

MEDTECH —
— **UNLOCKED**

**CROWN TOWERS
PERTH**
19-21 May 2026



AusBiotech AusMedtech 2026

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Governance, Process & Trust

In Medtech Recalls



Panel Chair: Sue Papadoulis, Director of Profile Media Communications. Profile Media is a trusted strategic communications partner with a special focus on the health tech sector. As a team of former journalists, Profile Media helps organisations build their reputation, grow their profile and broaden their credibility among audiences that matter.



Panellist: Nathan Coleman, TGA, Deputy Australian Recall Coordinator - Nathan has worked in Recalls at the TGA since 2019. His role involves objectively reviewing proposed recalls and other market actions, including the communication and action strategy. Between 2022 and 2025, Nathan managed the TGA's Recall Reforms Program, which focused on updating recall processes to reduce regulatory burden on industry, whilst still maintaining a strong emphasis on public safety and accountability.











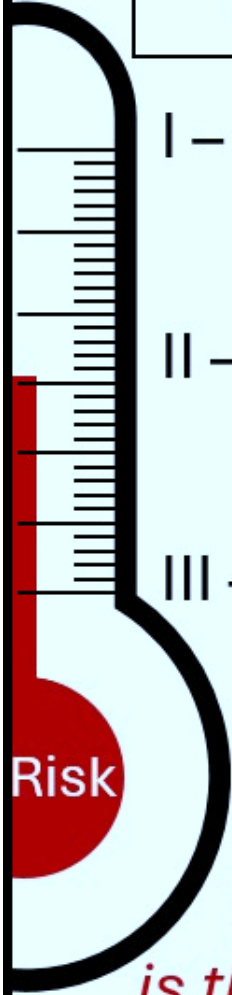
Panellist: Kylie Sproston, CEO Bellberry. A Chartered Engineer, Kylie has expertise across the full pharmaceutical product lifecycle, and has held key positions in both technical and management disciplines in the global Pharmaceutical and Biotech industries from research to global manufacturing and supply. Kylie is CEO of Bellberry, an Australian Not For Profit organisation that runs Australia's largest HREC programme. Bellberry HRECs have oversight of 42% of clinical trials in Australia run under the CTN scheme.



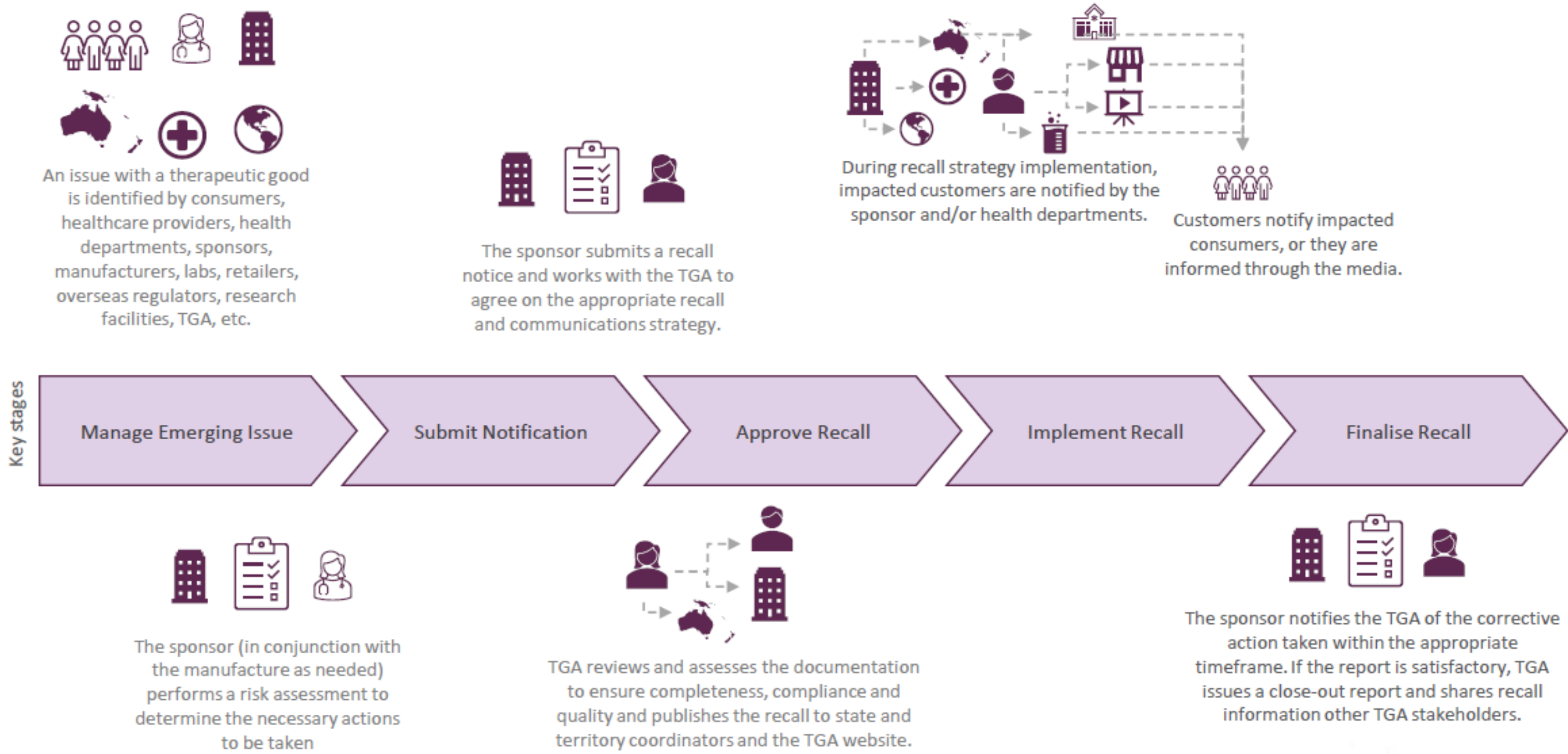
Panellist: A/Prof. Moreica Pabbruwe, EMHS, Senior Biomedical Engineer - Moreica is a biomedical engineer leading state-wide implant retrieval program based at Royal Perth Hospital. She provides critical insight into device failures and has contributed directly to major recalls including LCS Duofix, Metal-on-Metal hips, and Exactech systems.

Process

Market actions – more than just recalls

Market Action...		
"Class"	"Type"	"Level"
I – Critical	 Recall <input checked="" type="checkbox"/>	Wholesaler 
II – Urgent	 Product Correction <input type="checkbox"/>	Hospital 
III – Lowest Risk	 Product Alert <input type="checkbox"/>	Retail 
	 Quarantine <input type="checkbox"/>	Consumer 
 <p>Risk</p> <p><i>How serious is the problem?</i></p>	<p><i>How will the problem be fixed?</i></p>	<p><i>Who needs to know?</i></p>

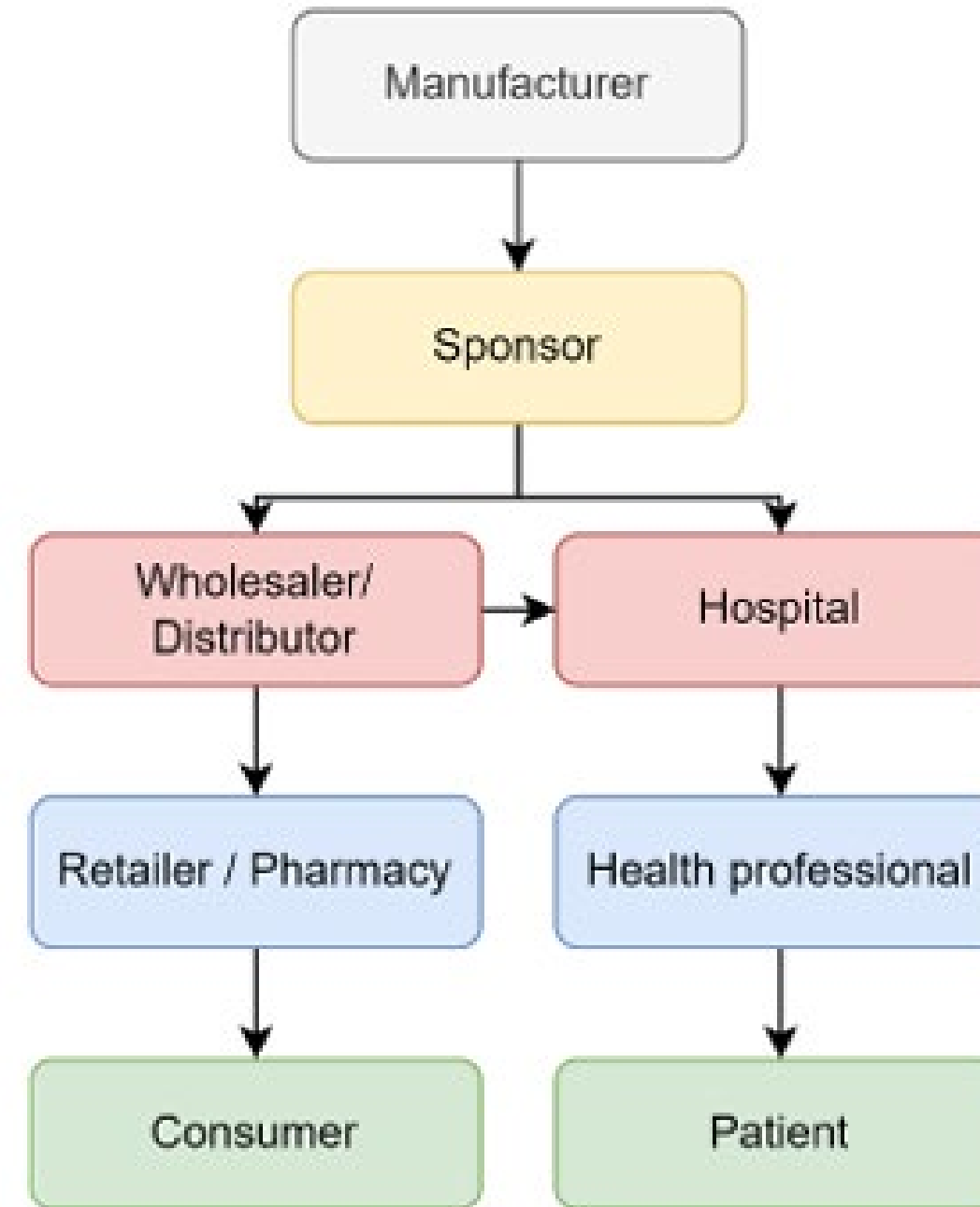
Process



Process

Everyone has a role to play in the recall process

- The TGA
- Sponsors and suppliers
- Wholesalers, distributors, and retailers
- Hospitals and health professionals
- Patients and consumers



Public notification & recall of therapeutic goods

If sponsors do not comply with our recommendations or procedure, the *Therapeutic Goods Act 1989* includes legal powers and processes that allow the TGA to mandate therapeutic goods recalls

Medical devices: Chapter 4, Part 4–9, s41KA – 41KD.

Medicines and other therapeutic goods (OTGs): Chapter 3, Part 3–2, Division 2A, s30EA – 30ED.

Biologicals: Chapter 3, Part 3–2A, Division 8, s32HA – 32HE.



Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 87

Compilation date: 14 October 2024

Includes amendments: Act No. 39, 2024

This compilation is in 2 volumes

Volume 1: sections 1–41A
Volume 2: sections 41B–69
Endnotes

Each volume has its own contents

Clinical Trials still operate under TGA Procedure for Recalls, Product Alerts and Product Corrections.

But...

How do these apply when the purpose of the clinical trial is to **assess the unknown**?



Sponsor role is critical, and includes:

- Understand regulatory requirements in the specific scenario
- Forward planning for the unknown – including planning for adverse events (expected and unexpected)
- Robust safety monitoring infrastructure and expertise, including plans for clinical response, investigation and escalation
- Forward planning for the device lifecycle, not just the duration of the clinical trial
 - Participant considerations – and fully informed consent
 - Risks associated with removal
 - Risks associated with retention
 - Governance and responsibilities in both scenarios above
 - Much easier to plan for the hypotheticals ahead of time rather than in an emergency scenario
 - Consider and contract for institutional arrangements, including insurance
 - Must consider capacity for immediate response, as well as what can be a longer investigative and recovery process



2009–2010 | LCS® Duofix™ Femoral Knee (DePuy)

Trigger: Early loosening and high revision rates

Retrieval findings: Microscopic manufacturing debris → accelerated wear, metallosis

Regulatory action (AU):

- July 2009: Surgeons report failures
- 24 Jul 2009: TGA-approved recall
- Jan 2010: ARTG cancellation

Trust inflection => Clinician-driven signals acted on relatively early

✓ **Trust reinforced**



Retrieval analysis translated surgeon concern into regulatory action; trust reinforced through responsiveness.

2003–2010 | Metal-on-Metal Hips (DePuy ASR and others)

Trigger: Registry-reported high revision rates

Retrieval findings: High wear debris, cobalt/chromium release, ARMD, pseudotumors

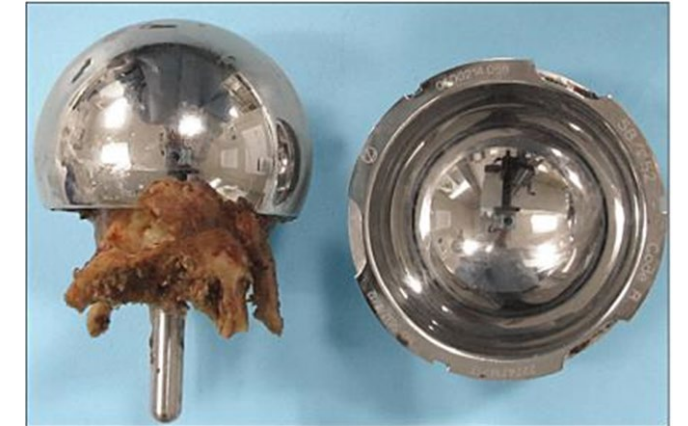
Regulatory action:

- AU/UK registries flag failures (2007–2009)
- Aug 2010: Global recall of DePuy ASR

Trust inflection: Significant delay between evidence and recall → erosion of trust

Retrievals explained why patients were failing, but recall followed years of data accumulation—key lesson on timing and governance.

⚠ ***Trust eroded***



2021–Present | Exactech Hip, Knee, Ankle (and Shoulder) Systems

Trigger: Packaging non-conformance (oxygen barrier failure)

Retrieval findings: Oxidised polyethylene, accelerated wear, early osteolysis—design intact but system failure

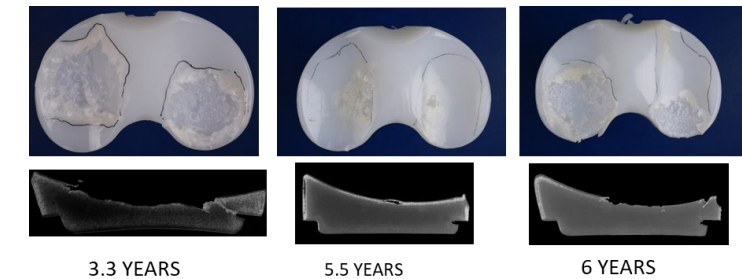
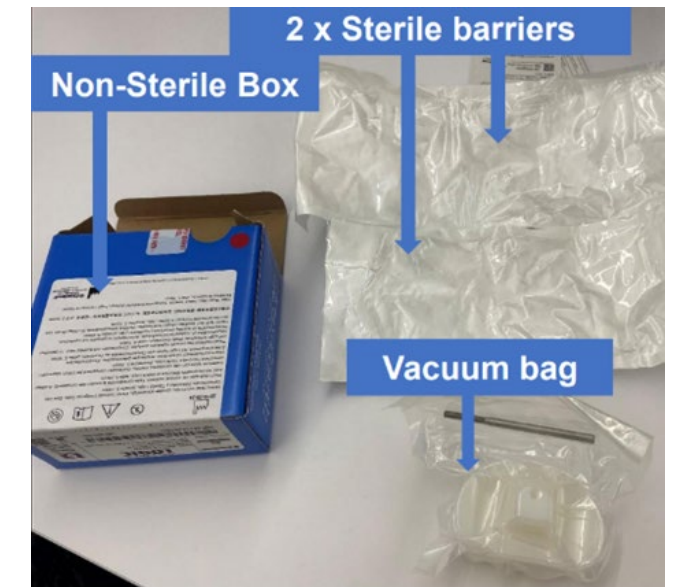
Regulatory action:

- 2021–2024: Progressive recall expansion
- 650,000 devices affected globally

Trust inflection: Transparency improved, but scale raises systemic confidence questions

Modern example of recalls driven by materials degradation and supply-chain oversight, not implant concept

Trust under strain



Australia

- Registry + retrieval-informed action
- Earlier decisive recalls
- Clinician input central

Global

- Manufacturer-led timelines historically
- Evidence acknowledged late
- Shift now toward proactive surveillance

Trust in implants depends on how promptly evidence from retrievals and registries triggers regulatory action

Recalls are rarely sudden events:

 **they are delayed acknowledgements of evidence. Retrievals often hold the missing truth**

 ***they mark the moment evidence can no longer be ignored***

Issues Management – 4 Pillars

1. Preparation

Build the infrastructure before anything goes wrong.

Issues plan, roles, escalation
Scenario planning + holding statements
Spokesperson training
Monitoring + early detection
Stakeholder relationships in place

Issues Management – 4 Pillars

2. Transparency

Say what you know, when you know it.

Be open, honest, available

Share facts early

Avoid speculation

The public forgives mistakes, not deception

3. Accountability

Own the issue and act quickly.

Acknowledge the situation

Speed: minutes, not hours

Apologise sincerely

Show what you're doing to fix it and prevent recurrence

4. Credibility

Align words, actions and evidence.

Consistent messaging
Verifiable facts
Competence and control
Right spokesperson
Follow-through on commitments

Issues Management – 4 Pillars




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Thank you!
Connect with me -
Sue Papadoulis

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