

ABSANZ

29 July | Melbourne

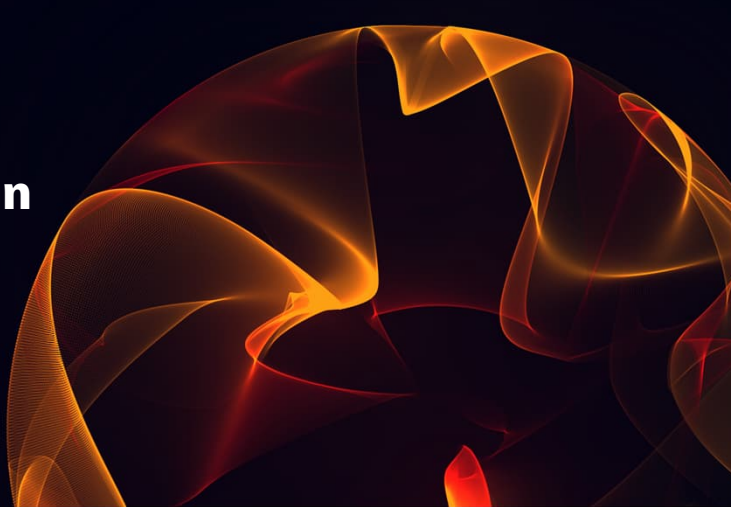
Derisking Early Design in Uncertain Futures

Risk-Informed | Scenario-Based | Adaptive

Speakers: Lydia Ginn & James Downing

Jacobs

Challenging today.
Reinventing tomorrow.



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Why Briefs Are Under-Defined?



01
Operational structure aligned with emerging science

02
Time and funding for briefing is constrained

03
Scope boundaries and interfaces are unclear

04
Competing priorities of stakeholders / Governance gaps

05
Lack of available users/operators

06
Incomplete capture of driving principles

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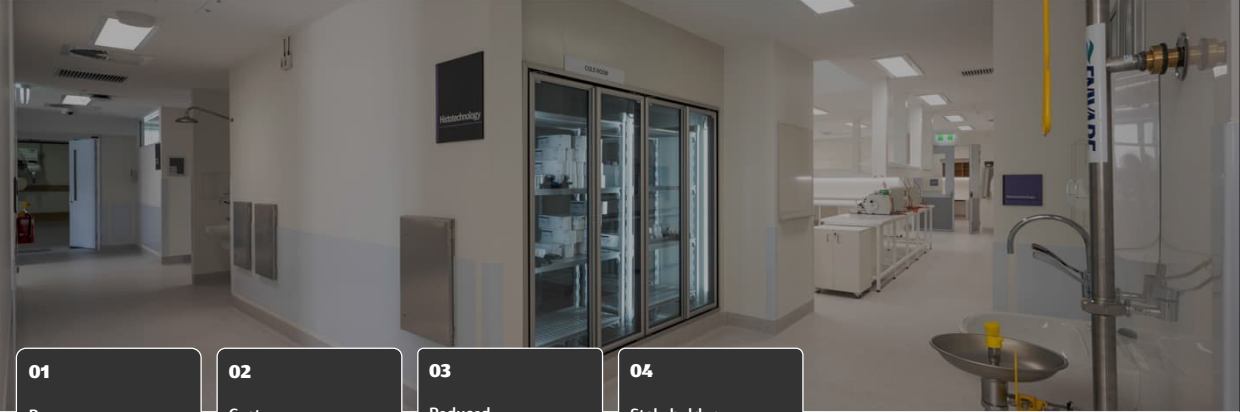
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Consequences



01

Program delays

02

Cost overruns

03

Reduced quality

04

Stakeholder dissatisfaction

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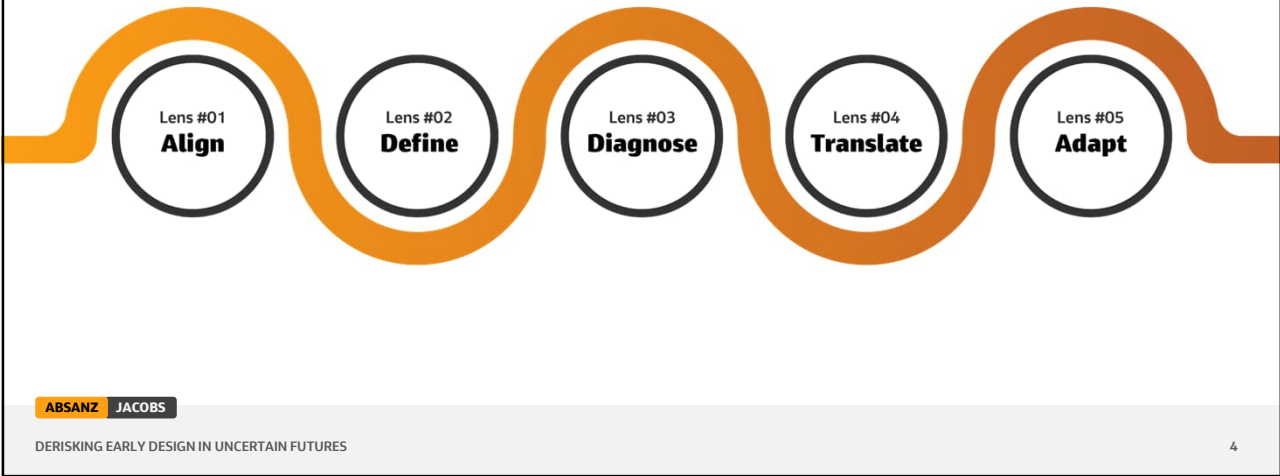
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Managed Uncertainty



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Setting the Foundation

Lens 01: **Align****VISION**

- Define project goals
- Agree success criteria
- Align scope & budget

**PEOPLE**

- Identify decision-makers
- Vision workshops
- Layered stakeholder engagement & challenge team

**EVIDENCE**

- Benchmark against precedents
- Validate technical assumptions
- Industry best practice

**COMMUNICATE**

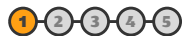
- Concise summaries
- Visual engagement
- 3D walkthroughs

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Governance, Co-Creation & Control

Lens 01: **Align**

Micron Team Member Center, Manassas, Virginia Campus – Micron Technology, Inc.

- Lifecycle impact
- Place & context
- Long-term value

**Sustainability
& Community**

- Targeted engagement
- Share understanding

**Stakeholder
Alignment**

- Gateways approvals
- Traceability
- Assumptions

**Decision
Control**

- Locks intent
- Aligns scope

**Return
Brief & Basis of Design**

Alignment builds upward - from clarity to outcomes

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Minimum Viable Brief

Lens 02: Define

Minimal Viable Brief

- Containment level
- Facility purpose
- Process flow
- Typologies
- Equipment
- Biosecurity systems

Lock the critical decisions –
allow the rest to evolve



Government Laboratory, Canberra

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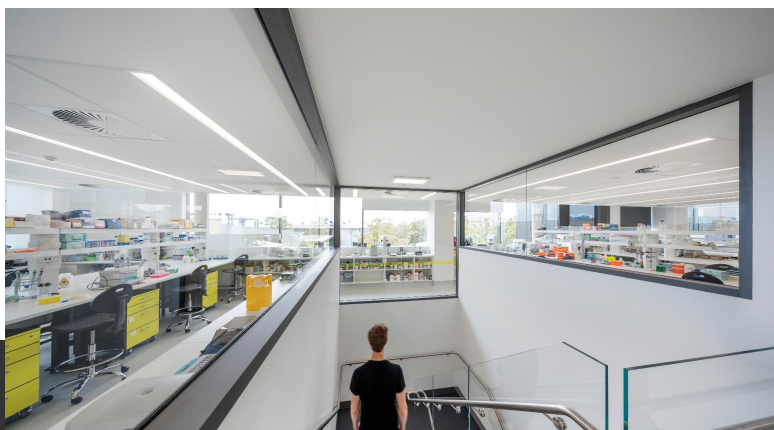
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Common gaps in early biosafety briefs

Lens 03: Diagnose the Unknowns



Molecular Horizons Unit, University of Wollongong

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Common gaps in early biosafety briefs

- Organism profiles
- Workflows
- Throughput
- Waste and decontamination
- Security

Invest early in uncertainty, because
it's far more expensive later on

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Scenario-Based Briefing

Lens 04: Translate



Molecular Horizons Unit, University of Wollongong

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Scenario-Based Briefing & Designing for Multiple Futures

- Base
- Surge
- Future

**We don't design for one future;
we design for a range."**

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Flexibility - Done Right

Lens 05: Adaptive Design Logic

Reality check

**Not everything
is flexible:**

- Containment
- Building Services
- Space & Structure

Method

- Test ideas and concept early
- Modular systems
- "Kit of parts" thinking

**The goal isn't maximum flexibility.
It's the right flexibility at the right cost.**



RPA Pathology, Sydney – Refurbishment

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Case Study: Advanced Therapy Medicinal Product (ATMP) Facilities

Design solution:

Parallel flexibility

- Not one flexible space — but multiple specialised suites in a flexible system

Multimodal Suite

- Single operating suite that supports multiple manufacturing processes over its lifecycle
- Rapid transition between modalities over a year

Multimodal Facility

- Concurrent processing of multiple modalities within the same facility
- Specialised suites for each modality, supported by shared infrastructure

What problem they solve:

- Rapidly evolving therapies (cell & gene therapy & RNA therapeutics)
- Changing manufacturing modalities



LandmarkBio, Collaboration and Innovation Centre, Massachusetts

Key insight

Flexibility comes from system - specialised suites supported by shared infrastructure that can adapt as needs change

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Case Study: Advanced Therapy Medicinal Product (ATMP) Facilities

Compatibility Assessment – What Works Well in Multimodal Suites

	Gene Therapy / Viral Vectors	Batch Monoclonal Antibodies	Delta	Pre-Investment
GMP Requirements	Grade C with Localized Grade A	Grade C with Localized Grade A		
BSL2 Containment	Yes	No	Containment oversized for mAb – airlocking may be more complex than needed	Considerations for integration of VHP for product changeover
Equipment	Large Scale Fixed and Portable Equipment	Large Scale Fixed and Portable Equipment	Would need some unique equipment for Downstream Processing	
Ceiling Heights	3m with High-Bays up to 4.5m	3m with High-Bays up to 4.5m	Larger Buffer Prep/Staging Space for mAbs	Additional warehouse, buffer prep, logistics and staging space for mAbs
Drains and Liquid Waste Systems	Biowaste, and pH Neutralization	Biowaste, and pH Neutralization		
Utilities	Major – Air, CO ₂ , and O ₂	Major – Air, CO ₂ , and O ₂		

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Key Takeaways

Plan the briefing process upfront

Map stakeholders, engagement activities, approvals, and decision timelines.

Set the scope to cover many facets

Cover strategic, functional, operational, technical, and design requirements

Establish cost early

Use assumptions, typologies, and benchmarks to test affordability and inform budgeting

Document & publish the brief

Create a clear baseline for design, approvals, and decision-making.

Manage change transparently

Record assumptions, departures, updates, and approval pathways from the outset.

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