Learning from the Unique Challenges of Start Ups
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Getting Started

• Typical Start Up constraints
  • Investors reward *results*
  • Tight budgets, tighter time frames
  • Subject matter experts on product’s technology and science, not Risk Management
  • (Perhaps) Little commercial GMP expertise among staff, including Design Controls
Perception vs Reality

If a picture is worth 1000 words, a prototype is worth 1000 meetings

@IDEO

Build something users love, and spend less than you make

Paul Graham

The critical ingredient is getting off your butt and doing something. The true entrepreneur is a doer not a dreamer.

Nolan Bushnell
Many Resources, But Enough?
A Challenge to the RM Experts: Why Don’t We Have … ?

• Better communication - making a business case for risk management
  – Clear analysis of ROI that “connects” with investors?
  – Same problem facing QMS compliance staff

• Better resources for first-timers
  – Start Ups need tools to get started early before they can afford a Risk Management specialist
  – Real world examples and Best Practices in the public domain. “This is what it really looks like”
Don’t ask why, ask why not:

• Make risk management less of a specialist’s domain?

• Develop risk management checklists to support inexperienced organizations?
Complicated, Not Impossible

• More guidance for
  – Specific high risk product categories
    • Example - life sustaining cardiac & respiratory devices
    • As with CDRH Hospital Beds Guidance and ISO 14971, Annex H - In Vitro Diagnostics
  – Combination product risk management
    • Drug-delivery and other combinations
    • Development era and post-market in combination products are particularly complex