Trending Observations for Combination Products

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- Predominant Citations for Combination Products Inspections from 2017-June 2019
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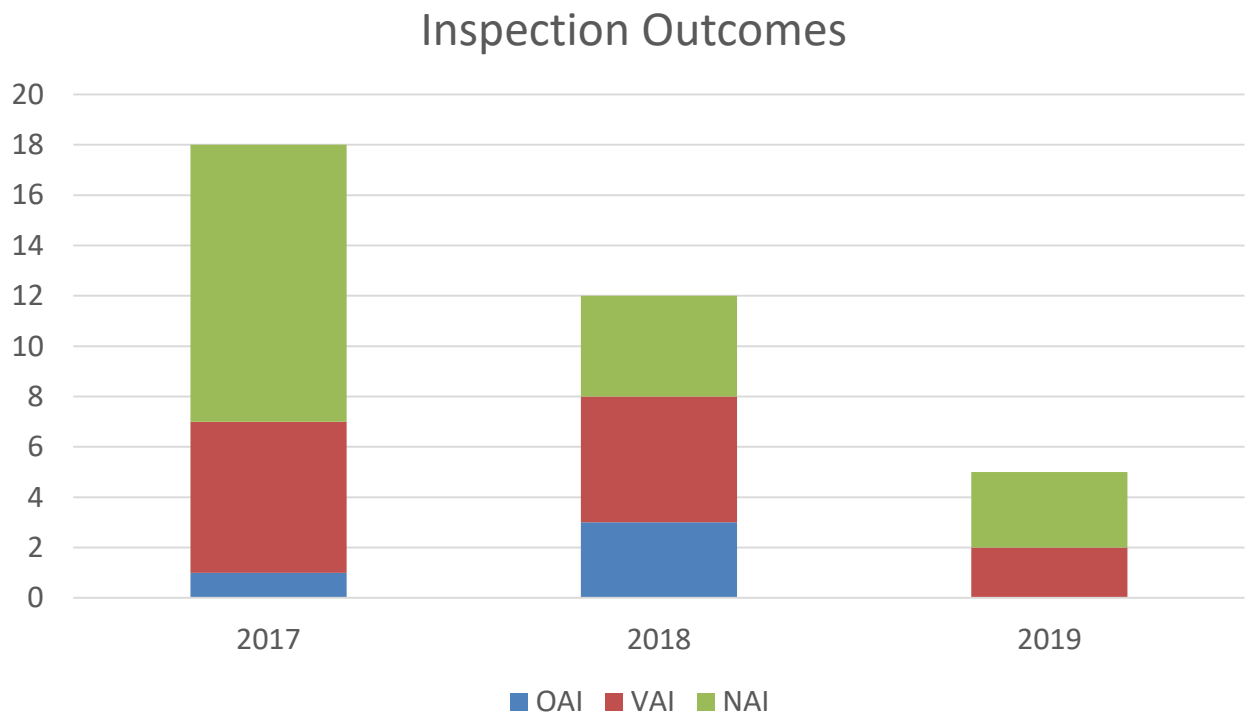
CDRH/ORA QS Inspection Outcomes from 2017-2019

QS Inspection Outcomes for Combination Product from Division 2/Central



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Predominant FDA-483 Citations for Combination Product from Div. 2

Top 5 FDA-483 Citations from January 2017 until June 2019

- 820.70(a), (c) Production and Process Controls
- 820.100(a) Corrective and Preventive Actions
- 820.30 (i), (f) Design Controls
- 820.198(c) Complaint Files
- 820.40 Documentation Controls

Predominant FDA-483 Citations for Combination Product from Div. 2(Cont.)

2017-2019

- *820.70(a) (c) Production and Process Controls*

Citations;

- (a) Process control procedures that describe any process controls to ensure conformance to specifications have not been adequately established.

- (c) Procedures to control environmental conditions have not been adequately established.

Predominant FDA-483 Citations for Combination Product from Div. 2 (Cont.)

2017-2019

- *820.100(a) Corrective and Preventive Actions (CAPA)*

Citations;

- Procedures for Corrective Actions have not been adequately established.

Predominant FDA-483 Citations for Combination Product from Div.2 (Cont.)

2017-2019

- *820.30 (i),(f) Design Controls*

Citations;

- (i) Procedures for design change have not been adequately established.

- (f) Procedures for design verification have not been adequately established.

Predominant FDA-483 Citations for Combination Product from Div.2 (Cont.)

2017-2019

- *820.198 (a),(c) Complaint Files*

Citations;

- (a) Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

- (c) Complaints involving the possible failure of a device to meet any of its specifications were not investigated when necessary.

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Predominant FDA-483 Citations for Combination Product from Div. 2 (Cont.)

2017-2019

- *820.40 Documentation Control*
- *820.184 Device History Records*

Citations;

- Document control procedures have not been adequately established.
- The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

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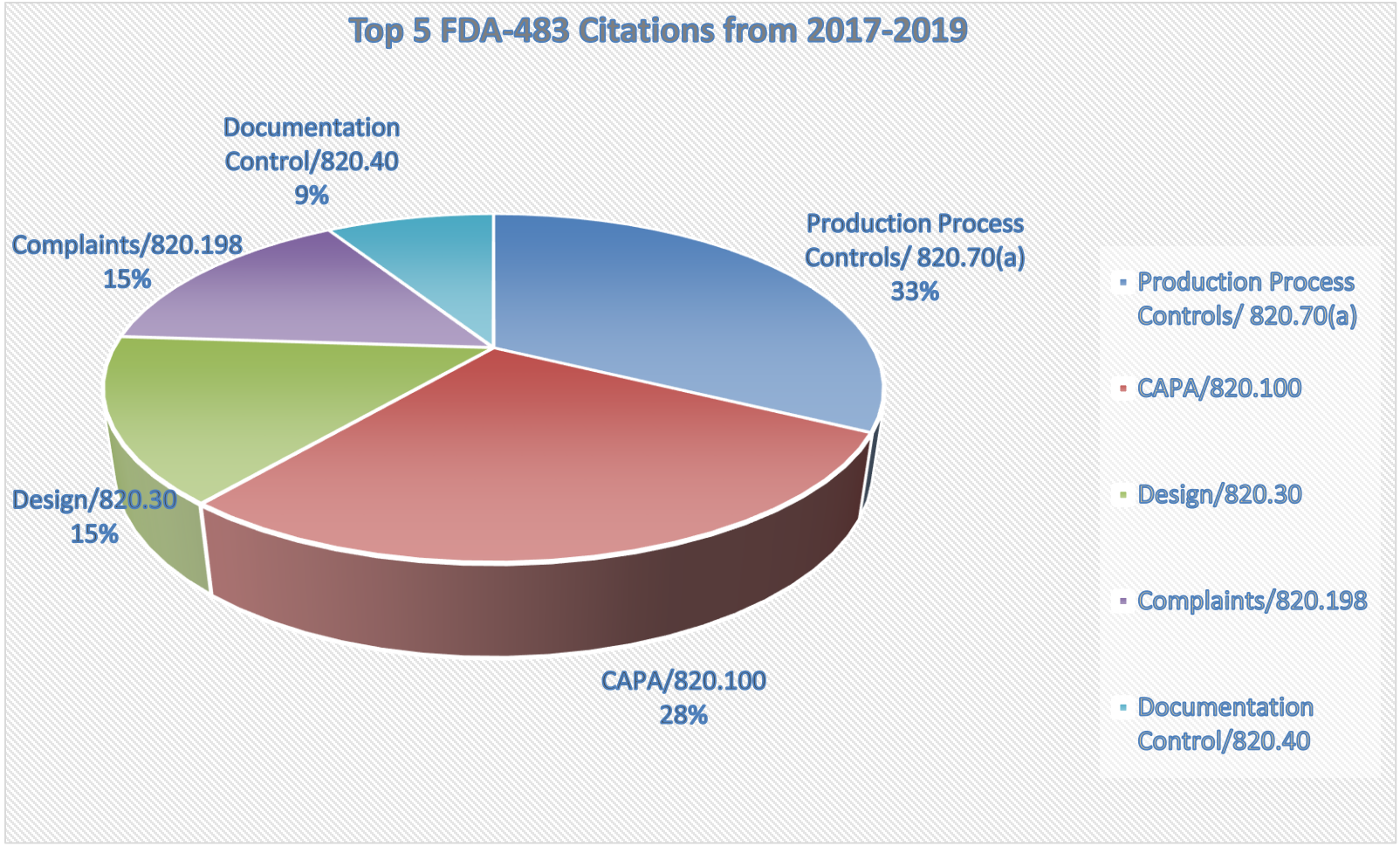
Top FDA 483 Citations for Combination Product from 2017-2019 (Division 2)



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Adverse Events (Reported Problems) Related to Combination Products from 2017-2019
Division 2

Infusion Pumps (Insulin)

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- An excess flow or over infusion of the infusion pumps.
- An insufficient flow or under infusion of the infusion pumps.
- False alarms of the infusion pumps.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019

Division 2

Drug Eluting Stent (Absorbable Coronary Drug Eluting Stent)

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- Material separation occurred for the drug eluting stent device.
- Malfunction/the absorb bioresorbable vascular scaffold may be related to under-expansion.
- Stents may not reabsorb as quickly as initially assumed and may be related to thrombosis, restenosis, target lesion failure.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Collagen Surgical Mesh containing drugs (Surgical Mesh)

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms :

- Material deformation/defective device.
- Incorrect, Inadequate or Imprecise Results or Readings.
- Material disintegration.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Autoinjector (Introducer, Syringe Needle)

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- A defective spring loading mechanism.
- A device operational issue, insertion issues.
- An unintended ejection, cannula does not release.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Drug Eluting Cardiac Stent

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- Material Integrity problems.
- Failure to sense/does not sense.
- Device sensing problems/ Over sensing.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Catheter, Hemodialysis, Implanted, Coated

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- The device fails to adhere or bond.
- The device is punctured/ leakage occurs.
- Material fragmentation of the device/ device quality problem.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Inhalers

Top 2 Reported problems from 2017-2019 from product code and all manufacturing firms:

- The drug is destroyed if carried at high temperature.
- The device shuts off in the middle of patient's treatment.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Dry Coated Peripheral Transluminal Angioplasty Catheter

Top 3 Reported problems from 2017-2019 from product code and all manufacturing firms:

- Detachment of the device or the device component.
- A retraction problem with the device.
- A deflation problem with the device/material rupture.

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Adverse Events (Reported Problems) related to Combination Products from 2017-2019
Division 2

Condom with Nonoxynol-9

Reported problem from 2017-2019 from product code and all manufacturing firms:

- No product problems reported.

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Recalls Related to Combination Products from 2017-2019

Infusion Pumps (Insulin)

26 Recalls for Infusion Pumps from 2017-2019

Drug Eluting Stent (absorbable coronary drug eluting stent)

1 Recall for drug eluting stent from 2017-2019

Autoinjector (Introducer, Syringe Needle)

1 Recall for the Autoinjector from 2017-2019

Inhalers

7 Recalls for Inhalers from 2017-2019

References

- Office of Combination Products
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  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm

  - CDRH's Total Product Life Cycle Database

  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

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Questions