Recent Changes to MDSAP
Overview

1. New MDSAP Transition Guidance
2. Audit Duration Adjustments
In light of stakeholders feedback
Health Canada announced modifications to the transition process

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
In light of stakeholders feedback, Health Canada announced modifications to the transition process.

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.
Audit Duration Adjustment

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%