Where does GMP for Plants and Herbs Begin?

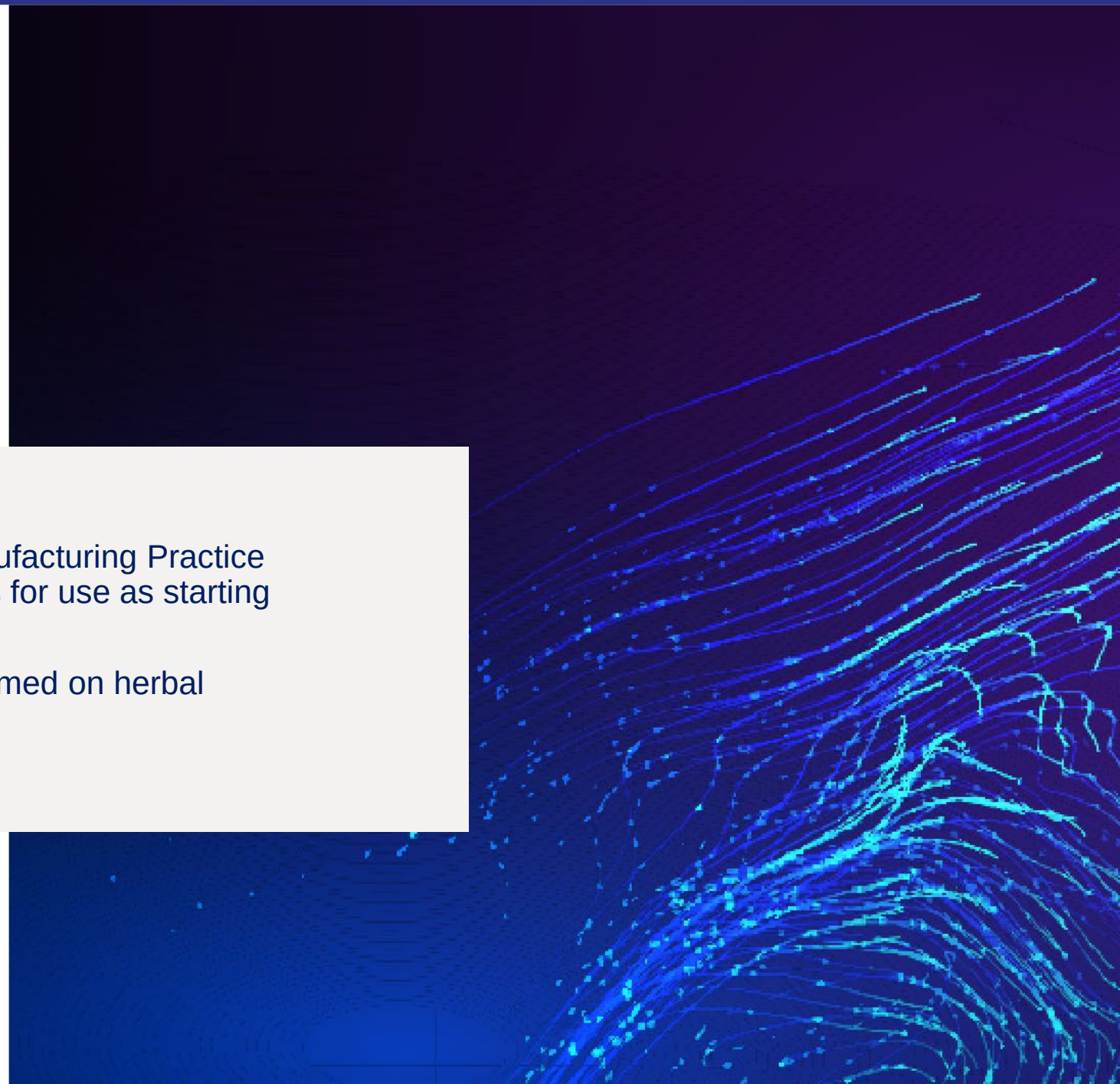
Nicole Bottle
Manufacturing Quality Branch
Department of Health and Aged Care, TGA

GMP FORUM 2024

Learning outcomes

At the end of this session you will:

- Improve your understanding of Good Manufacturing Practice (GMP) requirements for herbal ingredients for use as starting material.
- Understand what processes can be performed on herbal ingredients without GMP.



GMP licence requirements for herbal ingredients

Background

- Our engagement with the medicinal cannabis industry has identified an opportunity for greater clarity in our legislation for manufacturers to know when they require a licence for specific manufacturing steps

- Frequently asked questions include:
  - what processing steps required a GMP licence and
  - what constitutes medicinal cannabis starting material, as opposed to medicinal cannabis finished products, when the product is bulk dried cannabis flower

GMP licence requirements for herbal ingredients

When is a manufacturing licence required?

- Manufacturing of therapeutic goods in Australia must be conducted at a site that is issued a GMP licence by the Therapeutic Goods Administration (TGA).
- The licence authorises specific manufacturing steps, such as manufacture of API, physical and chemical testing, sterilisation, manufacture of finished dosage form, labelling, packaging, release for supply etc.
- There are exemptions from the requirement to have a manufacturing licence for some goods or persons

Exemption for certain goods – starting material

Therapeutic Goods Regulation 1990

Schedule 7 - Therapeutic goods exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits

Item 2

Ingredients, except water, used in the manufacture of therapeutic goods where the ingredients:

(a) do not have a therapeutic action; or

(b) are herbs, bulk hamamelis water or oils extracted from herbs, the sole therapeutic use of which is as starting materials for use by a licensed manufacturer

Exemption for certain goods - Starting material

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017

Section 13 – Manufacturing quality

(1) This section does not apply to the manufacture of a medicinal cannabis product that is:

(a) plant material; or

(b) oil extracted directly from the cannabis plant;

for use as starting material in the manufacture of another medicinal cannabis product manufactured in accordance with:

(c) subsections (2) and (3); or

(d) a licence under Part 3-3 of the Act.

Exemption for certain goods – starting material

When do the exemptions apply?

- These exemptions apply when herbal material, including medicinal cannabis, is used as starting material for further manufacture at a licensed site
- Starting materials in relation to therapeutic goods are any substance (active or excipient) used in the production of a medicinal product, excluding packaging materials.
- The exemptions in Item 2(b) of the Regulations and TGO 93 allow cultivation sites to grow,cut and dry herbal ingredients (including cannabis), or perform the first oil extraction step where the material is used to produce another therapeutic good at a GMP licensed site without themselves holding a GMP approval from a regulatory agency.

GMP licence requirements for herbal ingredients

INTERACTIVE SLIDO

We want to know what your understanding is of GMP requirements for herbal ingredients/oils for use as starting material in the manufacture of another therapeutic good.

1. What typically is the first extract for your starting material?
2. What manufacturing steps do you undertake with your starting material?
3. When do you perform irradiation of your herbal ingredients?
4. What manufacturing steps do you think need a GMP licence?
5. If we update the terminology ‘‘oils extract from herb’ and ‘oils extracted directly from the cannabis plant’ to mean first extract, what would be most appropriate?

Scan the QR code with your device to participate

GMP licence requirements for herbal ingredients

Next steps

- Provide clarity on what processes/activities can be undertaken with the material for the exemptions set out in the legislation to apply

- Provide clarity on the terminology “oil” extracted from herbs” in item 2(b) and “oil extracted directly from the cannabis plant” in paragraph 13(1)(b) of TGO93.

Questions?

Scan this QR code with your device to submit a question

GMP FORUM 2024

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration