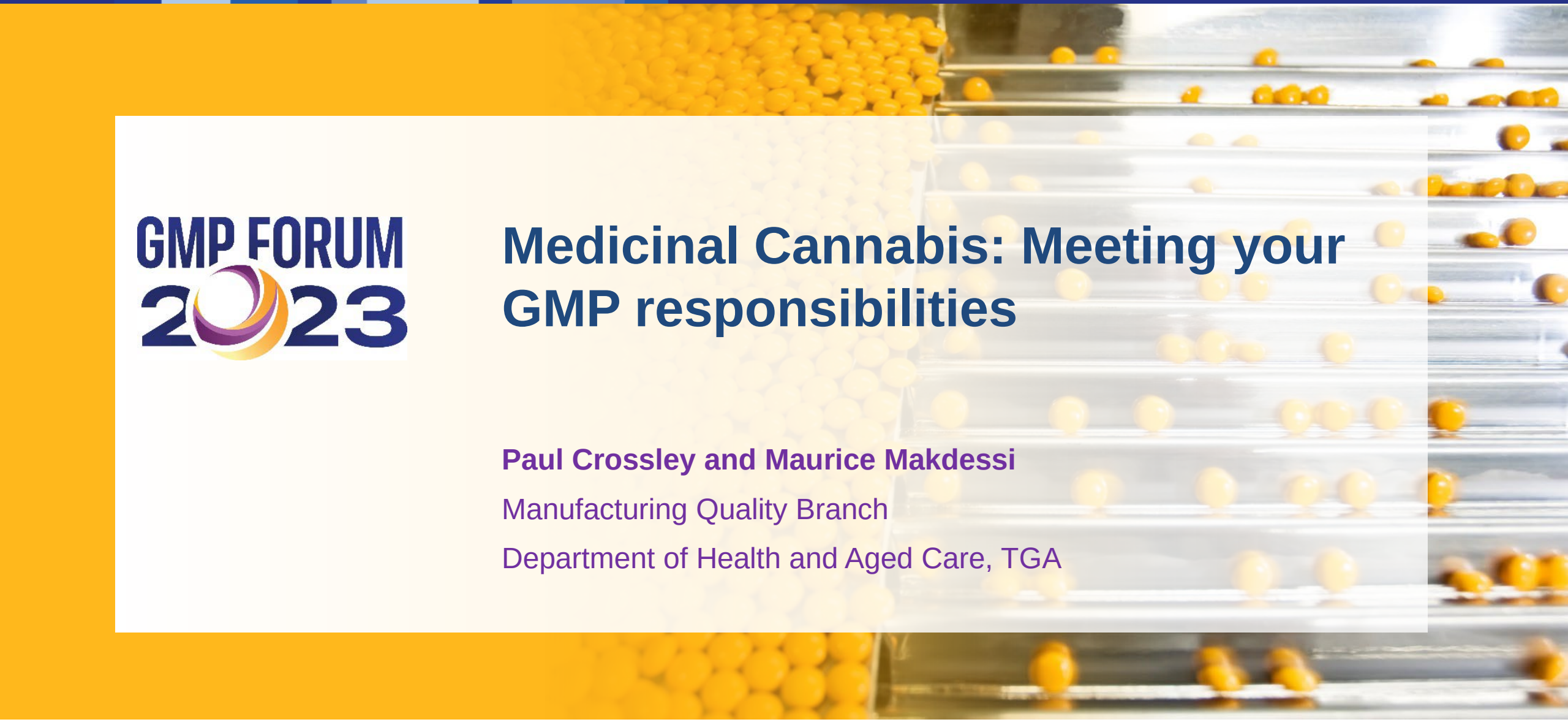


GMP FORUM 2023

Medicinal Cannabis: Meeting your GMP responsibilities

Paul Crossley and Maurice Makdessi

Manufacturing Quality Branch

Department of Health and Aged Care, TGA

Workshop agenda

Your expectations	5 minutes
What are the GMP requirements? Outline of today's activities.	5 minutes
Scenario 1	20 minutes
Scenario 1 insights	10 minutes
Scenario 2	20 minutes
Scenario 2 insights	10 minutes
Questions and general discussion	15 minutes

TGO 93 reforms

TGO 93: the quality standard for Medicinal Cannabis Products - introduced 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

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’

Medicinal Cannabis Workshop Scenarios

You are presented with two scenarios in relation to importation of medicinal cannabis products

In table groups, examine each scenario and respond to related questions

As a wider group, tables will be asked to share insights

Available:

- A copy of TGO 93 to assist as needed
- Printed copies of the two scenarios
- Paper and pens for brainstorming
- Facilitators in the room to guide / assist

Further information

TGO 93 guidance and FAQs available on the TGA website

medicinalcannabisreforms@health.gov.au

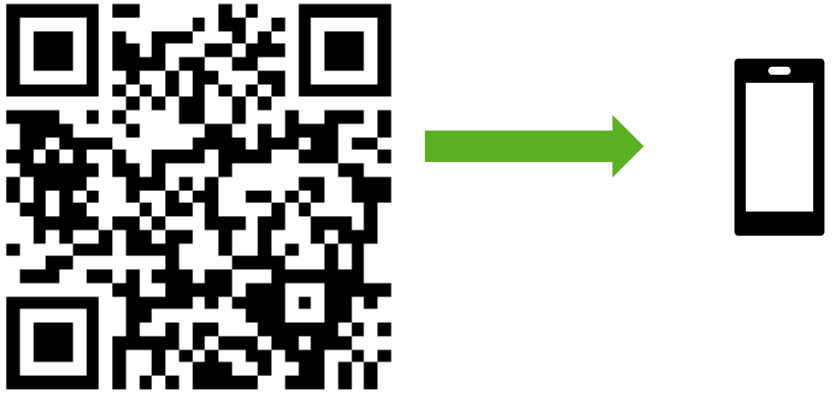
Participate in the Q&A

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

Therapeutic Goods Administration

Coming up next in this room

Jenny Hantzinikolas
Director, GMP Inspections Section
Manufacturing Quality Branch, TGA

Workshop – performing detailed investigations