FDA Quality System Regulations

FDA Complaint handling & how “Parts” 803 & 806 relate to an FDA Quality System Inspection

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DTA DENTAL TRADE ALLIANCE

FDA Complaint handling & “Parts” 803 & 806

The FDA Quality System Regulation was created to align with ISO 9001:1994 and ISO 13485:1996.

FDA QSR is 90% aligned with ISO 13485

It contains 20 elements, like the earlier ISO standards.

Unlike ISO 9001 or ISO 13485, FDA has very specific requirements for handling Complaints, especially when they involve serious injuries.

What about the other 10% ?

FDA Complaint handling & “Parts” 803 & 806

FDA Focus – Public Health Protection

ISO Focus – Customer Satisfaction

ISO 13485:2000 moved away from 20 Elements to 8 processes geared toward manufacturing, not toward regulatory compliance, to align with ISO 9001:2000.

ISO 13485:2000 also moved away from requiring as much documentation. Fewer written procedures = fewer records.

The FDA did not follow ISO 13485:2000 or ISO 13485:2003.

FDA Complaint handling & “Parts” 803 & 806

SUBCHAPTER H--MEDICAL DEVICES PART 820	ISO 13485:1996	ISO 13485:2003
§ 820.20 - Management responsibility.	4.1	5.1+ 5.3 + 5.4
§ 820.22 - Quality audit.	4.17	8.2.2 + 8.2.3
§ 820.25 - Personnel.	4.18	6.2.2
"Sales Contracts" not covered by FDA	4.3	
§ 820.30 - Design controls.	4.4	
§ 820.40 - Document controls.	4.5	
§ 820.50 - Purchasing controls.	4.6	7.4
"Customer property" not covered by FDA	4.7	7.5
§ 820.198 - Complaint files.	NOT COVERED	7.2.3 + 8.2.1 + 8.5.1

FDA is less customer focused...

...unless public health involved.

Part 806

Part 803

ISO 13485:2003 Improved, but still not complete !

What’s missing?

FDA Complaint handling & “Parts” 803 & 806

What we need to know:

What is a Complaint?

When do I report it to the FDA?

What does FDA want me to do with bad product on the market?
What is a “Risk to Health”???

§ 820.198 - Complaint files.	NOT COVERED	7.2.3 + 8.2.1 + 8.5.1

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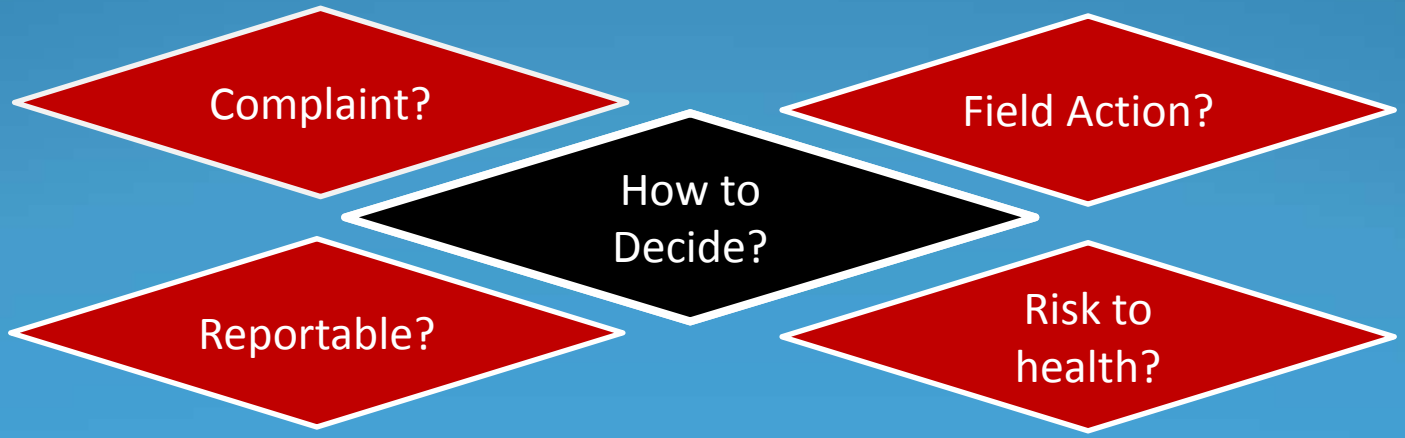

FDA Complaint handling & “Parts” 803 & 806

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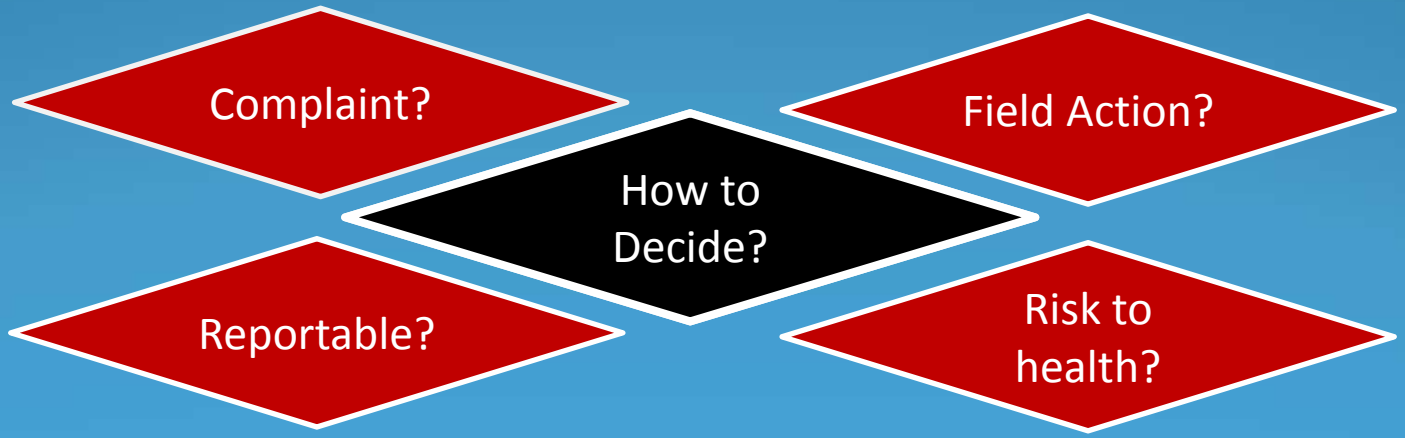
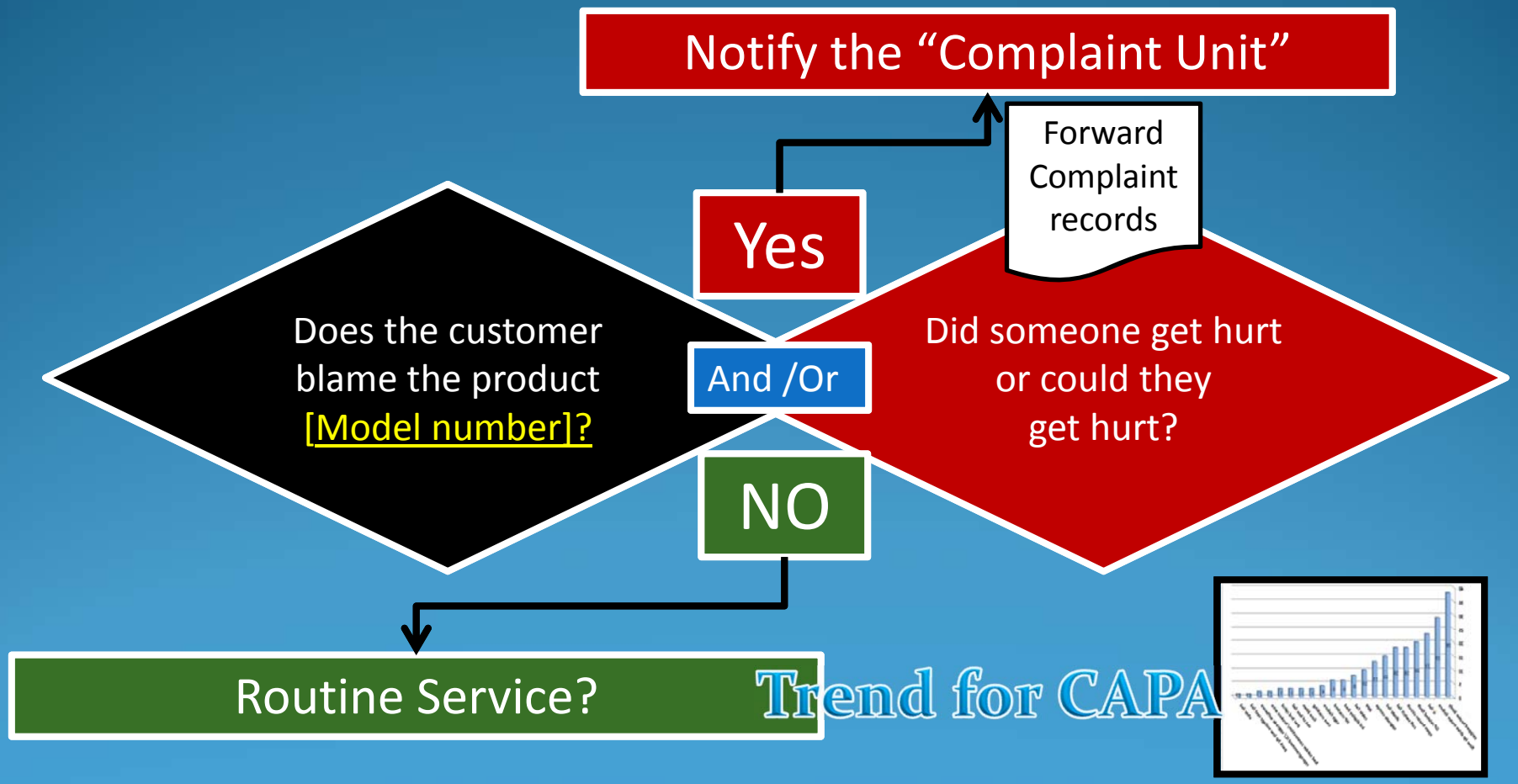


FDA Complaint handling & “Parts” 803 & 806

Keeping it Simple



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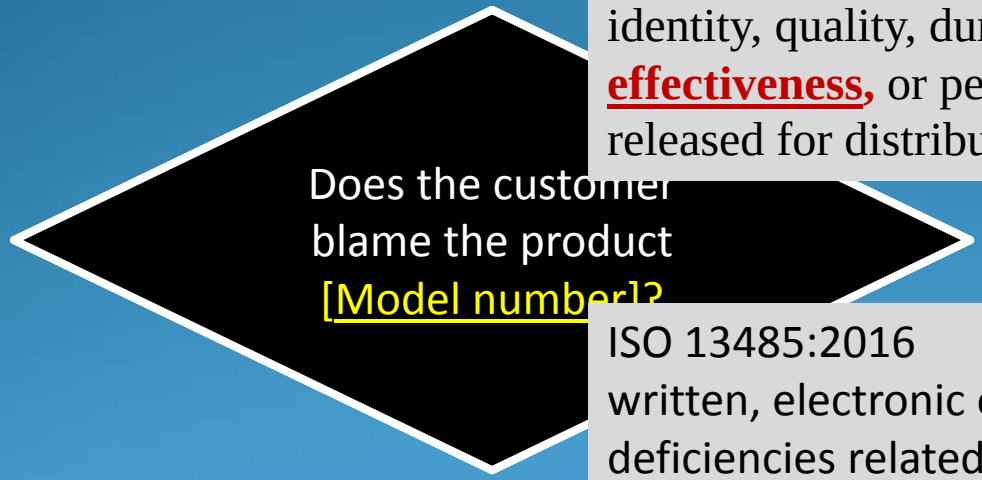

FDA 820.3
(b) Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, **effectiveness,** or performance of a device after it is released for distribution.

ISO 13485:2016
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, **usability,** safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices

FDA Complaint handling & “Parts” 803 & 806

FDA “fingerprint” on ISO 13485:2016

The ISO definition borrows from the FDA all but **“Effectiveness”.**

ISO adds *“Usability”.* FDA believes manufacturers should own more responsibility for ***“Use Errors”.***

FDA does not regulate “Servicing” unless it is performed by an organization that must apply that Part of 820.

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"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

Because…medical devices provide for the sick, injured, "dead" and dying,

Did someone get hurt or could they get hurt?

Automated defibrillators do not revive most people who are dead. Do I Report to FDA the incidences of un-revivable?

"Risk to Health" or "Serious Injury"
Parts 803 and 806

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Because…medical devices provide for the sick, injured, "dead" and dying,

Did someone get hurt or could they get hurt?

If the dentist cannot save a bad tooth, is this reportable?

"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

(1) Failure;

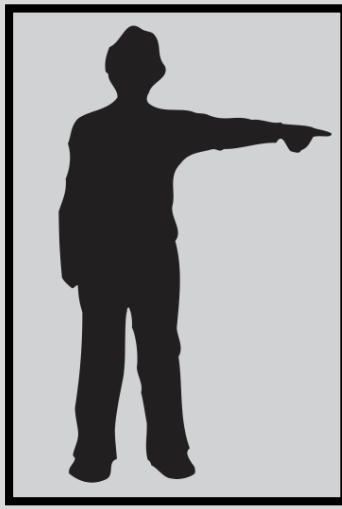
(2) Malfunction;

(3) Improper or inadequate design;

(4) Manufacture;

(5) Labeling; or

(6) User error.



Complaints that blame the device are reportable if they caused serious injury or death, unless it can be proven otherwise.

"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

The paramedics arrived too late to revive patient.

What was the cause of Death?

Not reportable

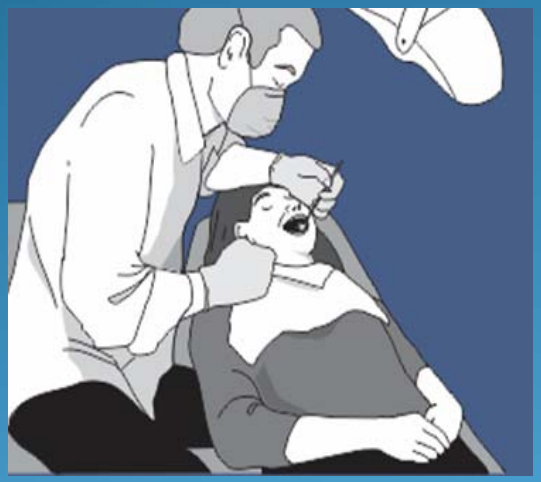
Reportable

The paramedics found the AED battery was dead.

"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

The tooth was too rotten to save



Not reportable

What was the "Serious injury"?

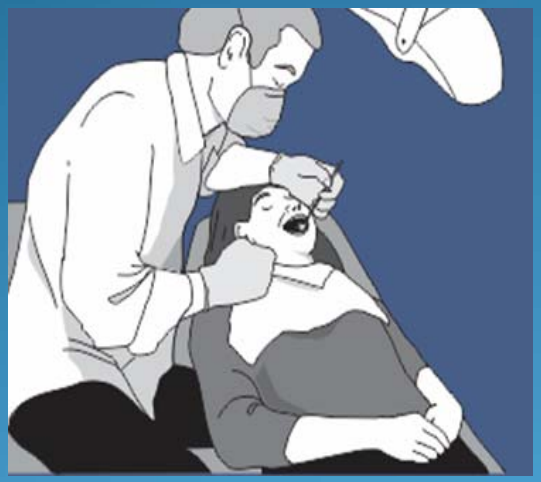
Reportable

"The root canal file broke, so I had to remove the tooth"

"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

Reportable



Losing a tooth ***permanently*** is not **"trivial".**

From Part 803.3

Serious injury means an injury or illness that:

(1) Is life-threatening,

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

"Risk to Health" or "Serious Injury"
Parts 803 and 806

It's…complicated

What is not serious?

Is not life threatening…and…

Did not cause,…and does not require Medical or Surgical Intervention…

Rx

To preclude **permanent** impairment of a body…
Function
Structure

Injuries that will heal without professional medical care.

From Part 803.3

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“Risk to Health” or “Serious Injury” Parts 803 and 806

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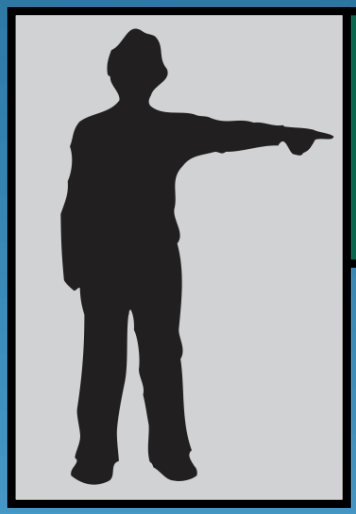

Complaints that do not blame the device, or its “usability”

Risk to Health?

You must investigate the *Complaint*

If an any injury occurred, document the injury and prognosis for recovery, with or without medical care.

Risk to Health?

It's…complicated

"Risk to Health" or "Serious Injury" Parts 803 and 806

From Part 806.2

(k) *Risk to health* means

(1) A reasonable probability that use of, or

Did they **need** medical care for an *Adverse Health Consequence*

(2) That use of, or exposure to, the product may cause temporary or **medically reversible** adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

Rx

"Medically necessary care"
The reasonable and appropriate diagnosis, treatment, and follow-up care prescribed by qualified appropriate health care providers…

Mosby's Dental Dictionary, 2nd edition.

"Risk to Health" or "Serious Injury" Parts 803 and 806

Risk to Health?

Part 806.2

(k) *Risk to health* means

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

"Risk to health" is not always "Serious injury"

Serious Injury

Part 803.3

Serious injury means an injury or illness that:

(1) Is life-threatening,

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(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

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"Risk to Health" or "Serious Injury"
Parts 803 and 806

Part 806.2

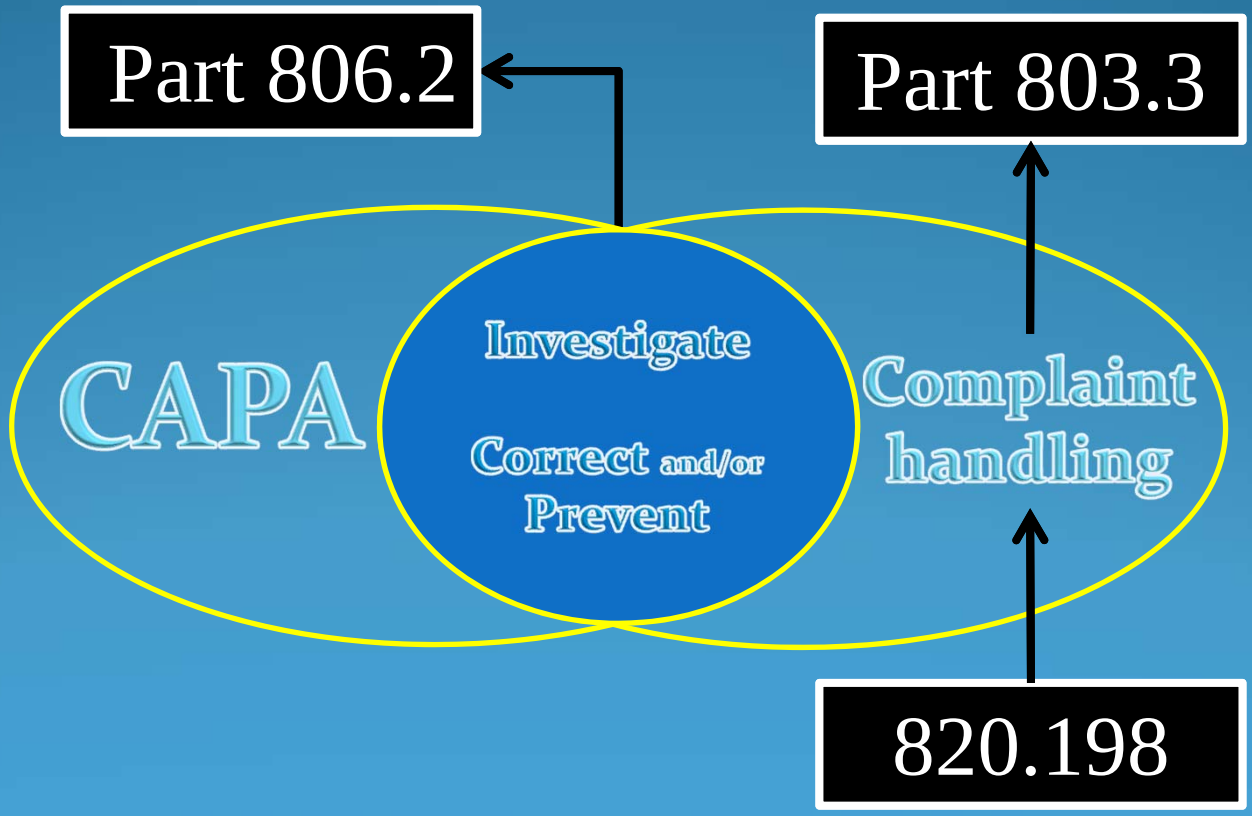
Part 803.3

Where do these "Parts" fit into the QMS?

"Risk to Health" or "Serious Injury"
Parts 803 and 806

Field Safety Corrective Action (FSCA)
Field Corrective Action (FCA)
Corrections and Removals

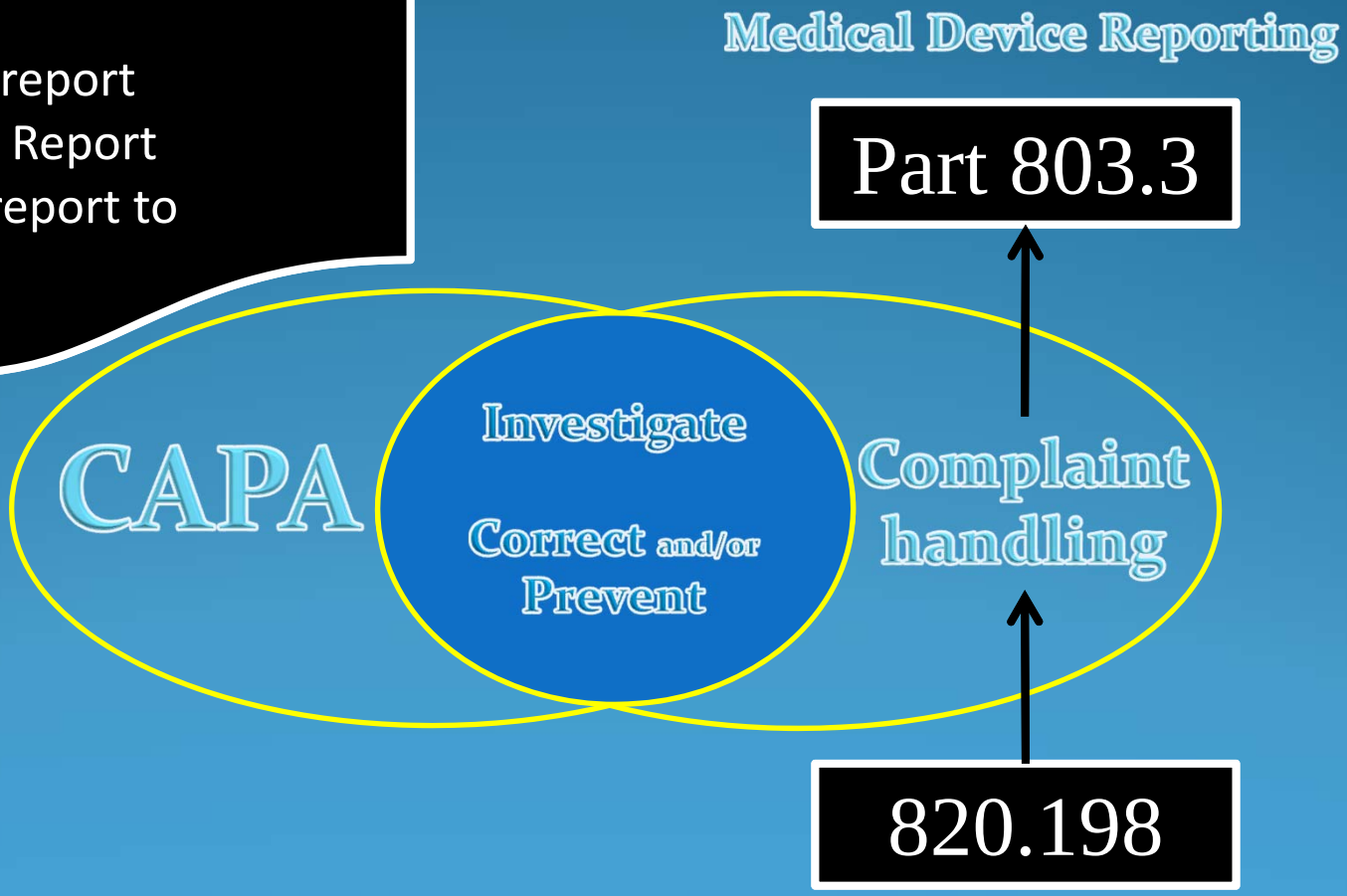
Medical Device Reporting



Create a quality system procedure for handling "Complaints" and include

What to report
When to Report
Who to report to

"Risk to Health" or "Serious Injury"
Parts 803 and 806



The Complaint Procedure

Create a quality system procedure for handling "Complaints" and include

What to report
When to Report
Who to report to

"Evaluation" of potential for "Serious injury" must be quick. Some countries require reporting within 48 hours! (European Union)

Include ISO 13485:2016 definition

Define "Complaint" using 21 CFR 820.3

Define "Serious injury"

Define "Evaluation" as a quick examination of first information, to determine whether or not the "Complaint" is reportable to FDA (Part 803)

Define "Investigation" like that used for CAPA; to thoroughly examine root causes for the Complaint.

The Complaint Procedure

Create a quality system procedure for handling "Complaints" and include

What to report
When to Report
Who to report to

Complaint and CAPA Forms can share the same form

Complaint forms will be like CAPA forms

Complaint forms should document how the customer was responded to, or why they could not be responded to.

Complaint forms will document if the "Complaint" was "Reportable" (MDR).

A copy of every Complaint, should be filed in a "Complaint file", even if CAPA and Complaints use the same form.

"Investigations" must follow quickly when a serious injury or death occurs, as section 806 "reporting" is different than section 803.

806? 10 Days!

Investigations will determine if field "Corrections and removals" are needed.

It's…complicated

- What's the Root Cause?
- What's the "Risk"?
- Is there a "Risk to Health"?
- Does the problem require a "Correction or removal"?
- What records do I keep?
- Who do I report to?

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Field Safety Corrective Action (FSCA)

Field Corrective Action (FCA)

Corrections and Removals

Part 806.2

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- What's the Root Cause?
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- Does the problem require a "Correction or removal"?
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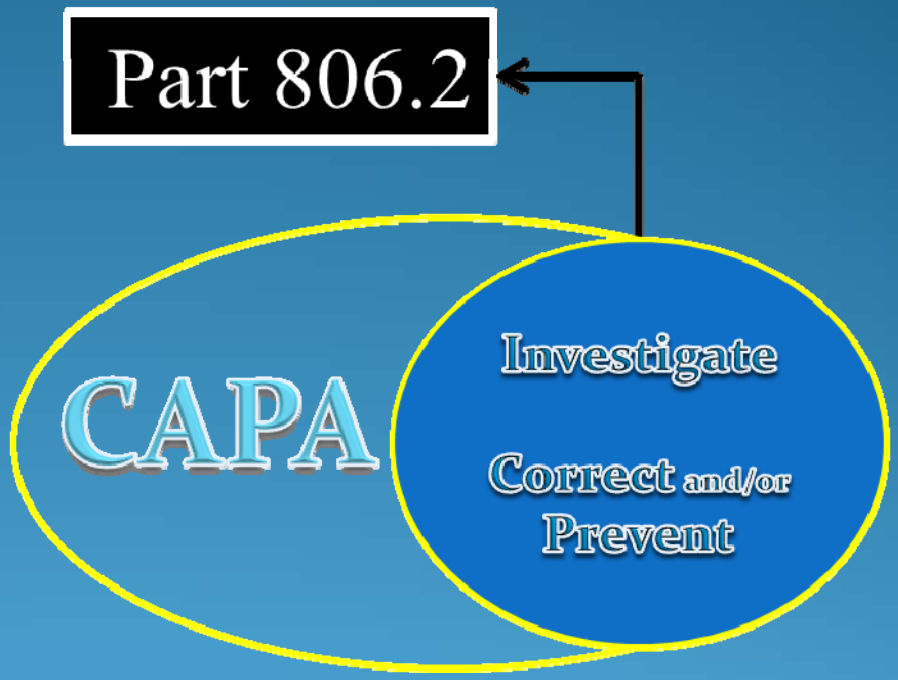
- How much time do I have to report to FDA?

Field Safety Corrective Action (FSCA)
Field Corrective Action (FCA)
Corrections and Removals



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PART 806 – Corrections and Removals

It's…complicated

- What's the "Root Cause"?
- What's the "Risk"?
- Is there a "Risk to Health"?
- Does the problem require a "Correction or removal"?
- What records do I keep?
- Who do I report to?
- How much time do I have to report to FDA?
- What do I have to report?

"Risk Management"!

Are many devices affected, in the field?

If the problem is not corrected in the field, will their be **too likely** an occurrence of patients being injured severely enough, that they require professional medical care?

"Risk To Health?

If the severity is high enough and action must be taken in the field to reduce the risk, than the local FDA district office must be notified within 10 days.

If the severity is low enough or the occurrence is "remote" enough, no report is required, but records must be maintained according to 806.20

If the severity is high enough and the occurrence is likely enough, records must be collected and reported according to 806.10 within 10 days.

PART 806 – Corrections and Removals

Risk Management!

"Risk To Health"

View from within a Risk Region Chart using ISO 14971

			Less Risk --- RISK --			More Risk	
			Noticeable by user	Patient or user inconvenience or temporary discomfort	Causes injury that does not require additional professional medical	Injury requiring additional professional medical attention	Potentially life threatening or causing permanent impairment
	**Likelihood of harm		1	2	3	4	5
5	More than 1/100	Frequent	5	10	15	20	25
4	1/100 to 1/1000	Probable	4	8	12	16	20
3	1/1,000 to 1/10,000	Occasional	3	6	9	12	15
2	1/10,000 to 1/100,000	Remote	2	4	6	8	10
1	1/100,000 to 1/1 million	Improbable	1	2	3	4	5
			Broadly Acceptable		Reasonably Acceptable		Intolerable

PART 806 – Corrections and Removals

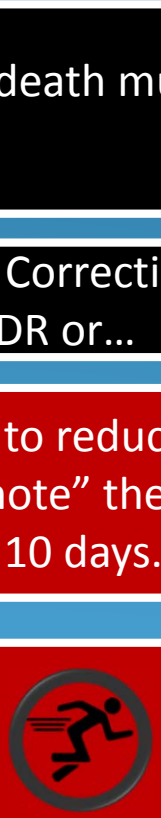
Risk Management!

803 - All Medical Device Reports of serious injury or death must be reported to FDA, (e.g. using form 3500)

806- The local District Office is only notified during a Correction or Removal (Product Recall) activity related to MDR or…

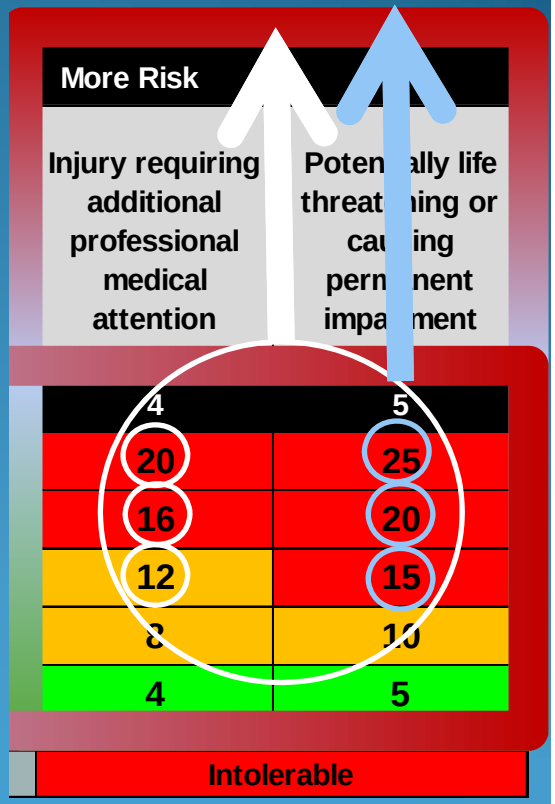
806 - When any Correction or Removal is undertaken to reduce a "Risk to Health" below a probability considered "remote" these must be reported to the FDA District Office within 10 days.

All injuries are Complaints –
But not all Complaints are "injuries"
Evaluate them fast. Investigate injuries fastest.



"MDR Reportable"

"Risk To Health"



FDA Quality System Training Videos

FDA Quality System Training
By US FDA Investigator
Trainer -

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