Health Canada Approach to ISO 13485

IACRC-MTS Workshop on ISO 13485

2022-05-26

Agenda

1. ISO 13485 in Canadian Regulations
2. Past Experience
3. Health Canada and MDSAP
4. Q&A

1 ISO 13485 in Canadian Regulations

Law and *Regulations*

The *Food and Drugs Act* authorize the Minister to create *Regulations* with respect to medical devices.

The *Medical Devices Regulations* require the licensing of class II, III, and IV medical devices and IVDs prior to importation and/or sale in Canada

1 ISO 13485 in Canadian Regulations

- The *Medical Devices Regulations* explicitly call for ISO 13485.
- Manufacturers of class II, III, and IV medical devices must maintain a valid ISO 13485 certificate on file to obtain, amend, and maintain medical device licences in Canada.
- Health Canada only accepts certificates issued by “registrars” (auditing organisations) recognised by the Minister.
- The *Regulations* set broad criteria for the recognition of registrars.

2 Past Experience

- Originally, the implementation of quality management system requirements in Canada was done under the Canadian Medical Device Conformity Assessment System (CMDCAS).
- This program leveraged an existing accreditation scheme operated by the Standards Council of Canada (SCC), the national accreditation body of Canada.

2 Past Experience

Voluntary conformity assessment (ISO)

- ISO/IEC 17011
- ISO/IEC 17021
- IAF Mandatory Documents

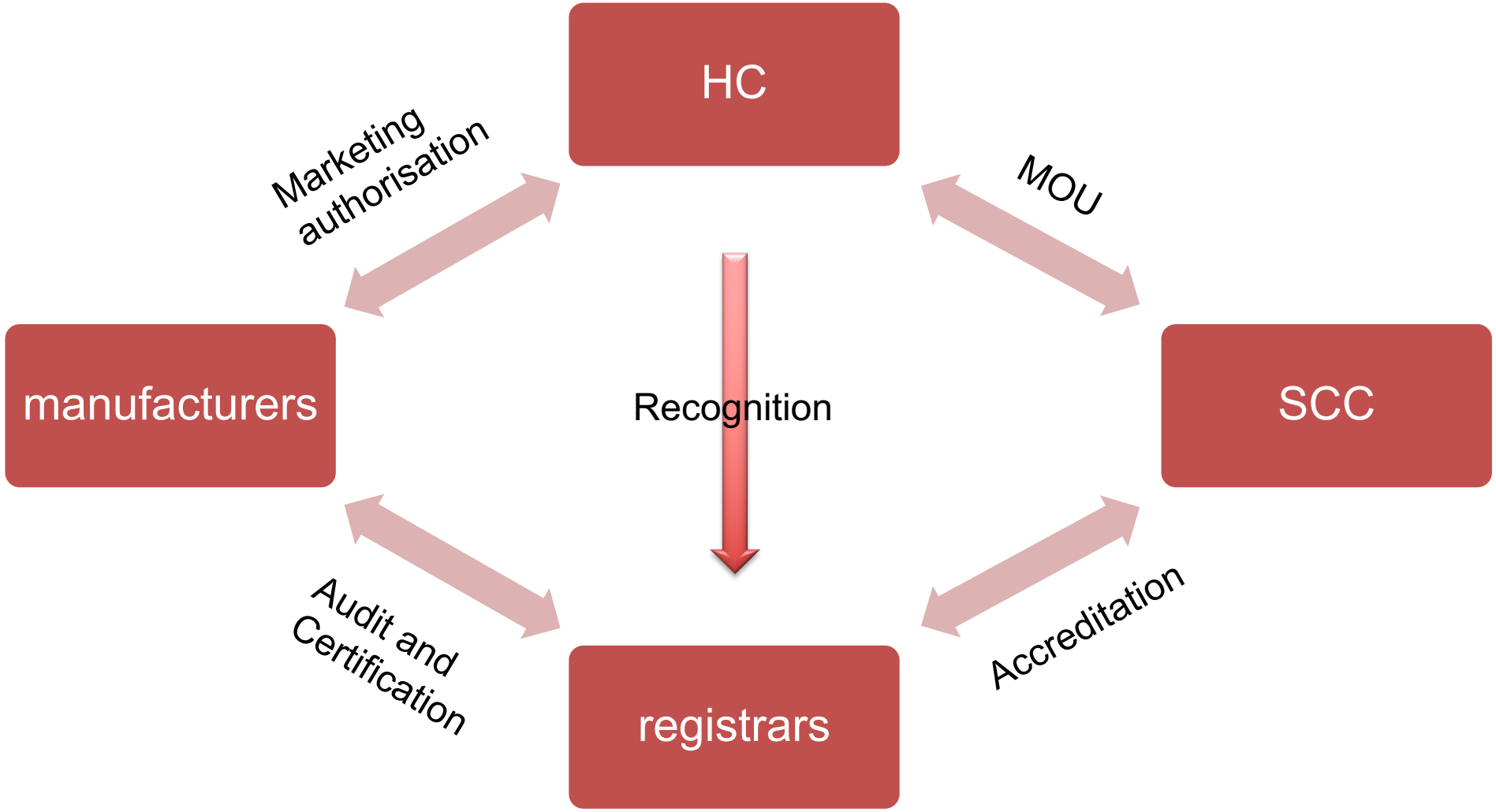
Mandatory requirements

- Medical Devices Regulations
- Policy on CMDCAS
- Guidance Documents

CMDCAS

- HC recognized registrars
- Certification of manufacturers to ISO 13485 under CMDCAS.

2 Past Experience



2 Past Experience

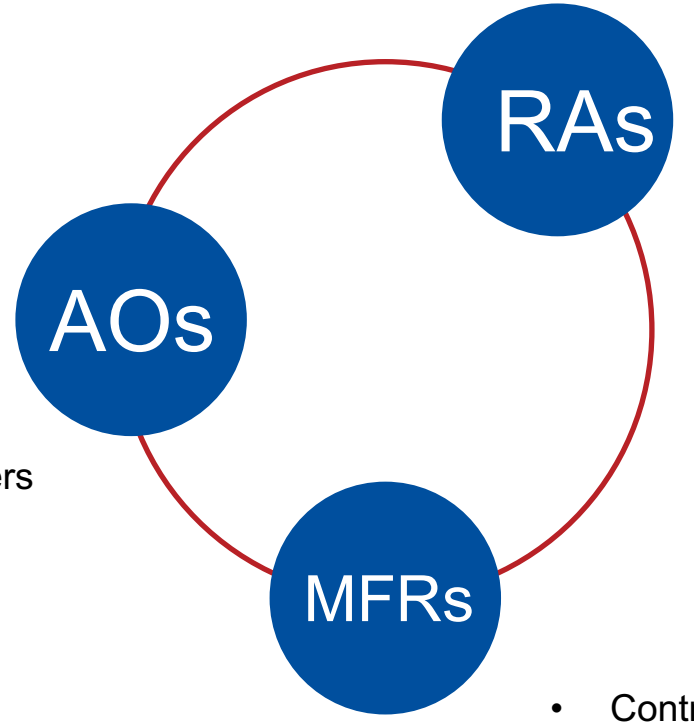
CHALLENGES

- CMDCAS was built on an existing accreditation scheme:
  - Rules and procedures already existed and not subject to HC
  - Rules for CMDCAS sometimes contradict broader accreditation rules
- Accreditation Body has its own interests and objectives
  - Accreditation Body must conform to other requirements (e.g. IAF)
- Program operated by Accreditation Body with HC as technical experts / observers

WEAK AREAS

- Insufficient competence requirements for auditors
- Lack of mandated structure to audits
- Significant variability in duration, depth, and breadth of audits between registrars
- Too much focus on process and not enough on output
- Insufficient enforcement tools
- Lack of notification requirements

3 Health Canada and MDSAP



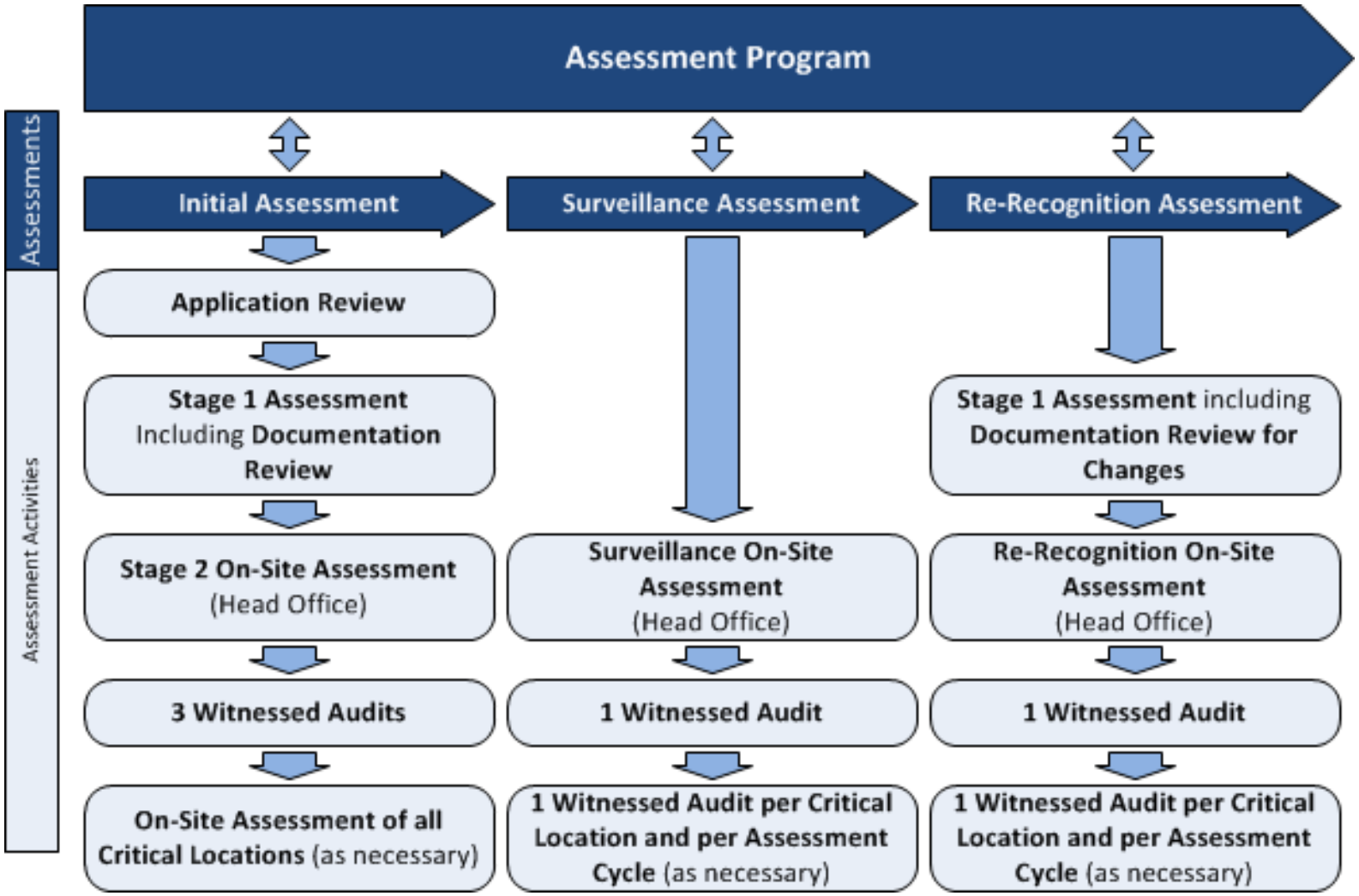
- Assess and recognise AOs
- Take regulatory decisions about manufacturers

- Audit and certify manufacturers
- Share audit reports and certificates with Regulators

- Contract with AOs for MDSAP audits and certification
- Submit MDSAP documents with license applications (as appropriate)

3

Health Canada and MDSAP



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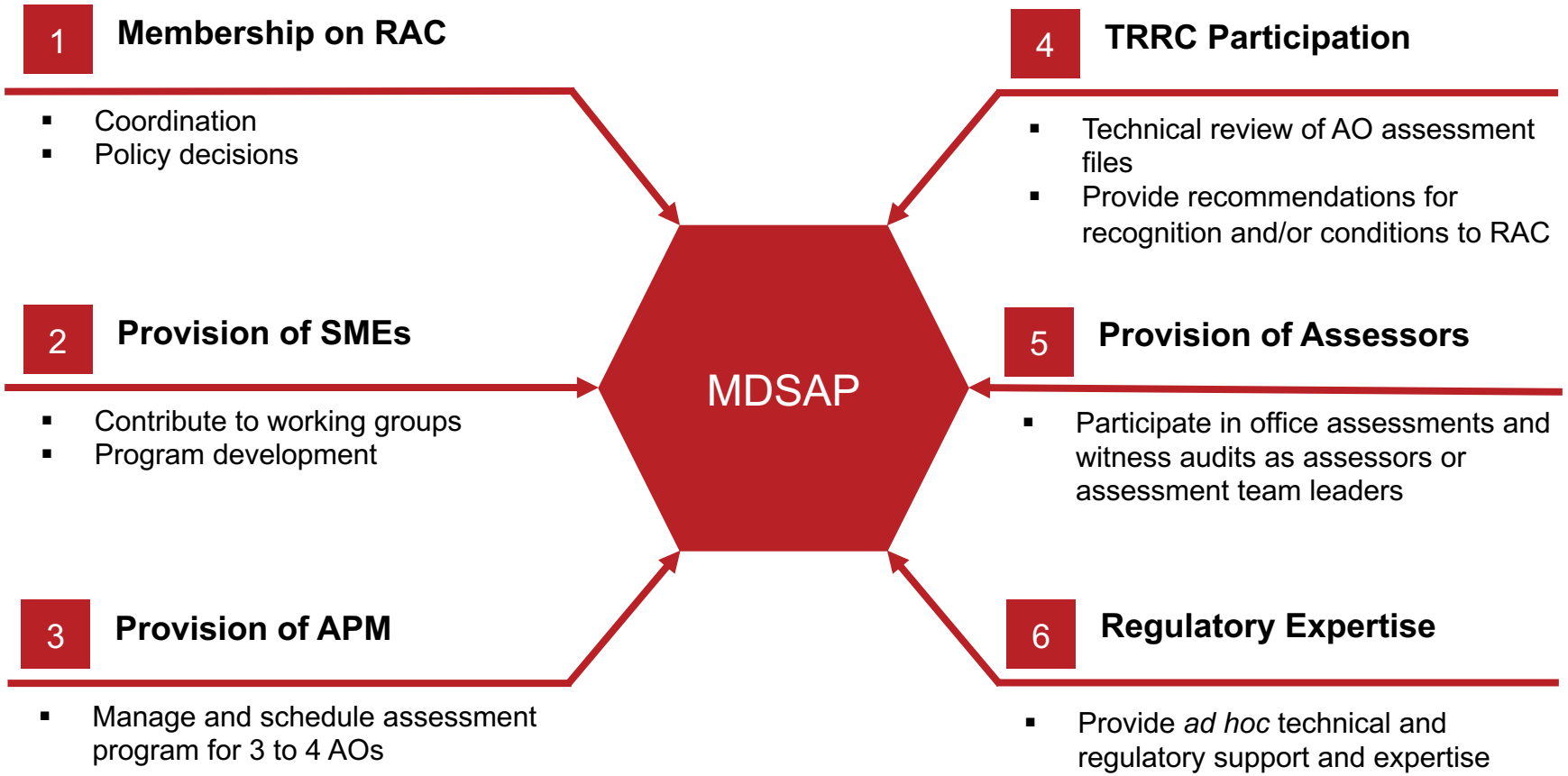
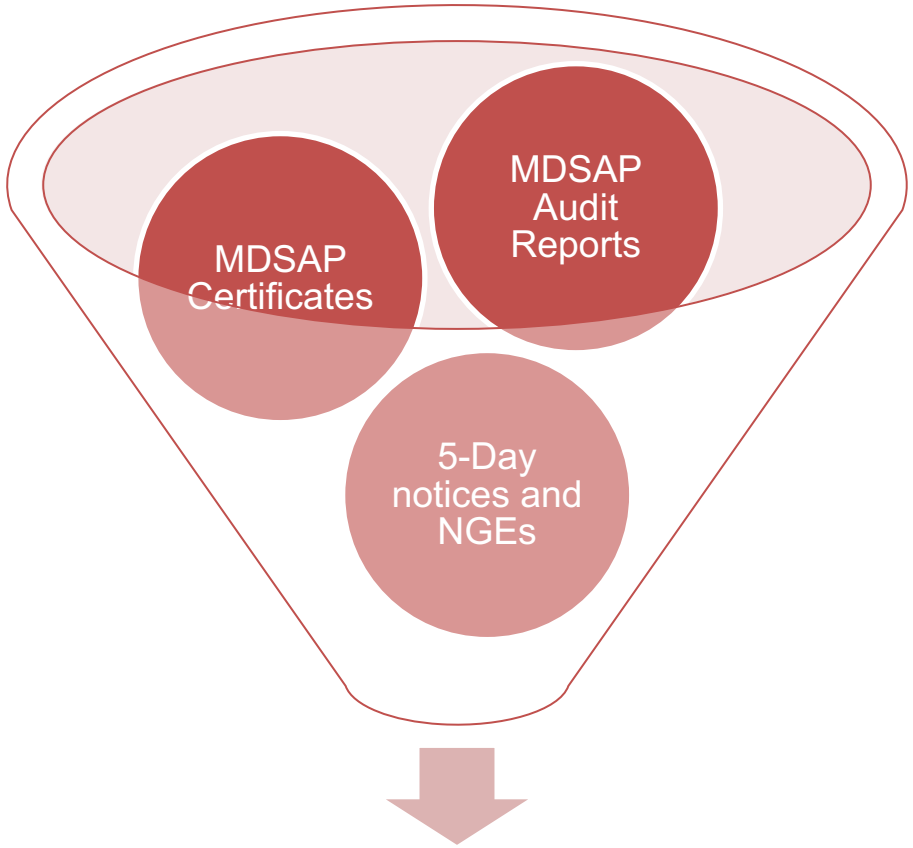
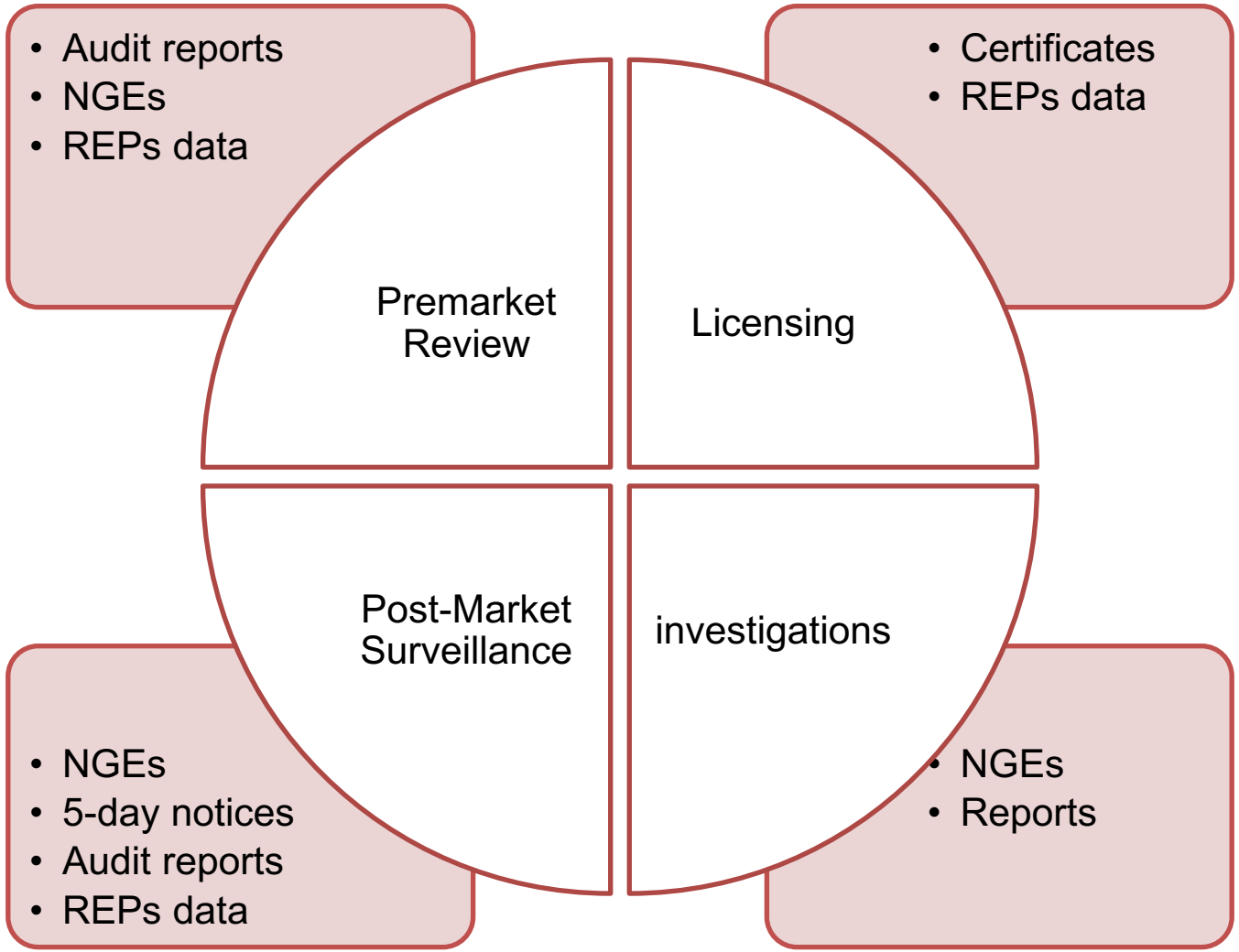


3 Health Canada and MDSAP



Regulatory oversight

3 Health Canada and MDSAP



3 Health Canada and MDSAP

Effective platform for harmonization, convergence, and reliance

Work Sharing with other Regulators

Confidence in outcomes

4 Questions and Answers

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