Recent Changes to MDSAP

Date: 2018/05/09

Overview

1. New MDSAP Transition Guidance
2. Audit Duration Adjustments
3.
4.

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New MDSAP Transition Guidance

Notice
April 4, 2018

In light of stakeholders feedback

Health Canada announced modifications to the transition process

Enforcement discretion for audits in 2018

Manufacturers to submit a valid MDSAP certificate by December 31st, 2018

- Health Canada will not take enforcement action against manufacturers that can demonstrate that they have undergone an audit
- We are sensitive to the challenges of both scheduling the audit and issuing the certificate

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New MDSAP Transition Guidance

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Transition to MDSAP through surveillance audits

Manufacturers must meet the following conditions:

- initial or re-registration audit after 2016/01/01
- certificate under CMDCAS valid until 2018/12/31
- Maintain a valid ISO 13485 certificate as of 2019/01/01

Manufacturers must provide the following:

- Certificate under CMDCAS valid until 2018/12/31
- Valid ISO 13485 certificate issued after 2016/01/01
- MDSAP Surveillance Audit Confirmation Notification

OR

evidence of arrangements to undergo MDSAP audit

Will allow manufacturers to maintain their existing certification cycle

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Audit Duration Adjustment

Notice
April 27, 2018

In light of stakeholders feedback

Health Canada & MDSAP Consortium announced revised procedure for audit duration calculations

Audit duration adjustments for SMEs

New procedure in effect - June 11, 2018

- AOs responsible to make the adjustments on a case-by-case basis as applicable

To be eligible, a manufacturer must:

- Have 100 or fewer employees
- Make lower-risk products (typically class II)
- Use only simple design and manufacturing processes using commonly available materials
- Have a good history of compliance to 13485

The adjustments are on a sliding scale and range from 5% to 42%

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