Future-Proofing GMP for Advanced Therapies

Fran Harding

Manufacturing Quality Branch

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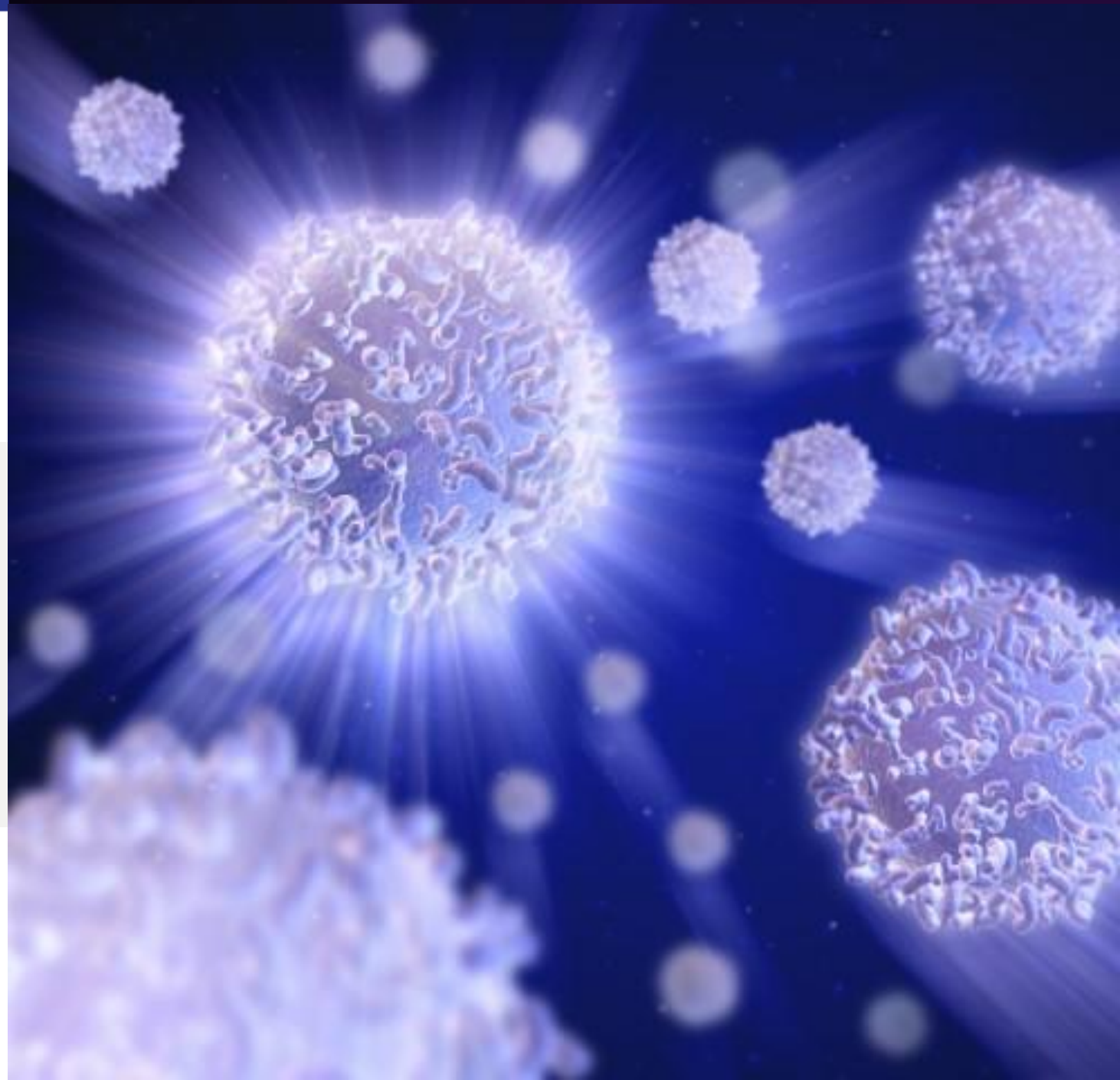
Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Purpose and Scope

- The future of GMP
- Increase in quality maturity
- Closed processing and automation
- Regulators in step with industry
- Priorities for teams



Global Industry Direction

Scaling and standardising manufacturing

- Consistent performance across lots, campaigns and sites

Platformisation

- Reusable product-platform workflows replacing bespoke runs

Increasing quality maturity

- Control strategy, investigations, CAPA effectiveness and release robustness.



What is Changing on the Floor

Closed / automated unit operations

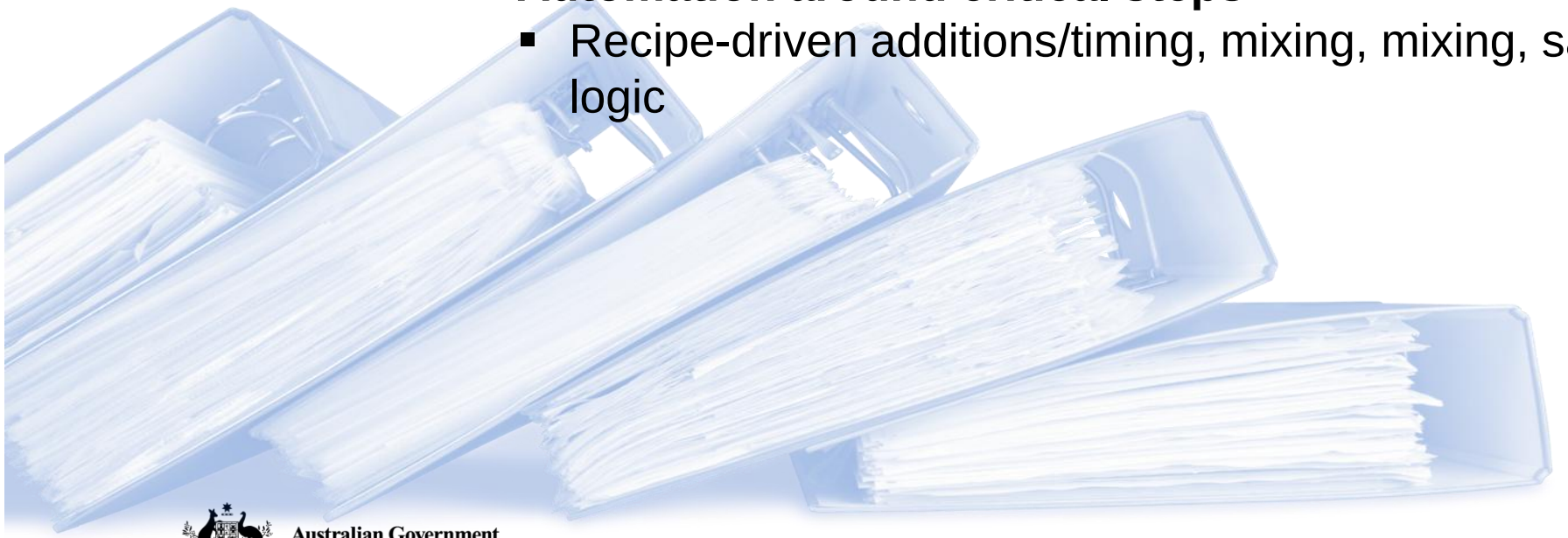
- Reduced contamination pathways and operator variability

Single-use and modular facility

- Standardized skids/suites to improve comparability

Automation around critical steps

- Recipe-driven additions/timing, mixing, mixing, sampling/pooling logic



Where Quality and Release strategy are Tightening



Potency and identity strategy

More process-connected assays and justified acceptance criteria

Deviation and CAPA effectiveness

Root cause depth plus recurrence prevention and trend impact.

Faster and reliable QC workflow

Automation and integration, with suitability, OOS handling and traceability.

Regulatory and Inspection Focus Areas in Step with the Industry



Data integrity and traceability

Electronic records, audit trails, access controls and verified lineage.

Comparability as a major driver

Scale, equipment, reagents and site changes need impact control.

Lifecycle validation mindset

Ongoing verification for system, process, software, equipment and service changes..

What teams should prioritise next



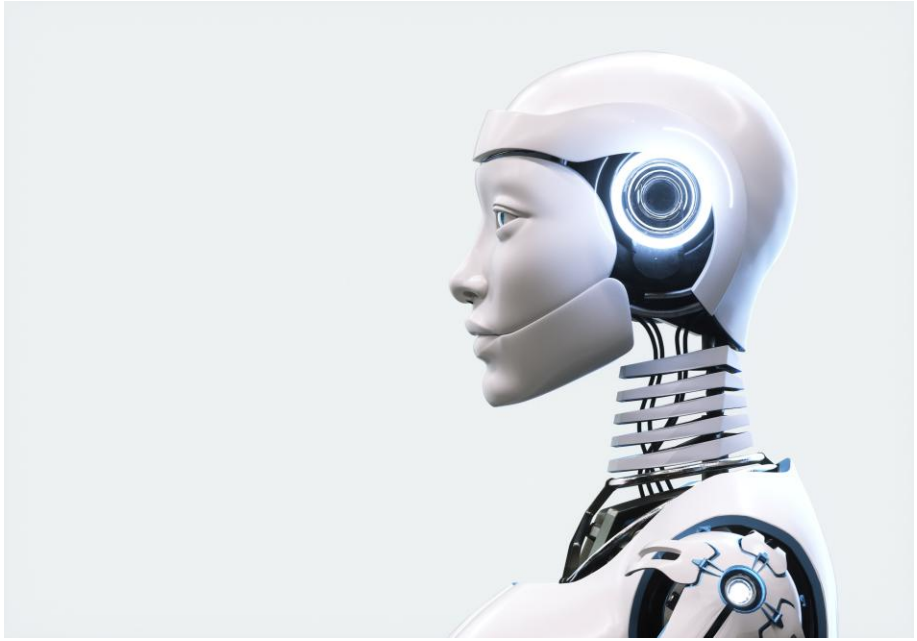
Strengthen control strategy linkage
CCS/EM, CPPs, analytics, investigations and batch disposition logic connected end-to-end.

Upgrade digital execution governance
Recipe/version control, interface validation and audit-trail completeness for release-critical data.

Build comparability-ready change processes
Structured impact assessment, predefined rationale and scalable evidence packages.

Take home messages

- GMP is becoming more future-focused for advanced therapies
- Automation and closed systems reduce risk, but increase expectations
- Quality and release strategies need to be more connected
- Comparability is a major regulatory theme



Questions?

www.tga.gov.au



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration