Update from Manufacturing Quality Branch

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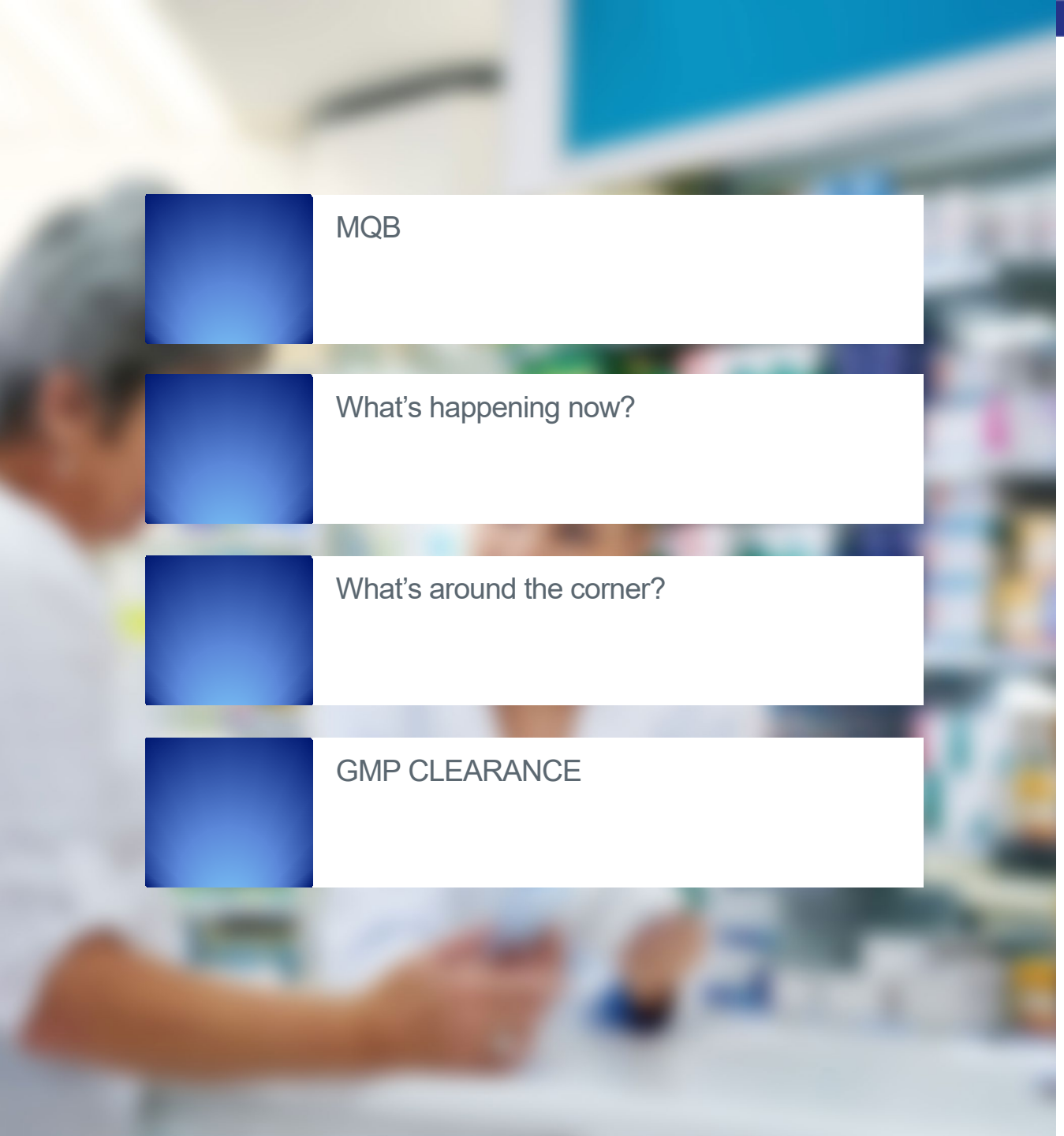


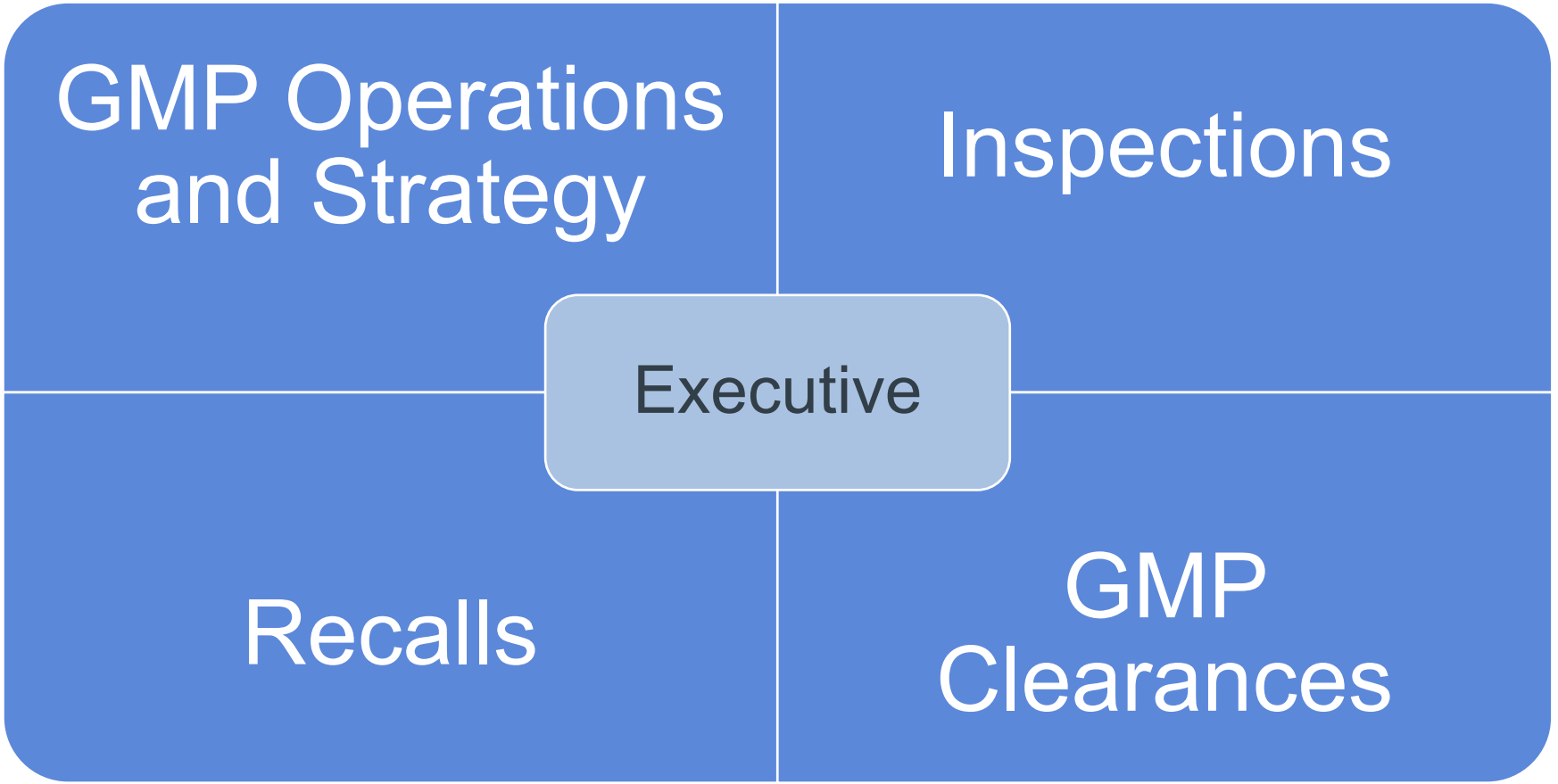
- MQB
- What's happening now?
- What's around the corner?
- GMP CLEARANCE

Outline

MQB …

… assists in the timely supply of therapeutic goods, ensuring they are of appropriate quality for their entire lifecycle.

MQB Structure



What we do

MQB

- assesses manufacturers' compliance with Good Manufacturing Practices for medicines, blood, tissue and cellular therapy products
- coordinates recalls for all types of therapeutic goods.
- is responsible for quality requirements for medicinal cannabis, MDMA, psilocybine.

What's happening now?

- Regulatory reform projects
- Business improvements
- International collaboration activities

New quality standards for MDMA and psilocybine

Supply under Authorised Prescriber (AP)

- First jurisdiction to supply as medicines, strict controls on access.
- Quality requirements to ensure alignment with clinical trial products.
- Testing of active ingredient by GMP-licensed labs before use in compounding

Medicinal cannabis – TGO 93 quality requirements

- New requirements – labelling and GMP for overseas manufacturing, came into effect mid-2023
- Most frequent medicine problem reports – appearance, mould contamination

Post-implementation review and testing survey

- Survey of sponsors supplying the most products under special access pathways
- Evidence of GMP certification, certificates of analysis, labels
- Samples of dried flower for microbiological testing.

Publication of results

Surveillance Inspections

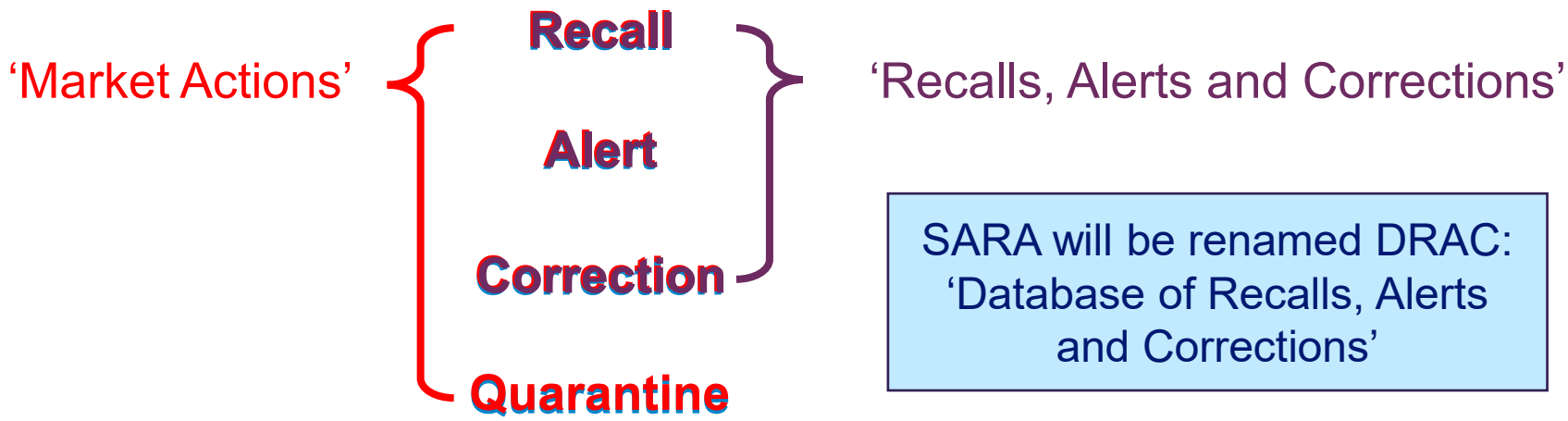
Reduced duration re-inspections – A1 and A2 sites

- Same scope, less depth
- Reduced time on site
    - reduced inspection costs
    - TGA covers more sites
    - reduces COVID backlog
- Modified Inspection Report
- Same outcomes
    - GMP Certificates
    - GMP Clearances

Recall Reforms Program

- Discussion Paper outcomes – Process changes
  - streamlined and flexible reporting
  - expansion of ‘Early Advice’ network
  - amended URPTG published
- Current work
  - recall action nomenclature improvements
  - updates to TGA databases in TBS
  - reviewing legislation – still fit for purpose?

Recall Reforms Program – new nomenclature



…all pending implementation of critical IT changes

Recall Reforms Program – legislation review

- **Timely** Recalls, Alerts and Corrections for defective therapeutic goods relies upon cooperation with industry.
- New supply landscape … e.g. medicinal cannabis
- How do we best use our existing legislation? Is it still fit for purpose?
    - mandating Market Actions other than recalls?
    - ensuring action completion in a timely manner?

HPRG Digital Transformation

- New portal and case management system
- Better user experience
- Improved business intelligence
- Robust digital platforms

Manufacturing information

- fundamental data in multiple business systems

- discovery phase

What's around the corner?

Looking towards 2024/25

Adoption of next revision of PIC/S Guide

- PIC/S Guide to GMP - Version 16 was adopted on 3 June 2024.
    - minor clarification for Annex 13 - Investigational Medicinal Products
    - new Annex 16 – Authorised Person and release for supply.
        - 3 month transition, ends 3 September 2024

But the fun doesn't stop …

- PIC/S Guide to GMP - Version 17 planned to be adopted in early 2025.
    - revision of Annex 1 - Sterile Medicines.

International collaborations

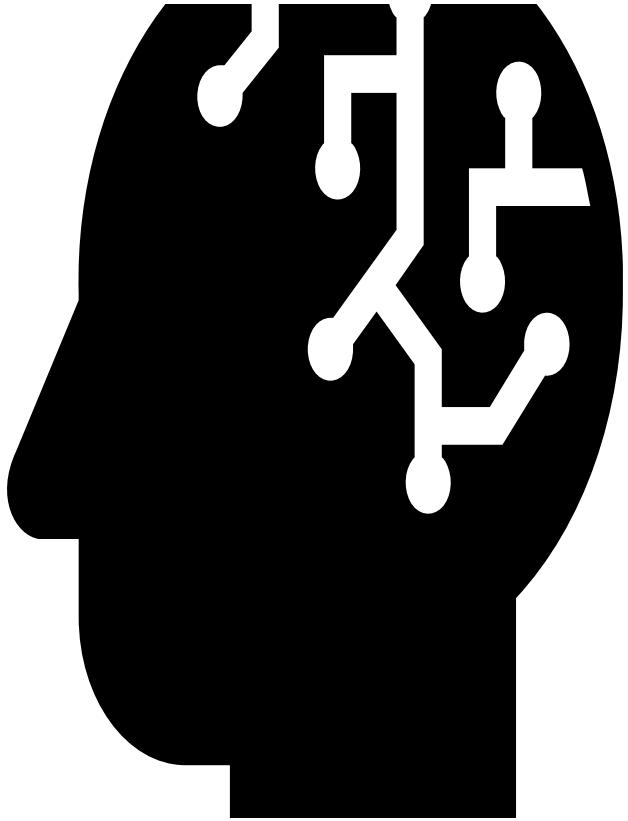
Good Manufacturing is a global industry – partnerships are critical

- Access
- PIC/S
- Single Inspection Pilot
- Maintenance activities on our Reliance Framework

New and emerging treatments

- Boundary products
- Combination products
- Manufacturing at the bedside
- ATMPs
- Maggots! leeches!

Artificial Intelligence



Major innovation: advancing science and technology

Major role in improving health care, costs and health outcomes

GMP Clearance

Stephen Farrell
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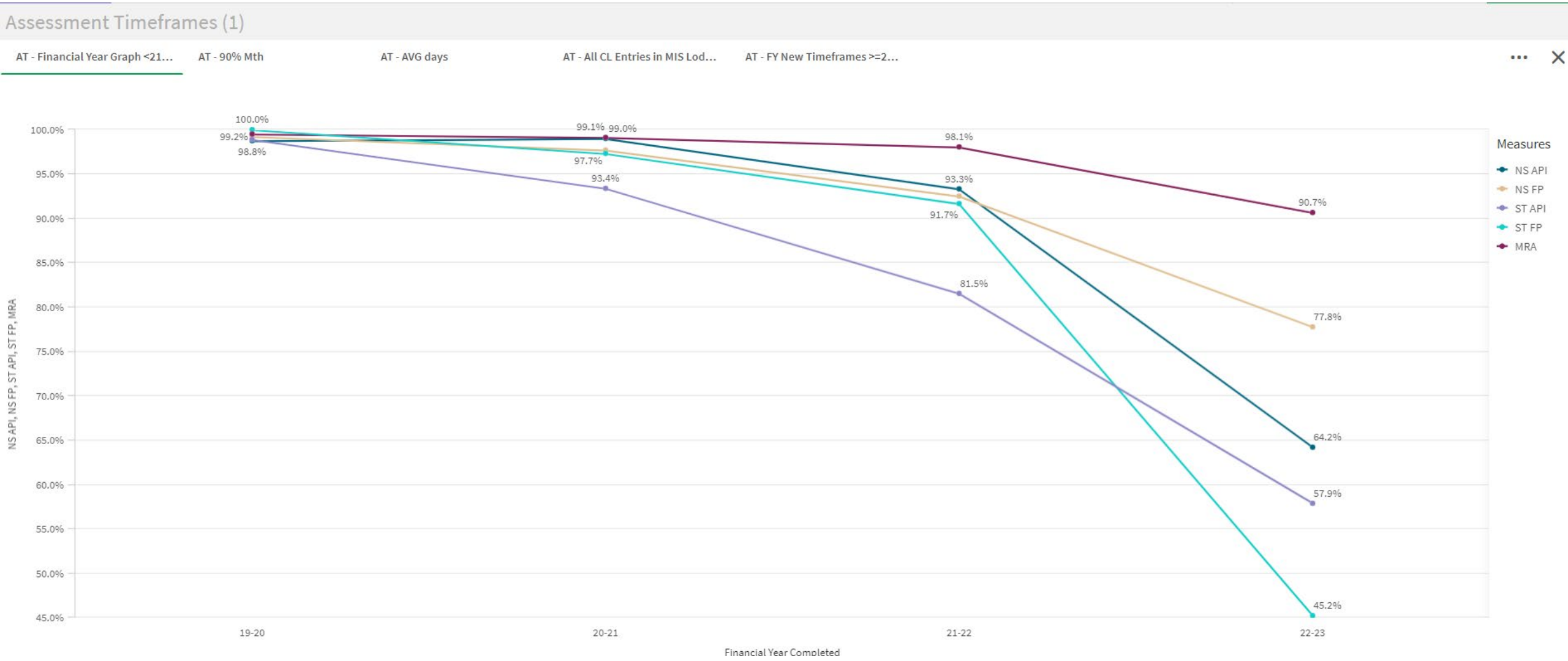
Department of Health and Aged Care, TGA

GMP Clearance

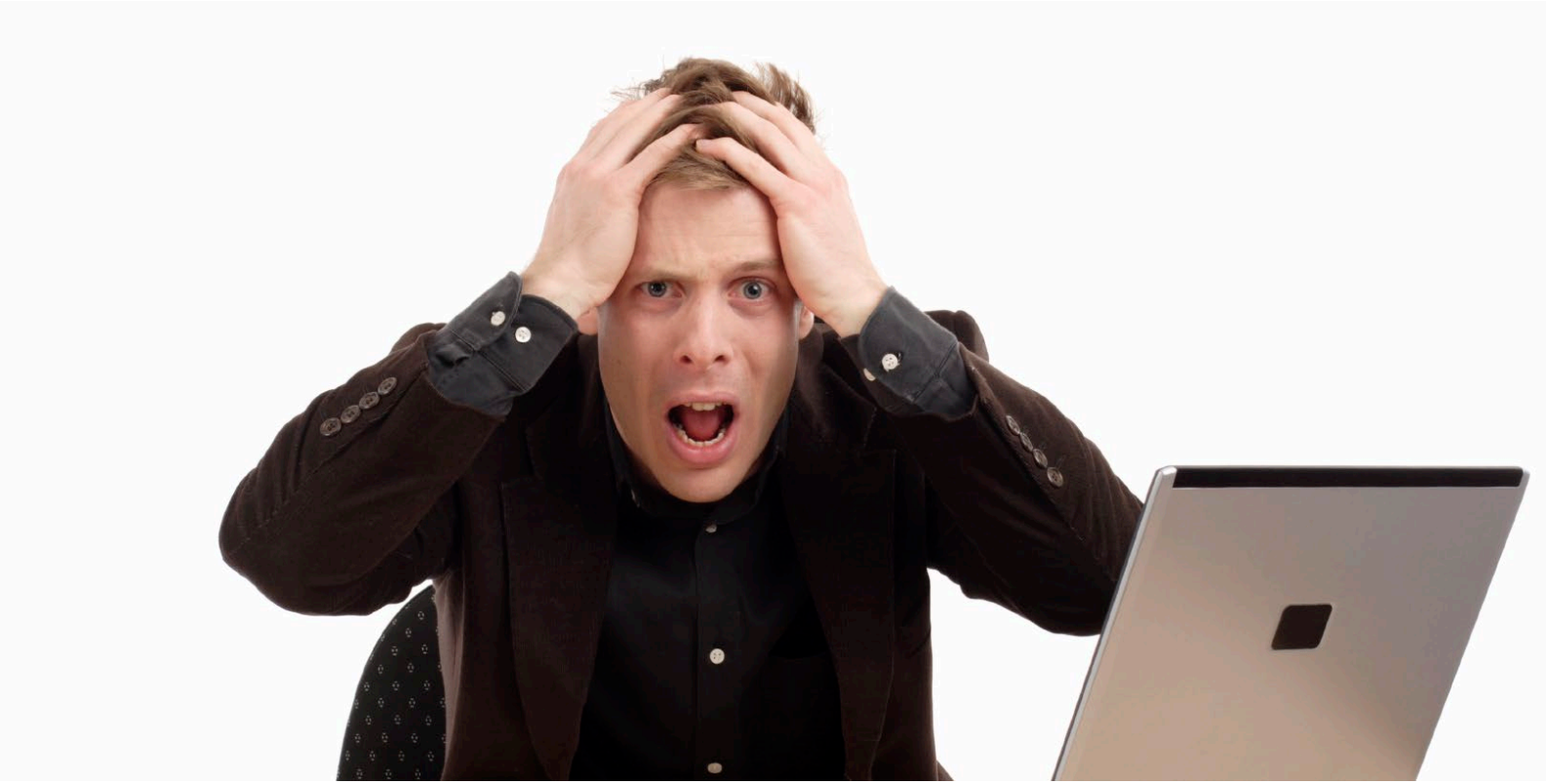
A quick recap



What changed?

- No on-site inspections
- Reduction in ‘reliance’ aspect of the GMP Clearance framework
- Increased complexity of evaluations
- Flow-on effect of decisions made during early stages of the pandemic
- Prioritisation of Vaccines, treatments and medicine shortages

But the pandemic is over so……..

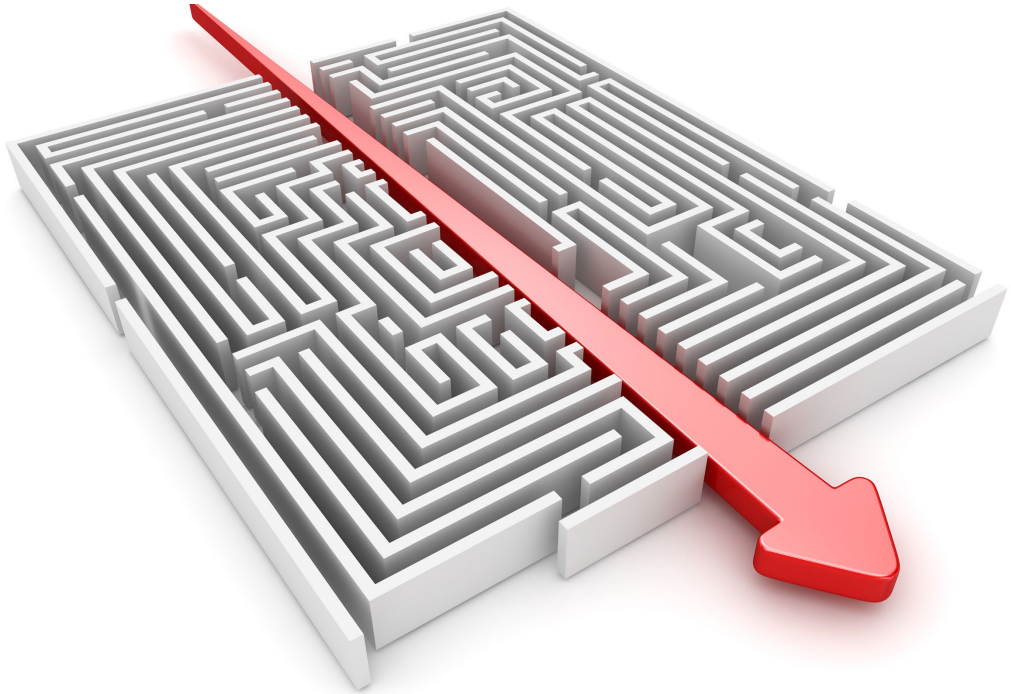


- ‘Pandemic’ Is not over for GMP
- Long term effect on processes, evaluation complexity and timeframes
- Return to a new ‘normal’ will take several years
- Medicine shortages continue to be a priority

Where we are now

- Backlogs in all Compliance Verification (CV) streams
- Significant increase in processing times
- Applications continue to be of poor quality
- Competing priorities:
  - New listings
  - Non-prescription medicine
  - COR-A, COR-B, Priority and provisional pathways
  - Project Orbis
  - International submissions (Access consortium)

The plan



- Increase Resources
- Streamline onboarding and training
- Same strategic approach as 2016 backlog
- Continue to deliver long-term strategic goals
- Digital transformation

GMP Clearance reforms

- Process has not changed since 2011
- GMP and regulatory framework has evolved
- A review of every aspect of the GMP Clearance framework
- Collaboration with industry via a GMP Clearance Working Group

WHEN:

19-20 November 2024

WHERE:

Melbourne Convention and Exhibition Centre (MCEC)

COST:

$690 per person

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Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

Want to chat with me further? Come visit us.

2024 ARCS ANNUAL CONFERENCE

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration