Does my GMP evidence comply with TGO 93

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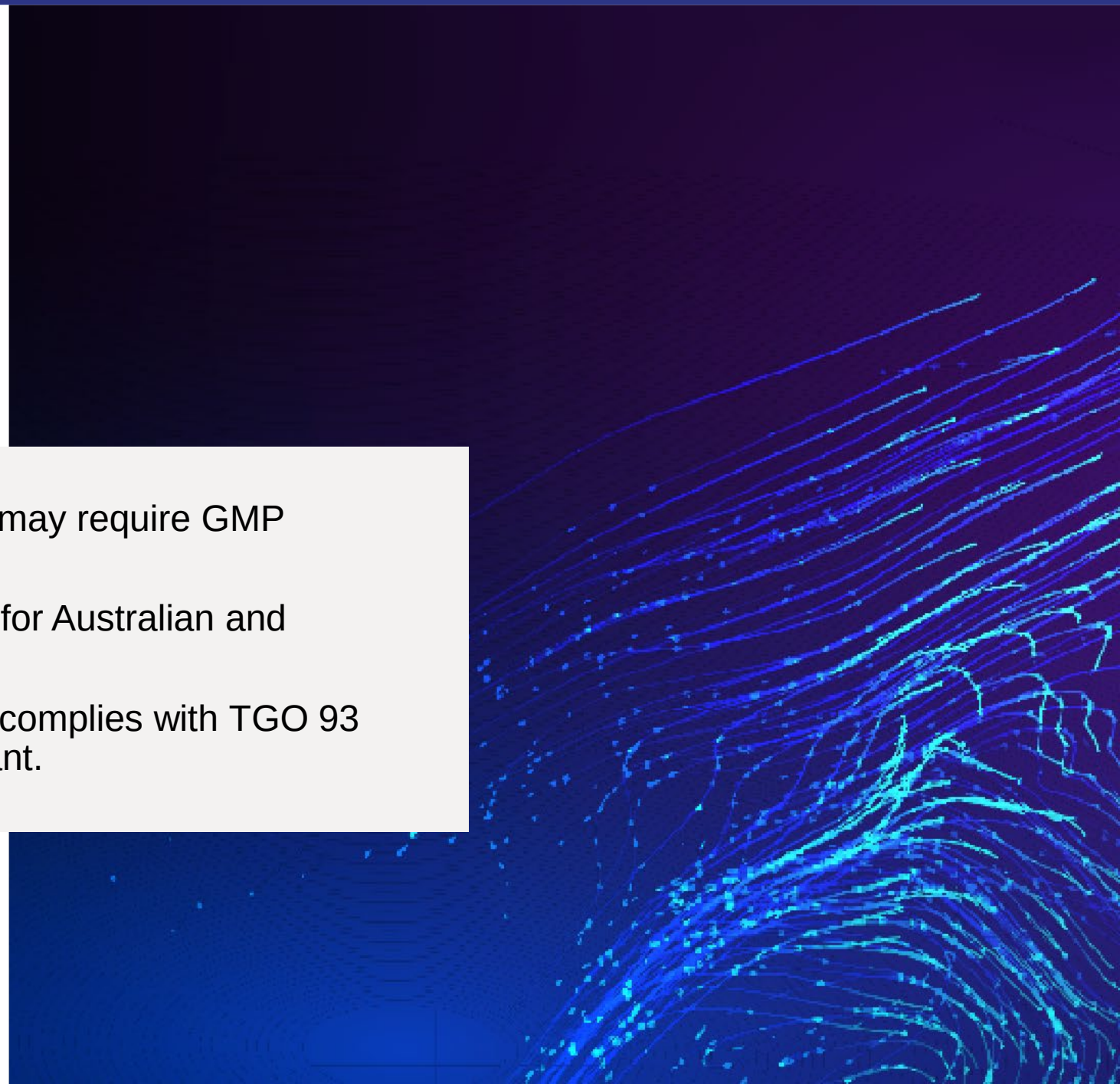
GMP FORUM 2024

Agenda

Learning outcomes

- Understand manufacturing steps that may require GMP evidence
- Understand what evidence of GMP is for Australian and overseas manufacturers
- Able to identify evidence of GMP that complies with TGO 93 and evidence that is not GMP compliant.



Evidence of Good Manufacturing Practice (GMP)

Manufacturing steps

Manufacturing steps that require Good Manufacturing Practice (GMP) evidence may include:

- any processing steps performed after the first crude extraction
- packaging
- labelling
- storage
- sterilising/decontamination e.g., irradiation
- testing
- release for supply.

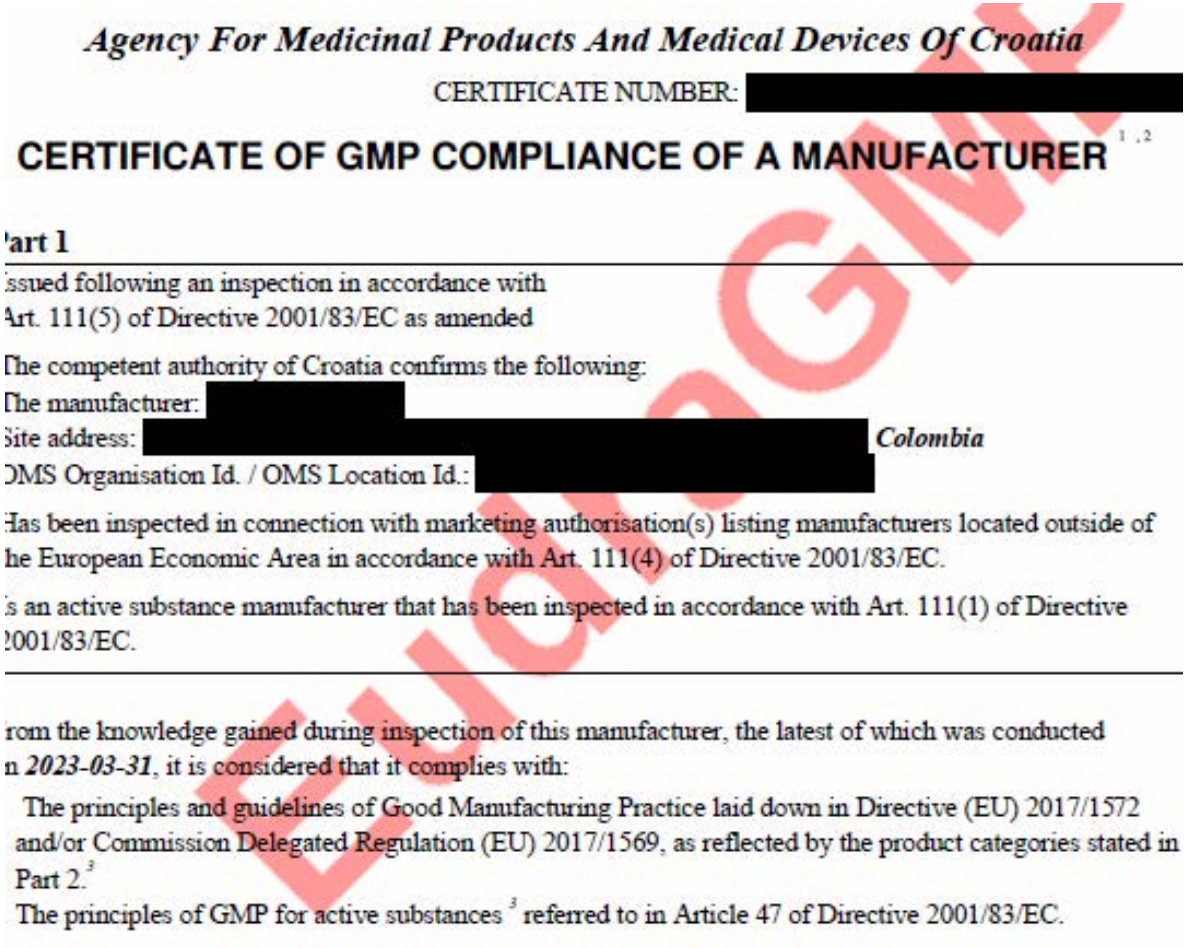
Acceptable evidence of GMP

What is acceptable evidence of GMP?

- For **Australian manufacturers** it is a TGA manufacturing licence, demonstrating compliance with Australian Good Manufacturing Principles (GMP).
- For **overseas manufacturers** the sites must comply with one of the GMP standards set out in section 13(2) and the Australian sponsor (the importer) of the medicinal cannabis product must hold evidence of GMP compliance, as specified in section 13(3) of TGO 93

Evidence of GMP

Cannabis extract from Colombia



Agency For Medicinal Products And Medical Devices Of Croatia

CERTIFICATE NUMBER: [redacted]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

'art 1

ssued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Croatia confirms the following:
The manufacturer: [redacted]
Site address: [redacted] *Colombia*
OMS Organisation Id. / OMS Location Id.: [redacted]

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of he European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

s an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

rom the knowledge gained during inspection of this manufacturer, the latest of which was conducted n *2023-03-31*, it is considered that it complies with:

The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

Scenario

Cannabis extract imported from Colombia to a licensed manufacturer to produce capsules for oral consumption.

Questions

1. Is this a GMP certificate or licence?
2. Does it comply with subsection 13(3) TGO 93?

Scan the QR code with your device to participate in this activity

Evidence of GMP

Dried flower from Canada

Landesamt Fuer Soziale Dienste Schleswig Holstein

CERTIFICATE NUMBER: [redacted]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: [redacted]
Site address: [redacted] *Canada,* [redacted]
OMS Organisation Id. / OMS Location Id.: [redacted]
DUNS Number: [redacted]

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2023-07-20*, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

Scenario

Dried flower imported from Canada for use by a compounding pharmacist to dispense as dried flower for inhalation.

Questions

1. Is this a GMP certificate or licence?
2. Does it comply with subsection 13(1) and 13 (3) TGO 93?
3. Does the sponsor need any other evidence?

Scan the QR code with your device to participate in this activity

Evidence of GMP

Dried flower from Canada

Landesamt Fuer Soziale Dienste Schleswig Holstein

CERTIFICATE NUMBER: [redacted]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: [redacted]
Site address: [redacted] *Canada,* [redacted]
OMS Organisation Id. / OMS Location Id.: [redacted]
DUNS Number: [redacted]

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-07-20***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

Scenario

Dried flower imported from Canada for use by a licensed manufacturer to produce a dried flower for inhalation.

Questions

1. Is this a GMP certificate or licence?
2. Does it comply with subsection 13(1) of TGO 93?
3. Does the sponsor need any other evidence?

Scan the QR code with your device to participate in this activity

Evidence of GMP

Gummies from USA

NSF Certificate of Conformity

Print Date
April 30, 2024
Certification Number
CXXXXXXXXXX
Initial Certification
April 29, 2022
Expiration Date April
25, 2025

NSF International has assessed and confirmed compliance of

[redacted]

Facility: [redacted] United States

Scope: NSF/ANSI 455-2 - 2021
which includes 21CFR Part 111, 21 CFR Part 117, 21 CFR Part 11, 21 CFR Part 1.5 Subpart L & 21 CFR Part 1.9 Subpart O

Product Technologies:
Bulk Packaging, Coating, Encapsulation, Mixing, Primary Packaging, Secondary Packaging, Tablet Compression, Liquid Formula, Dry Formula, Packaging/Labeling Operations, Quality Operations, Warehousing

Product Categories:
Capsule, Gummy, Ingestible Oil, Ingestible Liquid, Powder, Tablet,

Scenario

Gummies imported from the USA for oral consumption

Questions

1. Is this a GMP certificate or licence?
2. Does it comply with subsection 13(3) of TGO 93?

Scan the QR code with your device to participate in this activity

Evidence of GMP

Recap – what is evidence of GMP?

- Each overseas manufacturing site that performs a step of manufacture must have GMP evidence as specified in section 13(3) of TGO 93
- The certificate, letter or written confirmation must:
  - ✓ Cover the relevant manufacturing step for the relevant medicinal cannabis product; and
  - ✓ Relate to each manufacturing site where the medicinal cannabis product was manufactured; and
  - ✓ Have been current at the time the medicinal cannabis product was manufactured

Evidence of GMP

What is not acceptable evidence of GMP?

- A valid certificate of GMP issued to the manufacturer of the product by a licensing authority of an EU Member State for non-EU member state countries (excluding Canada), for example Colombia.
- ISO 22000:2018 Food Safety Management
- ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices
- NSF/ANSI 455-2: Dietary Supplements GMP Certification

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