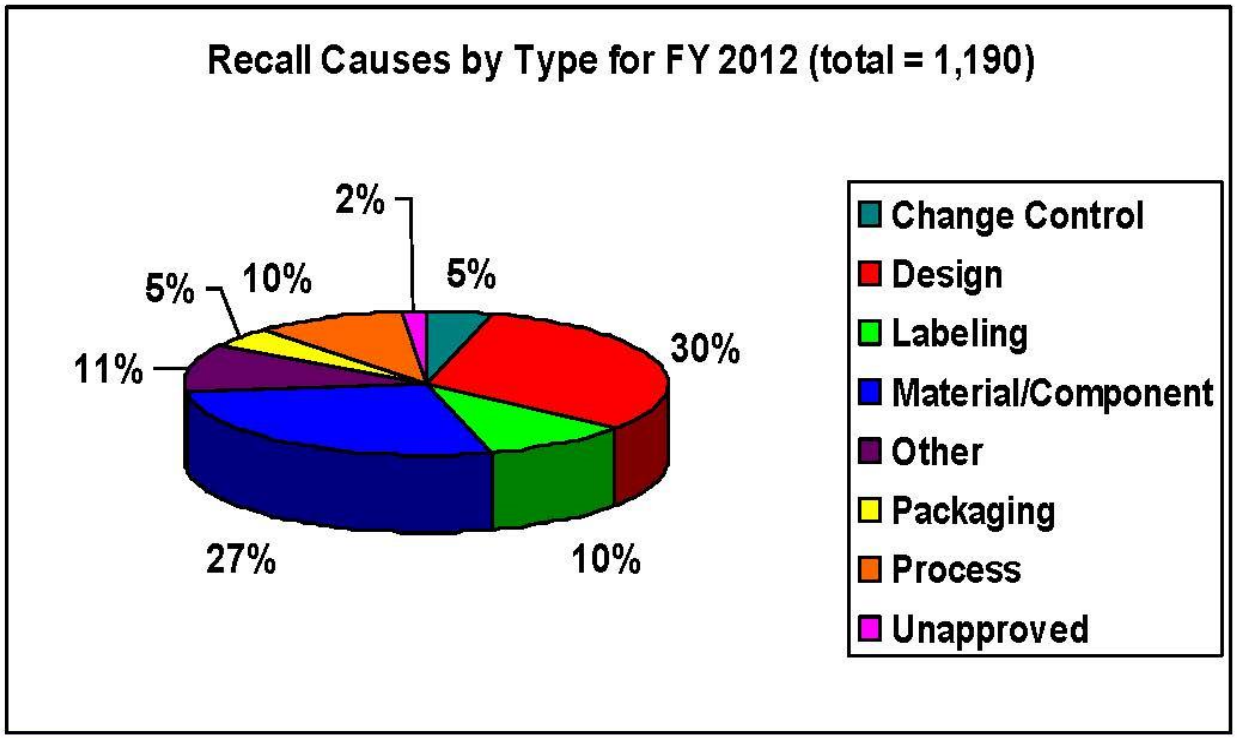
Purchasing Controls – 21 CFR 820.50

Food and Drug Administration

Why is FDA Concerned about Purchasing Controls?

- Inspections and FDA authority often extend only to the finished device manufacturer.... This regulation does not apply to manufacturers of components or parts of finished devices .... [820.1(a)(1)]
- Increasing outsourcing of critical components, and manufacturing of entire devices.
  - Increased overseas outsourcing
- Increasing recalls and product problems associated with purchased components.
  - CDRH FY2012 data suggests that 27% of recalls related to "nonconforming product/material

Recall Causes in FY 2012



What else is unique about medical devices?

- Wide range in risk associated with supplied products and services
  - Same supplied product or service may have different risks based on use.
  - Same supplier may have different risks for different supplied product or service.

When do purchasing controls apply?

- Supplied Product
- Supplied Services (“Contractors”)
- Consultants

2013 Warning Letter and FDA-483 citations

Purchasing Controls (21 CFR 820.50)

- **A total of 50 Warning Letters included Purchasing Control cites in 2013.**

- **A total of 236 Purchasing Control observations were cited on FDA-483s in 2013.**

Purchasing Control 2013 Warning Letter Cites

- 21 CFR 820.50 – 26 cites (52%)
  (15 firms had no procedures)

- 21 CFR 820.50(a) – 7 cites

Purchasing Control 2013 FDA-483 Observations

- 21 CFR 820.50 – 107 observations (45%)
- 21 CFR 820.50(a) – 25 observations

Purchasing Controls – 21 CFR 820.50

- Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

Supplier Evaluation – 21 CFR 820.50(a)

- Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

Purchasing Controls Link to Design Controls

... the quality of a product or service is established during the design of that product or service, and achieved through proper control of the manufacture of that product or the performance of that service. Section 820.50 thus mandates that products be manufactured and services be performed under appropriate quality assurance procedures.

Preamble to the 1996 QS Regulation, Comment #106

Purchasing Control 2013 Warning Letter Cites and FDA-483 Observations Cont.

- 21 CFR 820.50(a)(2) – 7 Warning Letter cites
- 21 CFR 820.50(a)(2) – 28 FDA-483 observations

Type and Extent of Control – 21 CFR 820.50(a)(2)

- (a)(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
  - Be mindful of higher risk processes (e.g., those that may require validation) and sub-tier supplier controls.

Purchasing Controls Link to Risk Analysis

... the degree of supplier control necessary to establish compliance may vary with the type and significance of the product or service purchased and the impact of that product or service on the quality of the finished device.

Preamble to the 1996 QS Regulation, Comment #99

References

- 21 CFR Part 820
- Preamble to the QS Regulation Final Rule
- Compliance Program (7382.845) – *Inspection of Medical Device Manufacturers*