Combination Products and MDSAP

Medical Devices Directorate
Health Canada

Agenda

1. Scope
2. Applicability to other jurisdictions
3. Audit of non-device components
4. Secondary considerations

1 Scope

This presentation will exclusively deal with combination products regulated as medical devices.

Combination products can incorporate drugs, biologics, or natural health products.

2 Applicability to other jurisdictions

Reminder:

The regulation of combination products varies between the founding agencies.

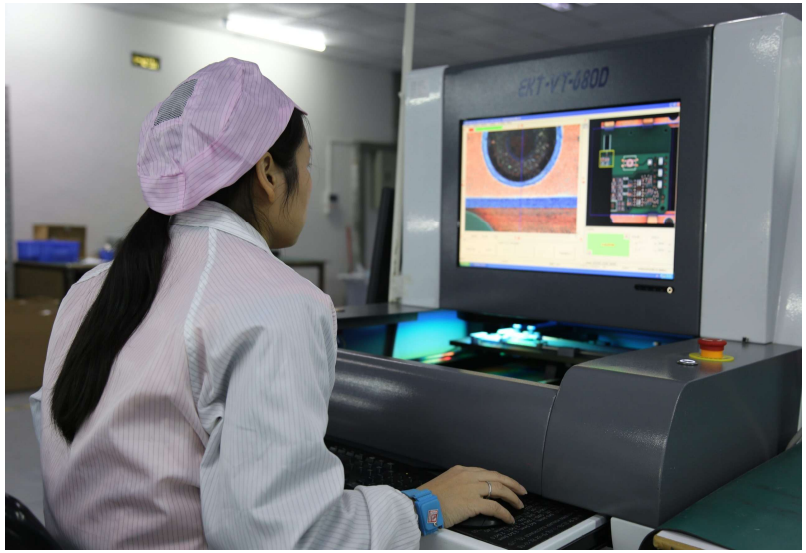
While Health Canada might regulate a particular combination product as a medical device, other jurisdictions could regulate the same product using very different pathways.

Manufacturers are encouraged to confirm the applicable regulatory pathways directly with the concerned Regulatory Authority.

3 Audit of non-device components

Key principles

- Device component will be audited as per normal practice.
- Relevant clauses of ISO 13485:2016 will be applied to non-device components.
- The audit of non-device components will be informed by the relevant GMP.
- Determinations of safety and effectiveness are outside the scope of the program.



3 Audit of non-device components

Design and Development

- Specification of non-device component (*e.g.*, API, NHP, biologic), including GMP certification (as applicable)
- Method of incorporation
- Labelling
- Compatibility
- Useful life / shelf-life

3 Audit of non-device components

Purchasing

- Supplier qualification and evaluation
- Component specification / purchasing documents
- Acceptance activities

3 Audit of non-device components

Production and Service Controls

- Handling and storage
- Traceability
- Validation of incorporation process
- In-process testing / QC
- Rework
- Labelling
- Final release

4 Secondary Considerations

- Post-market data
- Signals related to non-device components
- Application of relevant GMP
- Broader consideration within QMS (*e.g.*, competence, infrastructure, *etc.*)