Australian Government

Australian Pesticides and Veterinary Medicines Authority

Sterilisation by Gamma Irradiation: A regulatory perspective

CAPSIG Seminar

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To be discussed

- Legislation
- Inspections / Audits
- Validation
- GMP Agreements

Legislation – APVMA

Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)

- **Manufacture**, in relation to a chemical product, means:

  a) to produce the chemical product; or

  b) to engage in any part of the process of producing the chemical product, or any component or ingredient of the chemical product as part of that process, or of bringing the chemical product to its final state, including by formulating, processing, assembling, packaging, labelling, storing, sterilising, testing, supplying or releasing for supply.

Legislation - APVMA

Offences relating to manufacture and licences:

- 121(4)
  - A person must not carry out a step in the manufacture of chemical products at premises in this jurisdiction unless:

    (a) under the regulations, the person is an exempt person in relation to the manufacture of the products; or

    (b) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the products at those premises; or

    (c) the person holds a permit that authorises the carrying out of that step in relation to the product at those premises.

Legislation – Therapeutic Goods Administration (TGA)

Therapeutic Goods Act 1989 (Act)

- **Manufacture**, in relation to a therapeutic goods that are not medical devices means:

  a) to produce the goods; or

  b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storing, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process .

Legislation - TGA

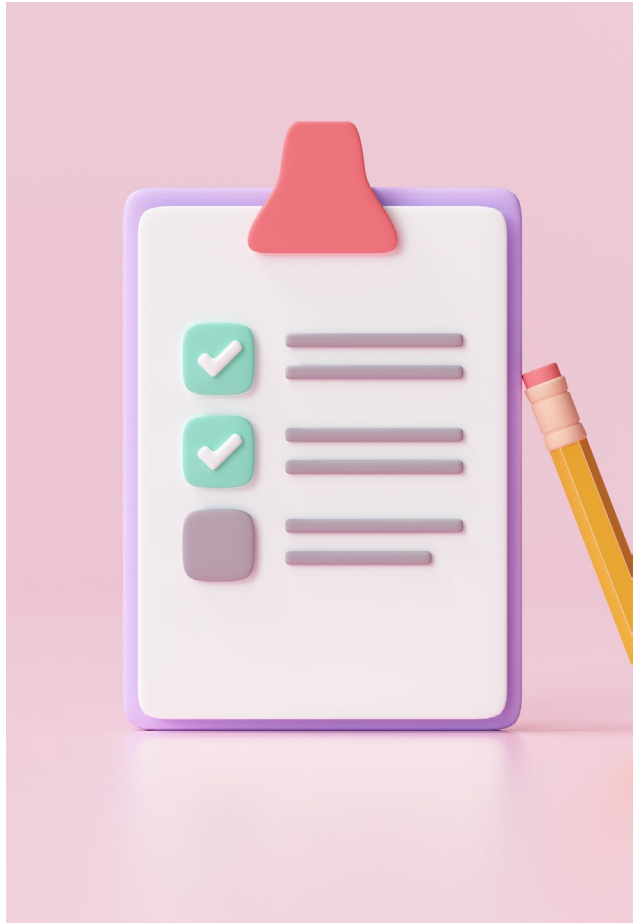
Criminal offences relating to manufacturing therapeutic goods:

- 35(4) A person commits an offence if:
  - (a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and
  - (b) the goods are for supply for use in humans; and
  - (c) none of the following applies:
    - (i) the goods are exempt goods;
    - (ii) the person is an exempt person in relation to the manufacture of the goods;
    - (iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Inspections / Licenses

Where human and veterinary medicines are both manufactured:

- TGA will conduct the inspection to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) guide to GMP for medicinal products (human and veterinary).
- APVMA do a review of the TGA inspection report and responses to any deficiencies (also called, non-conformances) to assess to the APVMA's code of GMP.
- APVMA & TGA issue and maintain separate licenses with their own conditions that license holders need to meet.



Why do Gamma Irradiation?

Key reference:

PIC/S Guide to GMP Annex 12 Use of ionizing radiation in the manufacture of medicinal products

What:

- Reduction in bioburden or sterilisation?
- Starting materials, packaging components or products?

Who:

- Manufacturer / product holder is responsible for the quality of the product including the attainment of the objective of irradiation.
- Radiation facility bears responsibility for ensuring that the dose of radiation required by the manufacturer is delivered to the irradiation container.

Validation

Validation should include:

- Dose mapping
- Details of packaging of the product
- Loading pattern(s) of product within irradiation container
- Loading pattern of irradiation containers around source
- Maximum and minimum limits of absorbed dose to the product (and associated routine dosimetry)
- Maximum and minimum limits of absorbed dose to the irradiation container and associated routine dosimetry to monitor this absorbed dose
- Other process parameters, including dose rate, maximum time of exposure, number of exposures, etc.

GMP Agreements

- Key document for roles and responsibilities between registered product holder / manufacturer and contract radiation facility.
- There is a clear and unambiguous breakdown of which entity is responsible for critical aspects of the agreement
  - Quality control
  - Manufacturing processes
  - Validation
  - Documentation
  - Communication

Key Points

- Gamma Irradiation is a step of manufacture for both TGA & APVMA Licenses.
- Inspections are conducted by TGA.
- Validation of the process.
- GMP agreements are key to establish roles and responsibilities.

- …. give us a call or email.

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Questions?