



Planning and Managing Expansion Projects

Balancing the Risks and Opportunities

March 2016



1



The challenge...



How the owner requested it



How the project manager understood it



How the architect designed it



What the contractor bid



How the marketing team described it



How the contractor installed it



How the project was documented



How the owner was billed



When it was delivered



What the owner really wanted

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Risks and Opportunities ...

Opportunity

- Business case generally sound

Risk = Inability to plan

- Project 1.5x budget and 2x time.
- Unable to commission HVAC – compromise
- Repeat validation – delay 4 mths/loss of face
- Unable to launch – regulatory/laboratory approval
- Failure to provide adequate segregation
- Delayed 6 mths - inability to produce stable product
- First shipment sent back from UK – border clearance
- Critical plant failure 6 months after start-up



Scope and Uncertainty

- Address scope & uncertainty early
- Plan to succeed – not just “hardware”
- **Planning ≠ Designing**
- Scope Plan ~ 1% cost
(high value-add potential)
- Project cost $\pm 25\%$
(contingency)
- Framework for decisions
- **Be Honest and Realistic**





Project Scope Document

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Risks and Sensitivities

Risks

- Your experience/knowledge
 - Replication at scale
 - Resource capability
- Base cost estimates
 - Baseline cost data
 - Optimistic budget or tendering
- Resource availability
 - Who you want when required
 - Fall-back position/affordability
 - Cost of Resource
- Process maturity/capability



Risks and Sensitivities

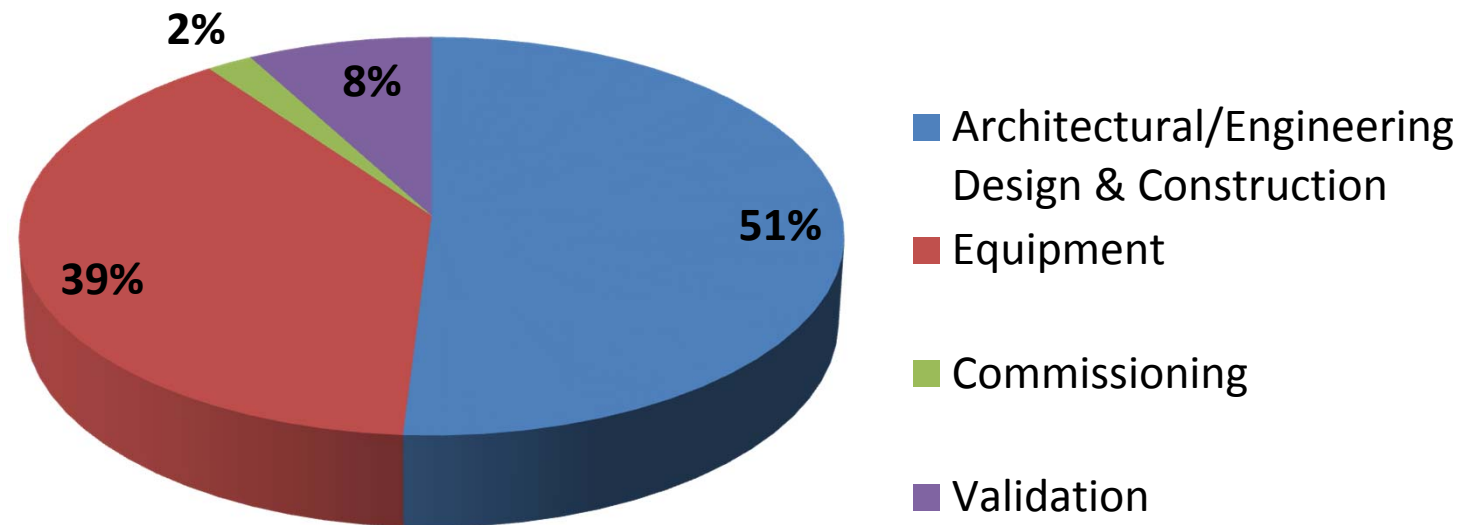
Sensitivities

- Time → cost creep
- Client expectations/changes
- Key assumptions made
 - Design completed in time
 - Resource/equipment timing
 - Test development completed
 - Regulatory approvals
- Significant cost drivers



Project Costs – typical

- Poor baseline data in NZ
- Not a dairy factory
- Facility is “functional” in the design

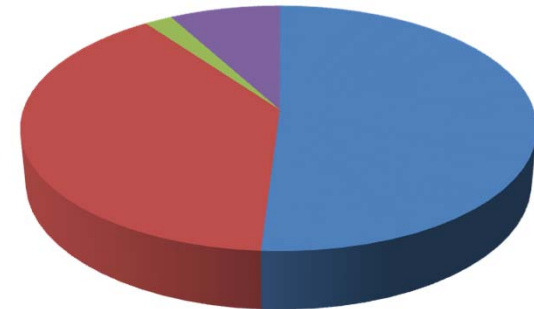


Source: NewWayz project data



Project Cost factors

- Base cost “build” costs vary
- C,Q,V cost varies by project type
- Benchmark data from peers
- Sector data
- Dairy industry + C,Q,V

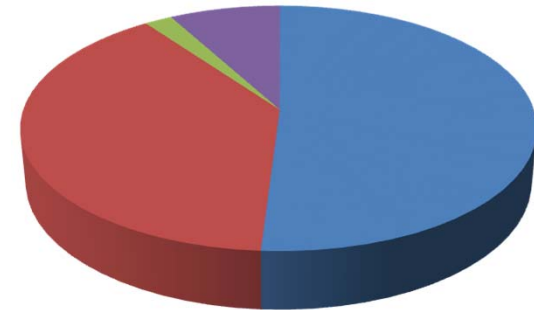


Source: NewWayz project data



C, Q & V

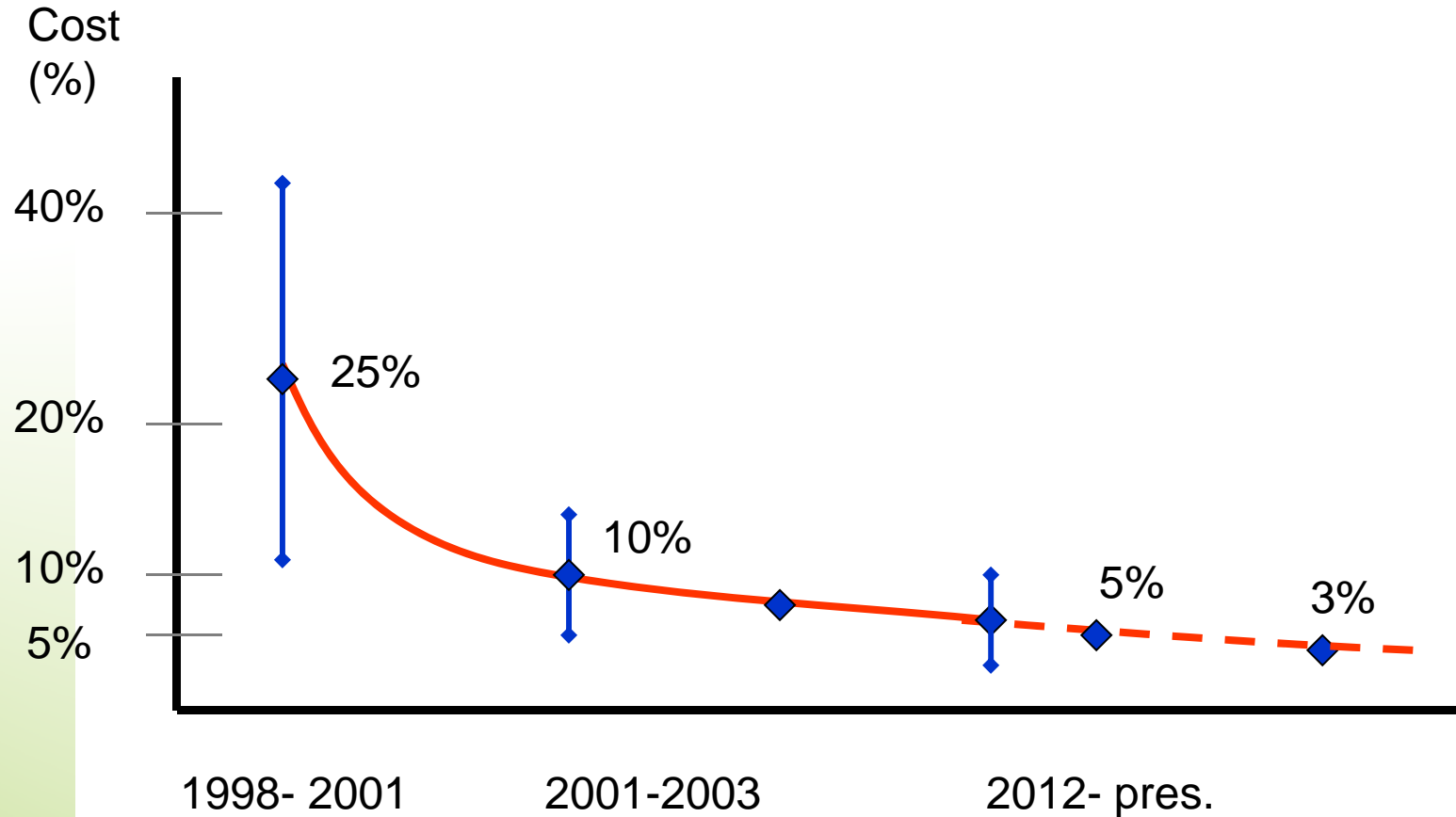
- Enhanced vendor documents
- Qualification = systems suitable for use
- Validation = process capable
 - More document rigor
 - Design reviews
 - Product – proof of concept
 - Contractor quality
 - Supporting resource



Source: NewWayz project data



Project Costs – CQ&V “premium”



Source: ISPE Great Lakes Chapter (2013)

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Project Delivery Planning

- Approx 2.5% commitment
- Plan to $\pm 10\%$ contingency
- User requirements
- Design brief/layouts
- Identify key project partners/options
- Concurrent with design – a living plan
- Further definition around
 - Resources
 - Work breakdown

Key insight for Project Team (not all SMEs)



Balance Cost and Risk

Want to deal with uncertainty....

Possible Strategies - either

- a. Risk sharing (lower cost)
- b. Risk averse (higher cost)

For both approaches

- Demand accountability
- Be diligent
 - NZ providers often lack experience
 - "Number 8 wire" mentality
 - Overseas support can be problematic

Approach 'a' (eyes wide open) often best for NZ



Balancing Risk

- Contracts/Specifications and RFQs
 - NZS 3910/FIDIC contracts
 - Understandable requirements
 - Technical requirements
 - Define inspection & testing expectations
- Retentions and guarantees
 - Liquidated damages pros/cons
- Consultant/Contractor selection
 - Taking of “contingency”
 - Diligence pays – does their experience fit



Balancing Risk

Generally best to:

- Engage early
 - Be prepare to own/pay for design to ensure competitive bids
- Manage commercial expectation (tender process requirements)
 - “Pitch” tenders
 - Business expectation of tender process



Reducing Cost

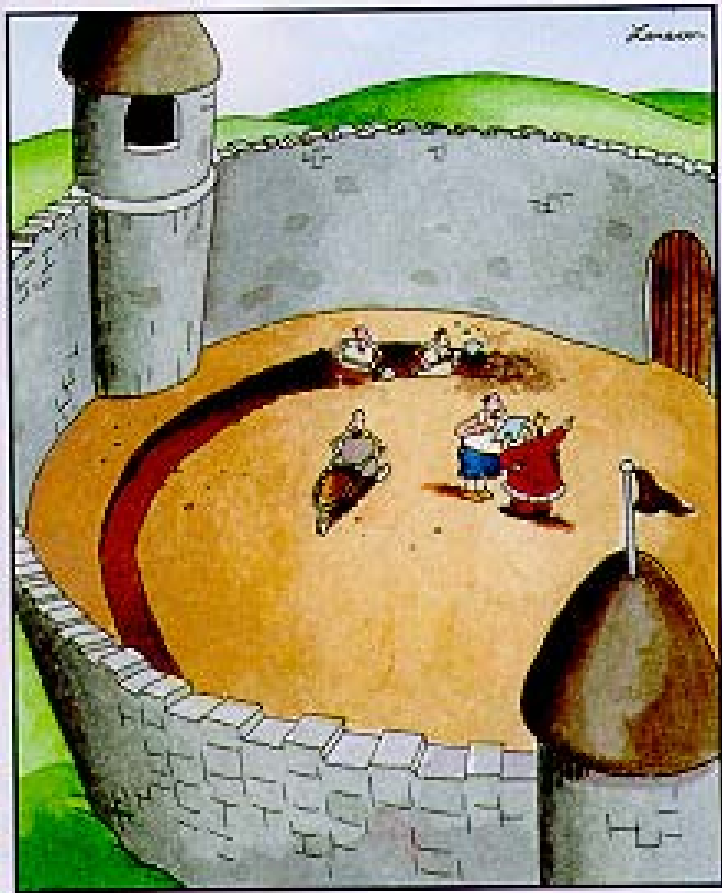
- Avoid jargon or unfamiliar standards
 - ASME BPE, GMP, FDA, ISPE
- Be clear on cost/quality decisions
- **FOCUS:** Facility is often is low risk compared to equipment and process
- Retain control of C,Q&V
 - Practical completion/completion statements

Generally best to:

- Leverage vendor deliverables/documents
- Introduce a Project Quality Plan early
- Utilise Inspection and Test (ITP) program



Review deliverables



- Important where design is delegated
- Design Review is a “gate” for scope.
- Review strategies
 - Simple requirements
 - Traceability matrix
 - Design/functional summaries

Demand attention

A heated exchange resulted between the King and the moat contractor....

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Demanding Attention

- Key owner personnel
- Brief reviewers on budget constraints.
- Scheduled gates as part of the program
- Document review/approval
- Review Vendor's understanding
 - peer review if necessary
 - do not assume alignment
- Good Change Mgmt (Scope Document)



Requirements – fact and fiction

- URS ≠ Procurement Specification
- Validation/QA expectations
 - not designers – or owners
 - applicability of overseas experience
- Presume GMP = higher specification
- “FDA approved”, or “GMP compliant”
- Regulations are not prescriptive
 - Expect high degree of process understanding
- MPI vs GMP (assumed vs measured risk)



Customer Requirements

- The requirements “game”
- Often commercially biased
- Good QA/SMEs to defend standards
- Supplier guidelines often exist
- Auditor interpretation

Clarify early if they have specific

- Standards or needs you may not understand
- Compliance requirements

Positive relationships are rewarding



Leveraging Vendors

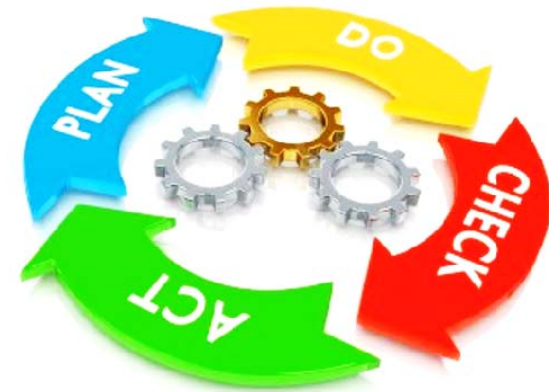
- Understand vendor systems – use them to assist with compliance
 - Useful for stick built and computer system projects
- Suitable standard of documentation required
 - Appropriate approval pre and post use
- Ensure the system delivers to expectation...**Its actually their job**
- Pros/Cons of vendor IQ/OQ

Requires a willing vendor and adequately trained staff.



Project Quality Plan

- Based on ISO QMS concepts not GMP
- Delegate quality to the project team
- Define responsibilities
- Clarify requirements
- Content
 - Document management
 - Change control process
 - CAPA/defect
 - Self Inspection
 - TRAINING





Inspection and Testing Program

- High level plan and sequence
- Must be specified
- Inspections and Tests
- Most consultants/contractors have these processes
- Levels of rigor commensurate to risk
 - [1] Formal approval pre/post event
 - [2] Witness and sign vendor documents
 - [3] Contract deliverable/approved process
- **Evidence over elegance**



Completion

- NZ vendors and visible completion
 - Not the normal situation e.g. calibration
 - Typically unstructured
 - Most vendors will co-operate
 - End of the job attention
- Project Quality Representative
- Operational requirements
 - Spares, especially long lead time
 - Maintenance/service agreements
 - NZ support capabilities
 - "Configuration" management
 - Training



Completion

- Strategies for success
 - **Manage the contingency**
 - Separate focus on C, Q and V
 - Worked examples
 - Create a habit of completion - incentives
 - Linked to progress payments
 - Commissioning and handover plan/schedule
 - Sign the guarantees early/close contracts

Manage the Risks...



Thank You

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