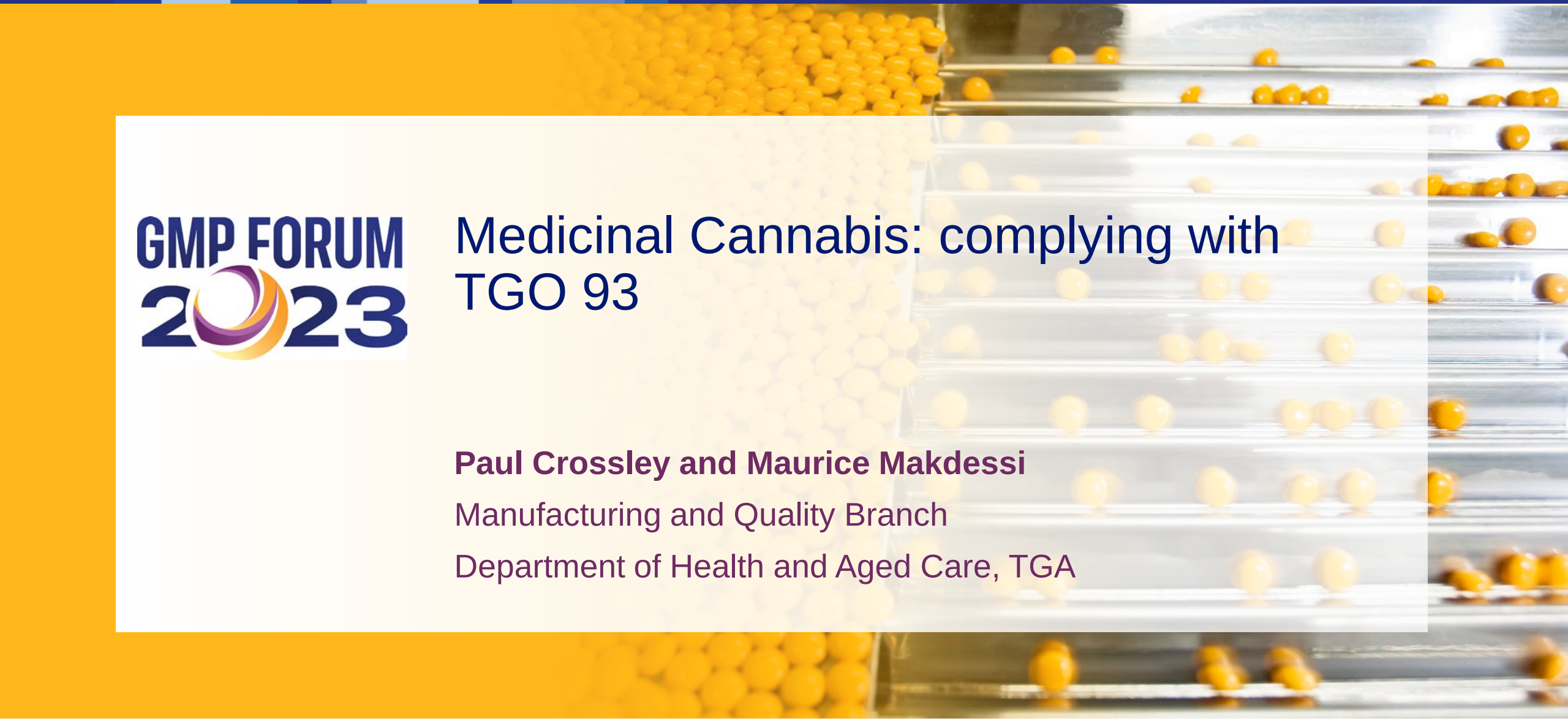


GMP FORUM 2023

# Medicinal Cannabis: complying with TGO 93

**Paul Crossley and Maurice Makdessi**

Manufacturing and Quality Branch

Department of Health and Aged Care, TGA

# Overview

- *TGO 93 requirements – a refresher*
- *GMP Evidence*
- *Focus on quality*
- *GMP inspections*
- *Your questions answered*

# TGO 93 requirements: refresher

## TGO 93: the quality standard for Medicinal Cannabis Products – updated in March 2022

- New GMP requirement:

  *each step of manufacture, in relation to a medicinal cannabis product, that occurs outside Australia must meet one of the GMP standards set out in section 13(2) of TGO 93*

- GMP requirements, microbiological quality requirements and labelling/packaging changes apply to all products **released for supply on or after 1 July 2023**.

AUSTRALIA

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

made under subsection 10(1) of the

*Therapeutic Goods Act 1989*

**Compilation No. 2**

**Compilation date:** 28 March 2022

**Includes amendments up to:** F2022L00384

Prepared by the Department of Health, Canberra

Authorised Version F2022C00332 registered 28/03/2022

# TGO 93 requirements: refresher

- TGO 93 sets out the minimum requirements for product quality
    - Type of products
    - GMP
    - Labelling/packaging
    - Testing
    - Microbiological attributes
- Harmonises with Regulations: GMP already applies to Australian products

# GMP Evidence for Imported Products

- Each step of manufacture outside Australia must be in accordance with GMP.
- Australian sponsor must obtain/hold acceptable written evidence
- TGA will recognise certification by specified foreign regulators

- TGA inspection can be requested (certificate not a clearance)
- ‘Starting material’ exemption **when going to a GMP site**
  - ‘Starting material’ for this purpose is ‘plant material’; or ‘oil extracted directly from the cannabis plant’

# Points to remember

- Unless a compounding site has a GMP licence, all starting material needs to have been manufactured under GMP
- Australian sponsor must hold GMP evidence, ready to provide to the TGA if requested
- Every participant in the chain needs to be satisfied that a medicinal cannabis product is compliant with TGO 93
- Quality means more than just a GMP certificate or '*putting something into a box*' in Australia.

# Regulation focused on quality

Need to justify decisions:

- When to do testing
- Whether testing is under GMP
- Expiry dates based on stability studies

TGA will investigate reports of quality:

- Packaging issues
- Active ingredients within requirements
- Labelling
- Expiry dates

# GMP Inspections

## What you need to know:

- Application submission/review
- Inspection scope
- Knowledge of regulations
- Key standard requirements
- Self assessment
- Readiness

# Applying for an inspection

**Application for GMP inspection**

- Application would require 9-12 months review/inspection scheduling

**Scope of Inspection:**

- Awareness of scope (Product type/ steps of manufacture)
- Mapping processes/ identify where GMP starts/ Justification


**Knowledge of Regulations and GMP Standards**

- Awareness of regulations/ any GMP exemptions?
- Current PIC/S Guide / Interpretation guidance
- Default standards
- Relevant TGOs

# Getting ready for inspection

## Personnel

- Suitably qualified/ Gowning/Hygiene requirements
- Training
- General and specific/ training effectiveness measures


## Quality System

- Deviations, Out of specifications, Change Controls, Complaints/Returned Goods, Reworks, Risk Management
  - Depth and effectiveness of investigation/root cause identification
  - Appropriate impact and risk assessment
  - Appropriate CAPA /correction/prevention
  - Rework/ reprocessing feasibility documented/justified/ Quality Control

# Getting ready for inspection

**Documentation system Management**/ controlled documents/ adequate reviews
**Production (Storage/Manufacturing/Packaging/cleaning/ cross contamination)**

- Clean storage and temperature monitoring
- Processes clear steps-controls /in-process checks
- Cleaning/ Clearance: Pre- and post checks/ verifications/ labelling system

**Engineering – Maintenance/Calibration programs**

- Traceability/appropriate frequency
- Conducted to equipment specifics/thoroughly documented

**Utilities-** HVAC, water systems, compressed air/gases

- Description/Schematics/Controls/Monitoring
- Data Management/Trends

# Getting ready for inspection

**Validation Program**

- Covering process/equipment/cleaning/computerized systems/analytical
- Study protocols: Specific, who, how, justification, acceptance criteria
- Report to protocol/data analyses/clear conclusions
- Assessment of Revalidation policy/frequency

**Quality control testing (Chemistry and Microbiology)**

- Representative sampling/ Supplier approval
- Approved methods/specifications/Standards/Reagents
- Suitably calibrated and maintained instruments
- Test records/reports/links/traceability/Data integrity

# Getting ready for an inspection

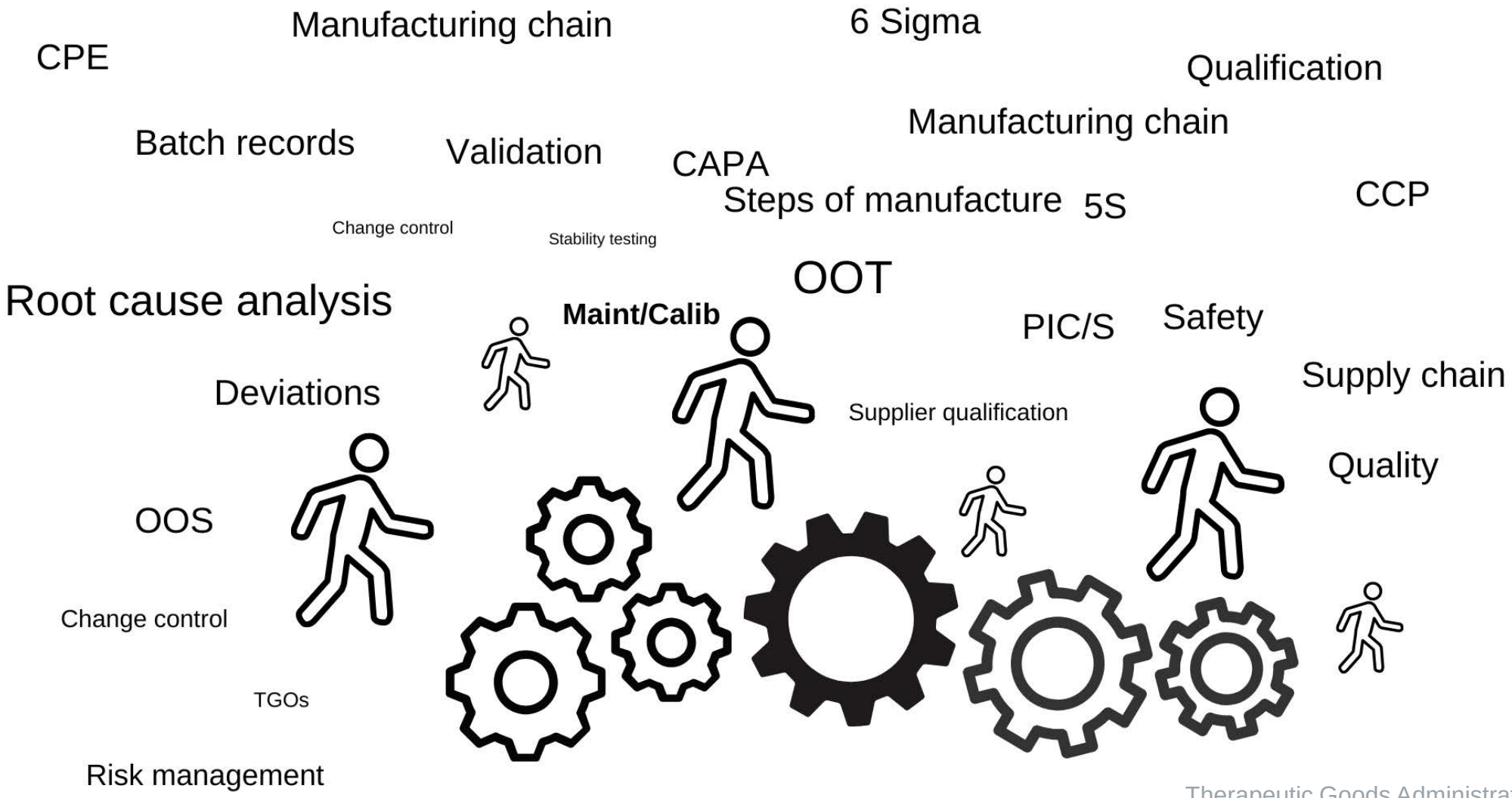
**Batch Documents**

- Covered all steps of manufacture
- Equipment/area cleaning/clearance
- Checks and verifications of major steps
- Yield/reconciliations
- RFS (satisfy relevant TGOs)

**Product Quality Review** (Best in batch real time)

- Ensure covering all elements of the PICS Guide
- Data analytics/process capability/consistency
- Incidents assessments/ trends
- Conclusions/improvement recommendation

# Self- Assessment/ GMP inspection readiness



# Further information

## TGO 93 guidance and FAQs available on the TGA website


medicinalcannabisreforms@health.gov.au

# Participate in the Q&A

## Verbal questions:

Raise your hand to ask a verbal question. A member of the GMP Forum staff will provide a roaming microphone.

## Written questions:

Scan the QR code below or click the link in your calendar to access Slido via your mobile device. You can submit your question, and vote on other questions submitted.

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

# Coming up next in this room

Cath Brown
Director, Medicine Shortages Section

Medicines Shortages Strategies to mitigate supply chain disruptions