GMP FORUM 2023

# Australian Sponsors & GMP

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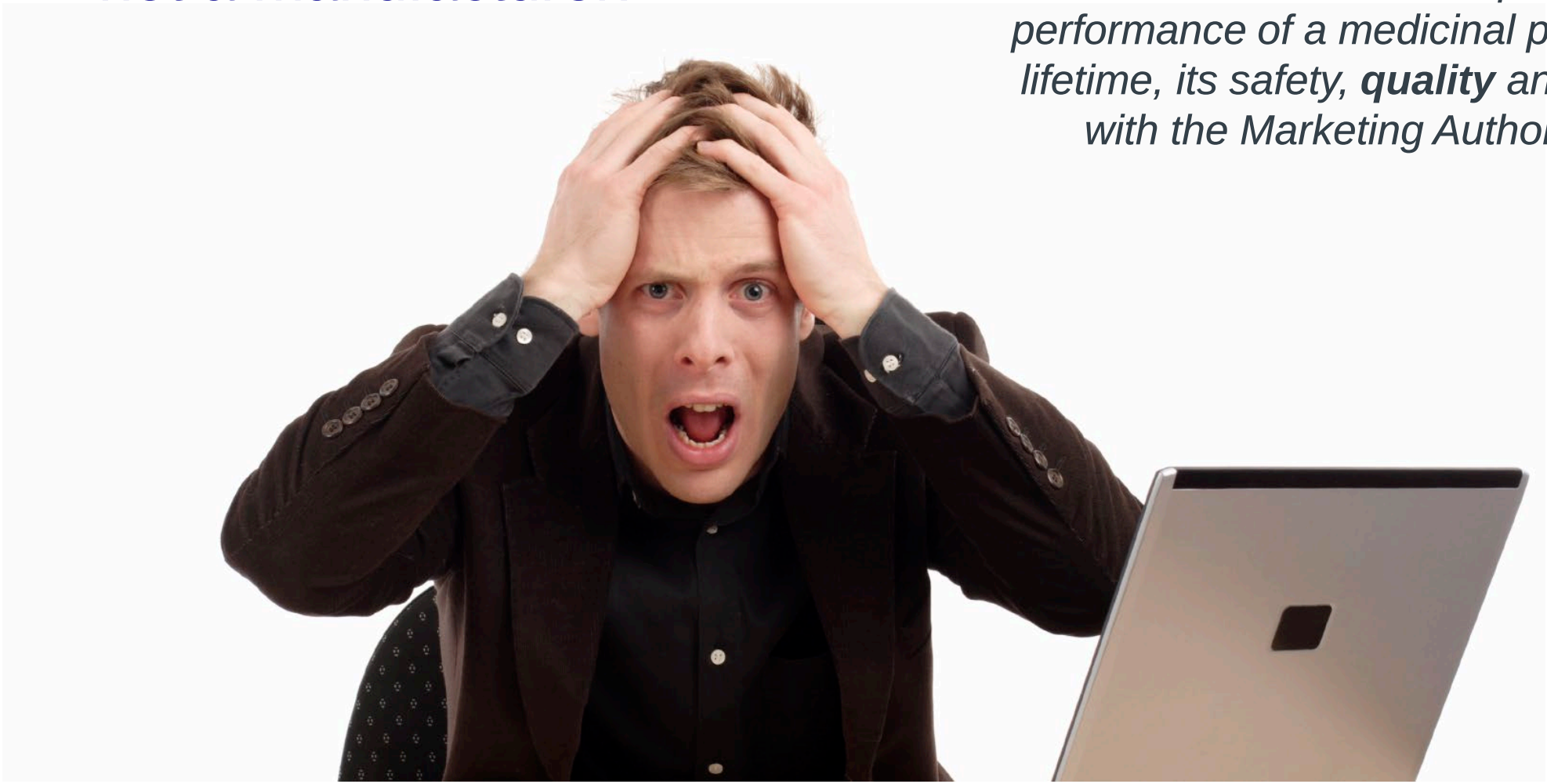
# Overview

- GMP?....But I’m a Sponsor not a manufacturer!
- So what are your Responsibilities….the 4 key areas
- Best practice for GMP Clearance

# GMP?...But I'm a sponsor not a manufacturer!

*"The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, **quality** and efficacy, lies with the Marketing Authorisation Holder (MAH)"*



Reference – PIC/S Annex 16

# GMP?...But I’m a Sponsor not a manufacturer!

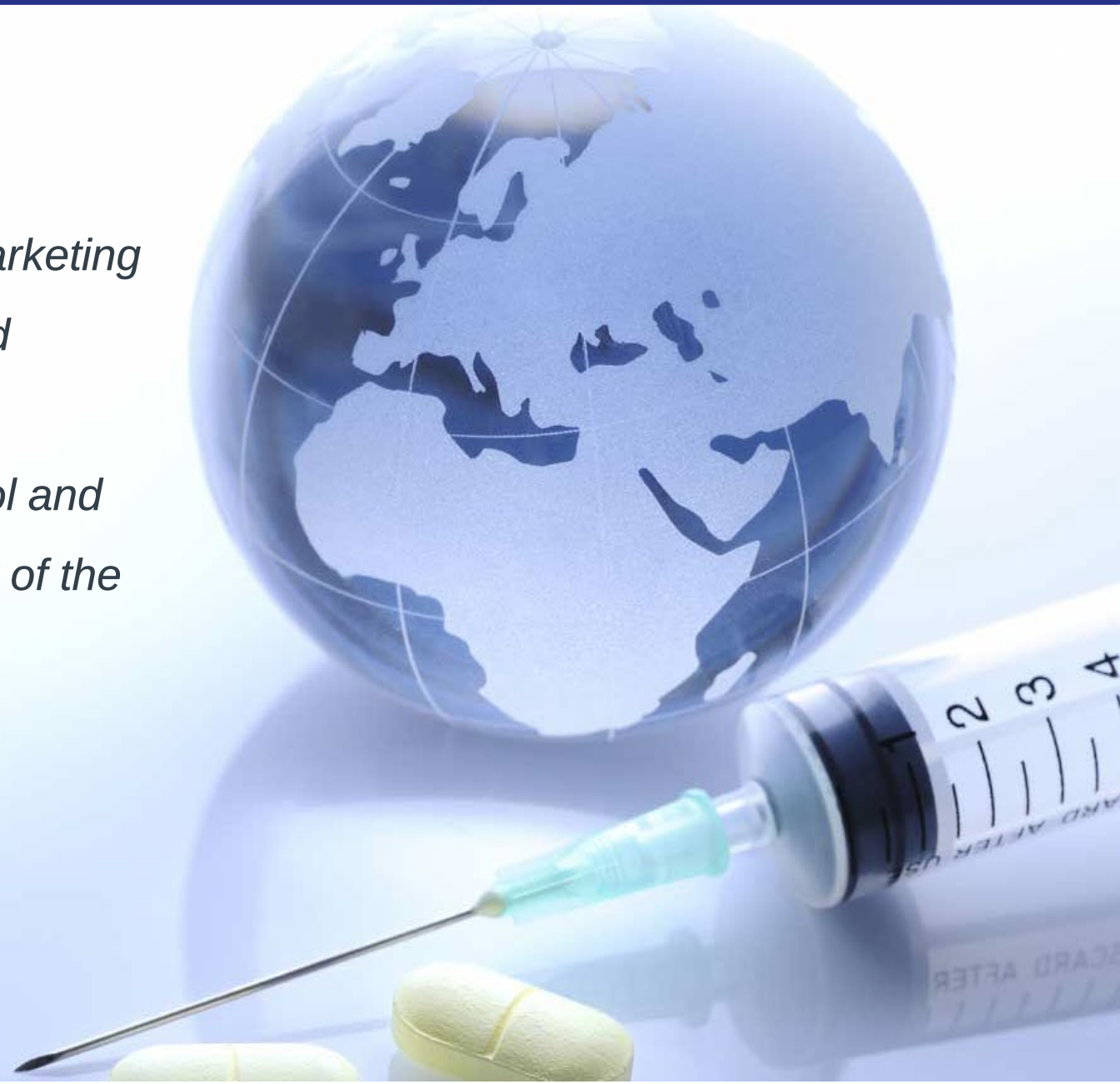
- It is acknowledged that many Sponsors are not directly engaged in the manufacture of medicines
- ***However***, the GMP guide contains several references to Sponsors and their GMP related responsibilities
- These are spread over various chapters and annexes and range from the general to the specific

**Pop quiz!**

# GMP?...But I’m a Sponsor not a manufacturer!

- Modern supply chains are complex and may consist of global organisations and shared Pharmaceutical Quality Systems (PQS).
- The GMP Guide does not provide for reduced Sponsor responsibilities even when the Sponsor and manufacturer belong to the same overall group of companies.
- Whilst certain tasks may be delegated to other groups or entities within the global organisation, the actual ***responsibilities*** may not be delegated.

*“It is assumed that the requirements of the Marketing Authorisation relating to the safety, quality and efficacy of the products, are systematically incorporated into all the manufacturing, control and release for supply arrangements of the holder of the Manufacturing Authorisation”*



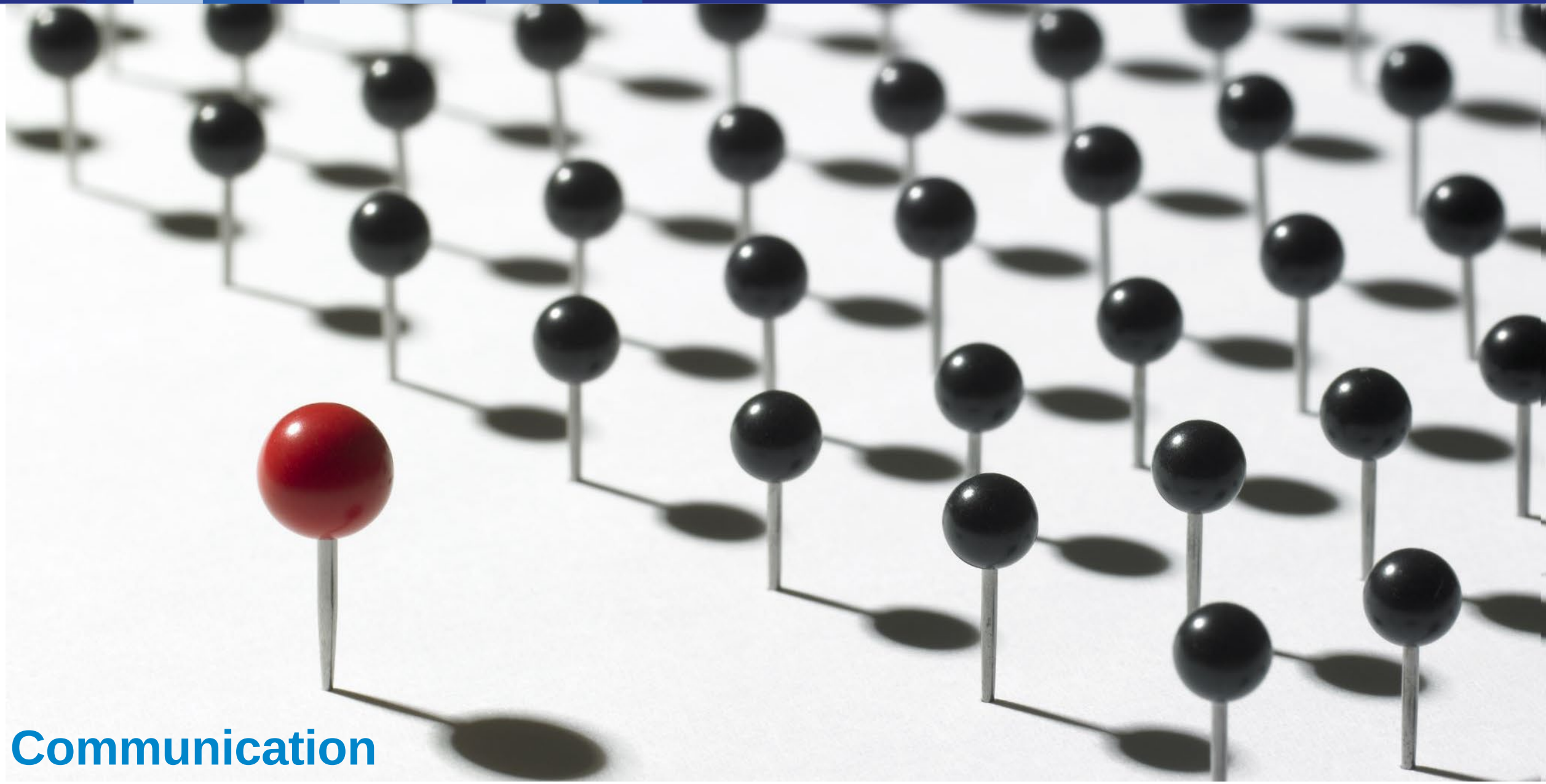
Themes

1. Communication
2. Outsourced Activities and GMP Agreements
3. Product Quality Reviews
4. Quality Defects, Complaints and Recalls

# So what are your responsibilities?

4 key areas

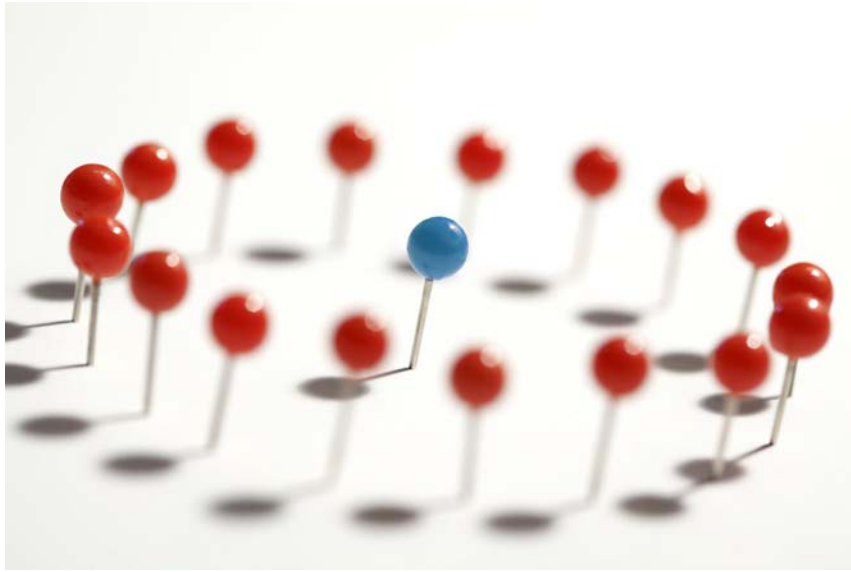
Establishing effective two-way communication processes and/or systems between Sponsors and relevant parties throughout the product lifecycle is the critical aspect underpinning these responsibilities



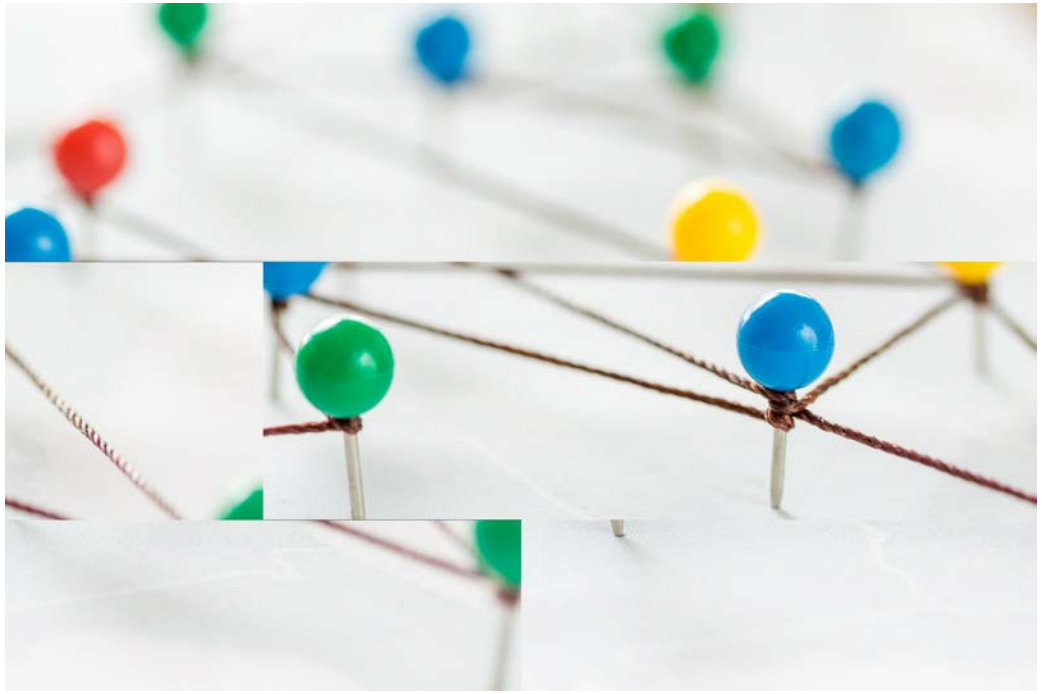
# Communication

# Communication

- Sponsors should have **effective two-way communication processes** with the following parties:
  - TGA
  - Manufacturing sites
  - Authorised Persons (APs)
- This helps ensure that:
  - Manufacturers and APs have visibility of what is registered in the MA and any commitments that have been agreed with TGA
  - Manufacturers are informed of any changes in a timely manner (packaging, labels, specifications etc.)
  - Sponsors are informed of the change management activities at the sites



# Communication



**Effectiveness and frequency of communication:**

- Sponsors should ensure their communication processes are **effective** and of the required **frequency**
- Action should be taken when communication issues arise

**Documenting communication processes:**

- How communication processes are documented depends on the relationship between the entities in the supply chain
- Complexity in the supply chain may warrant more robust communication processes

# Outsourced Activities & GMP Agreements

**“Where the marketing authorisation holder and the manufacturer are not the same, appropriate arrangements should be in place, taking into account the principles described in this chapter”**

# Outsourced Activities & GMP Agreements

- You cannot delegate *responsibilities,* but you can delegate certain tasks
- These should be described in writing and agreed to by the relevant parties
- Sponsors have a responsibility to ensure that the person or entity a task has been delegated to possess the required competence, information & knowledge to carry it out
- Not all tasks can be delegated, and certain tasks always require direct action by the Sponsor

# Outsourced Activities & GMP Agreements

Areas you should consider in your GMP Agreements include:

- **Document retention** – Given the role of certain documentation in supporting the MA, you should be satisfied with the policies and practices of the manufacturer
- **PQRs** – You should have defined roles and responsibilities for the creation, compilation and evaluation of the PQR
- **Use of Ionising radiation –** There should be agreement on the design of the radiation cycle and notification of unplanned interruptions. Document retention should also be agreed.
- **Reference & Retention samples** – Agreement should cover the responsibility for taking and storing samples, AP access to samples and the control of samples across multi-site supply chains

# Product Quality Reviews

**“The manufacturer and, where different, marketing authorisation holder should evaluate the results of the review and an assessment made as to whether corrective and preventive action or any revalidation should be undertaken”**

# Product Quality Reviews

It is acknowledged that generating the PQR primarily sits with the manufacturer.

However…….

- Chapter 1 is quite prescriptive on the Sponsor's responsibility
- There is a clear obligation on the Sponsor, when they are not the manufacturer, to evaluate the results of the PQR
- Specific reference to the need for an agreement between the parties to define the roles and responsibilities
- Delegation of this responsibility to the manufacturer should not occur

# Product Quality Reviews

Sponsors can play a crucial role in the generation and review of the PQR by:

- Ensuring **all the required information** that they may hold directly is included in the PQR (i.e. product complaints received directly from the market)
- Focussing their review on the marketing authorisation compliance
- Cross-referencing the information in the PQR with their own records for accuracy
- Reviewing the change-control section to ensure these have been adequately managed

# Quality Defects, Complaints and Recalls

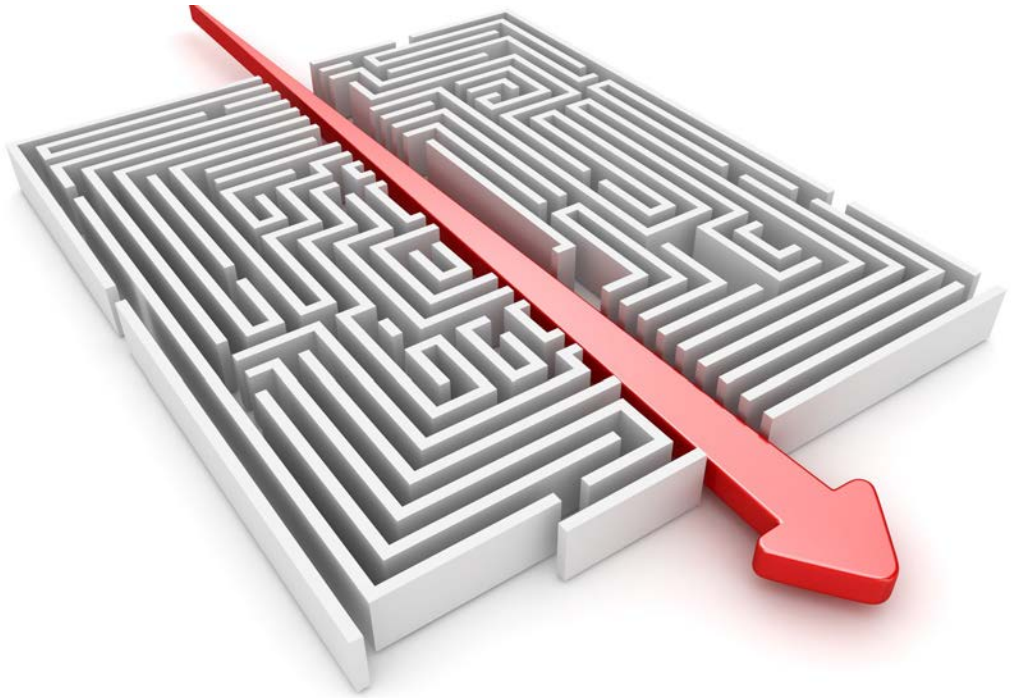
**“a contract should describe the role and responsibilities of the manufacturer, the marketing authorisation holder and any other relevant third parties in relation to assessment, decision-making, and dissemination of information and implementation of risk-reducing actions relating to a defective product “**

# Quality Defects, Complaints and Recalls

- Sponsors are required, along with manufacturers and any other party, to define and agree on roles & responsibilities
- Responsibilities to notify TGA of potential supply restrictions and/or product recalls as a consequence of quality defects
- Sponsors should ensure the contract clearly outlines the requirement for the manufacturer to notify them **in a timely manner**
- Recall management activities – particularly mock recalls and whether these should be performed

# Best practice for GMP Clearance

- Demonstrating that you have effective communication practices in place gives us confidence
- Ensure your GMP agreements adequately cover the expectations outlined here today
- Keep up to date with the changing GMP requirements that affect your role
- Prepare for GMP Clearance assessments to focus on these requirements
- Reach out to us



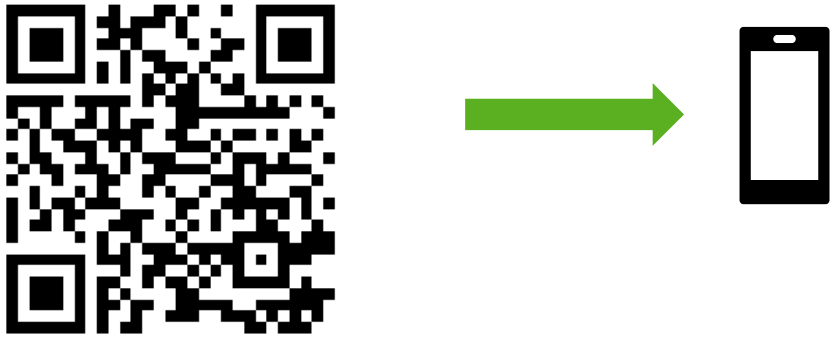
# Participate in the Q&A

## 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

Matt Davis
Senior Inspector

PIC/S Annex 1