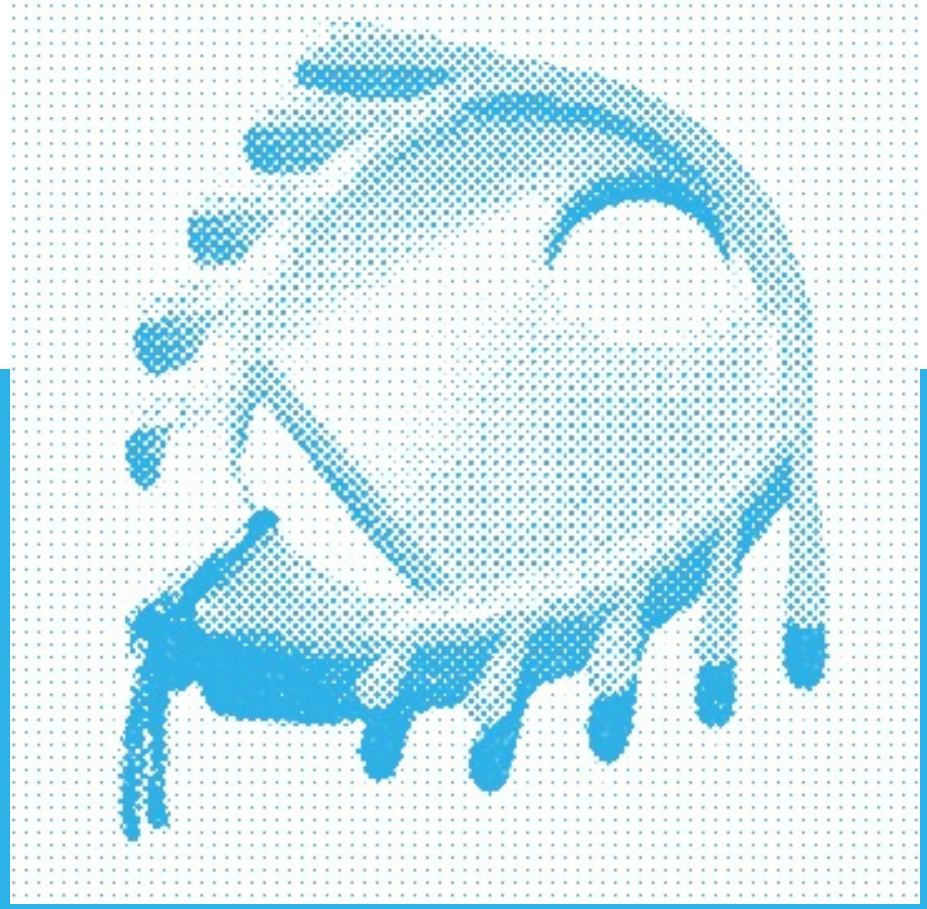
Established by private-sector bodies that establish industry expectations

The process flows from laws to regulations to guidances. Standards are similar to guidances but in some cases may be used in place of regulations.

The first fraudulent device (est 1700s): Elisha Perkin's patented tractors' claim was to eliminate disease from the body. George Washington's family even supposedly used them.

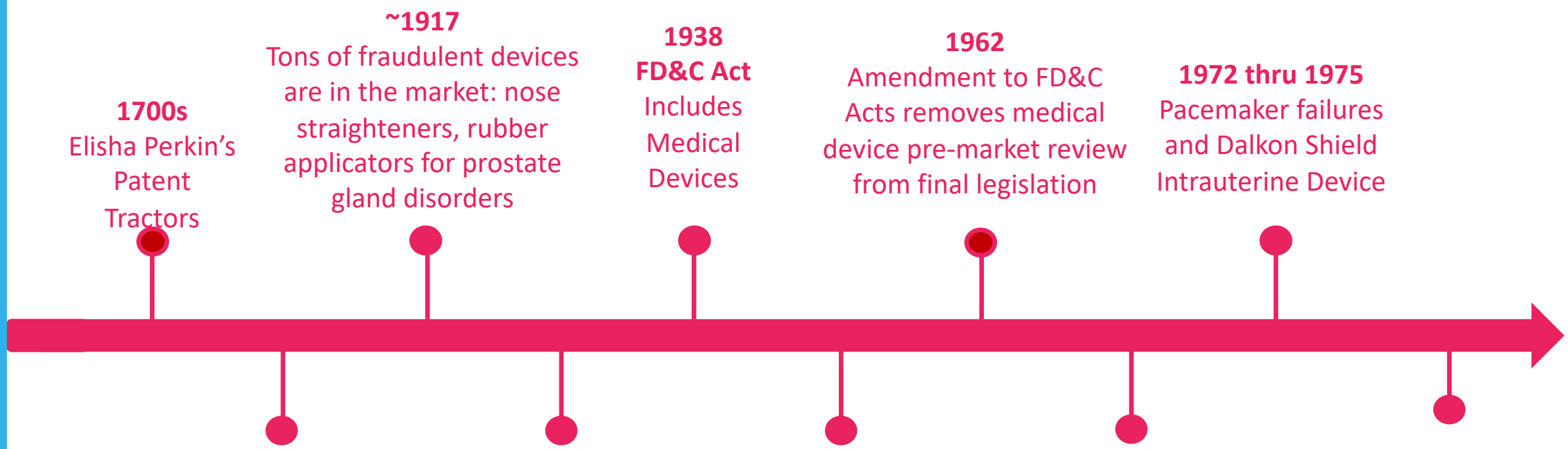
The Relaxacizor was an electrical muscle stimulator supposed to result in relaxing feelings. Users could adjust the frequency and strength of stimulation. Ultimately resulted in a complications, including miscarriage.

Dalkon Shield was an IUD with a major design flaw: porous multifilament string upon which bacteria could travel into the uterus of users, leading to sepsis, injury, miscarriage, and death.



A History of Medical Device Regulations

Device regulation took over 200 years and lots of quackery to establish



Additional measures were added after the Medical Device Amendment of 1976.

Some additional laws that give FDA further oversight and resources

1	**Safe Medical Devices Act of 1990**	Healthcare facilities report to incidents of patient's death, serious illness, or serious injury, post- market surveillance and tracking of implanted devices, product recalls
2	**Medical Device User Fee and Stabilization Act (MDUFSA) of 2005**	Allows the FDA to charge a fee for medical device product review
3	**21st Century Cures Act**	

FDA 21 CFR 820 and ISO 13485:2016 share many similarities.

FDA QSR (21 CFR PART 820)	ISO 13485:2016
820.1 Scope	1 Scope 2 Normative References
820.3 Definitions	3 Terms and Definitions
820.5 Quality System	4 Quality Management System 4.1 General Requirements 4.2 Documentation Requirements
820.20 Management Responsibility	5.0 Management Responsibility
820.20(a) Quality Policy	5.3 Quality Policy
820.20(b) Organization	4.1 Management Responsibility – General
820.20(b)(1) Responsibility & Authority	5.5 Responsibility & Authority
820.20(b)(2) Resources	5.1e Management Commitment
820.20(b)(3) Management Representative	5.5.2 Management Representative
820.20(c) Management Review	5.6 Management Review
820.20(d) Quality Planning	5.4 Quality Planning
820.20(e) Quality System Procedures	4.2.1 General 4.2.2 Quality Manual
820.22 Quality Audit	8.2.4 Internal Quality Audits
820.25 Personnel	6 Resource Management
820.25(a) General	6.1 Provision of Resources 6.2 Human Resources
820.25(b) Training	6.2 Human Resources
820.30 Design Controls	7.3 Design and Development
820.30(a) General	7.3 Design and Development
820.30(b) Design and Development Planning	7.1 Planning of Product Realization 7.3.2 Design and Development Planning
820.30(c) Design Input	7.2.1 Customer Related Processes 7.2.2 Review of Requirements Related to Product 7.3.3 Design and Development Inputs
820.30(d) Design Output	7.3.4 Design and Development Outputs
820.30(e) Design Review	7.3.5 Design and Development Review
820.30(f) Design Verification	7.3.6 Design and Development Verification

FDA has been planning to adopt ISO 13485: 2016 since May 2018.

Why the update?

The QSR hasn't been updated since 1996 and is harmonized with an outdated version of ISO currently.

Allows for closer work with foreign regulatory authorities and more globally harmonized QMSes

The two are not significantly different as is, so it's not a major overhaul

Better guidance and stronger risk management ties

FDA has been planning to adopt ISO 13485: 2016 since May 2018.

What is happening now?

The rule is open for comment from industry and stakeholders through May 24, 2022.

Overhaul of inspection policy

One year to prepare for full compliance

Better guidance and stronger risk management ties

FDA has been planning to adopt ISO 13485: 2016 since May 2018.

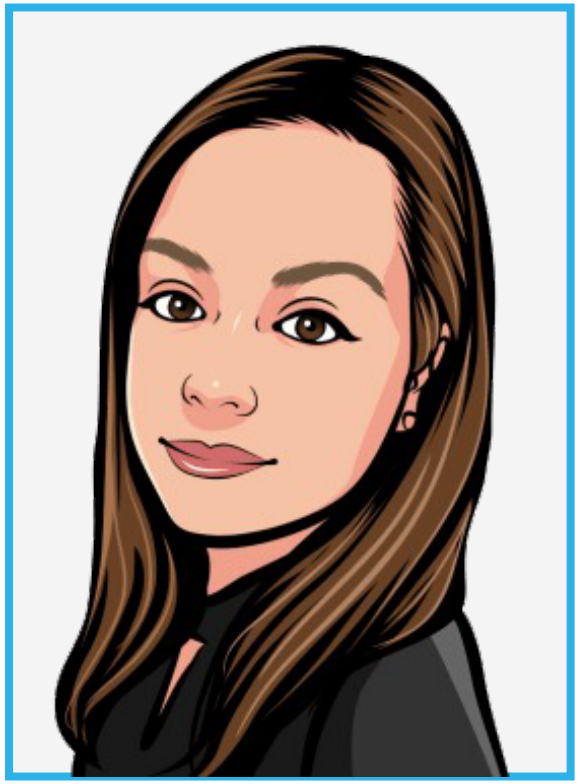
What else does this mean?

Estimated cost savings to medical device establishments in the $439 million to $533 million range over the next ten year

No, FDA will not provide ISO 13485: 2016 certifications

Manufacturers with ISO 13485:2016 certifications must still have FDA audits

Faster access to market in multiple regions



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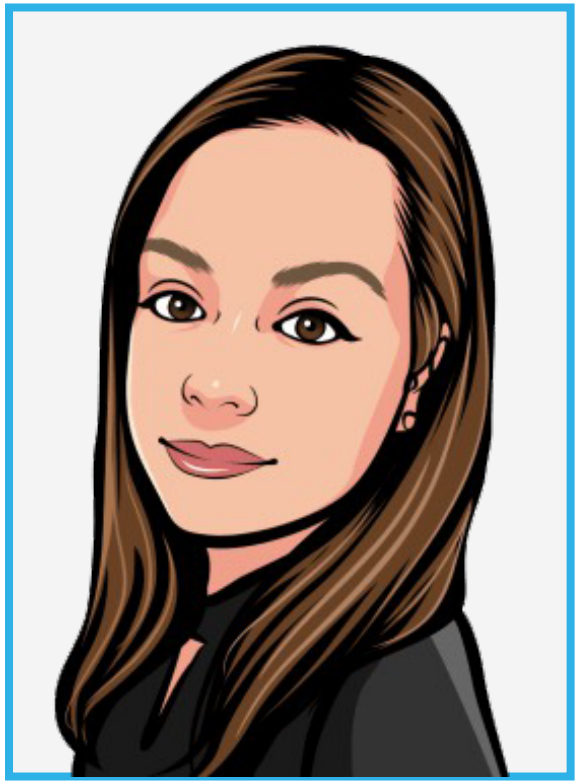

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