

Medical Devices Regulation

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Experience as a contract supplier – what are the key factors for assisting clients meet regulatory requirements



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Australian Medtech

An overview of the Australian industry; size, employment and capability with Supplier Compliance in mind.

Outline of the Australian Medical Device and Diagnostics Industry

- Of the order of 650 medical device and diagnostic companies in Australia
- Approx 50 of those are ASX or other listed companies
- Exports of the order of \$1.4 billion
- 90% of the product manufactured in Australia is exported
- More than 10,000 people employed
- 80% of device companies in Australia have fewer than 20 people.
- Not enough “serial offenders”
- TGA say they audit between 90 and 100 Medical Device companies in Australia

Outline of the Australian Medical Device and Diagnostics Industry

- **Tier one** - Companies with large markets, products in the market, existing sales and strong revenue - Cochlear, Resmed, CSL, Ellex Medical Lasers
- **Tier two** - Companies with large markets, existing sales or products just entering markets and positive outlook – Universal Biosensors, Fairmont Medical, Acrux
- **Tier three** - Potential large markets, products in pipeline, funding to proceed, regulatory processes in progress, still some unknowns
- **Tier four** – A market, don't know what they don't know, funding an issue, regulatory approvals required (not started) and a lot of unknowns

Today's topic applies to ALL four of these categories

Outline the Australian Medical Device and Diagnostics Industry

- Those companies who do everything in house – non existent
- Those who use suppliers who only serve the Medical technology sector
- Those who use suppliers who see Medtech as a large percentage of their business
- Those who use suppliers who see Medtech as a small or zero percentage of their business

Today's topic applies to the last THREE of these categories

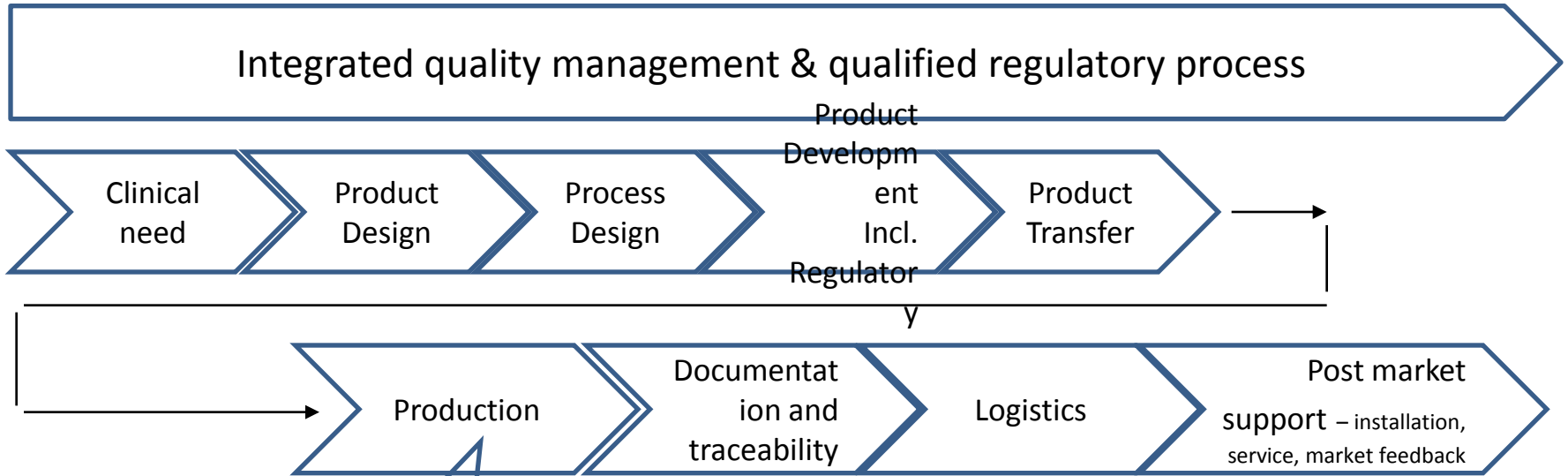
Why Outsource?

Companies decide to outsource for many reason, what are some of those reasons?

Reasons that Companies Outsource

- Not a Core business activity
- Access skills and capabilities that the organization doesn't have in house
- Heavy workload
- Cost
- Space
- Size of the Company – 80/20 rule, more than 80% of device companies in Australia have fewer than 20 people.

Steps in the Value Chain



Supplier evaluation is not just about buying parts – its more than that!!

All Companies need to outsource, so get used to it!!

Outsourcing Tips

Some tips to consider when developing a process and when talking with potential suppliers to evaluate their capability.

Outsourcing – Tips for your internal system

- Do it well because your success will be dependant on it
- Understand what makes a good supplier for you – it varies from company to company
- Develop a criterion for “what makes a good supplier” for you
- Standardise your process for supplier selection to allow comparisons within and outside specific sectors
- Develop a simple standard “Service Agreement” that includes all commercial AND regulatory terms

Outsourcing – Tips when talking with Supplier

- Do they really have the capability you require?
- Make sure they have a customer focus, do they communicate well, do they have integrity etc. – Cultural Alignment
- Do they already have accreditation to a quality standard? ISO13485 the GOLDEN standard!
- Are they: thorough, have a proved track record?
- On time delivery, after sales follow up (do they deliver and forget)

Outsourcing – Tips when talking with Supplier

- Level of documentation both product and process
- Transfer of IP – don't get caught!
- Who will be your contact? Don't fall for the lawyers and accountants trick where you speak with Partner but the junior does the work. You are important no matter what size project and you need to have the right people on the job
- PRICE – sometimes it's NOT all about price!! - China example

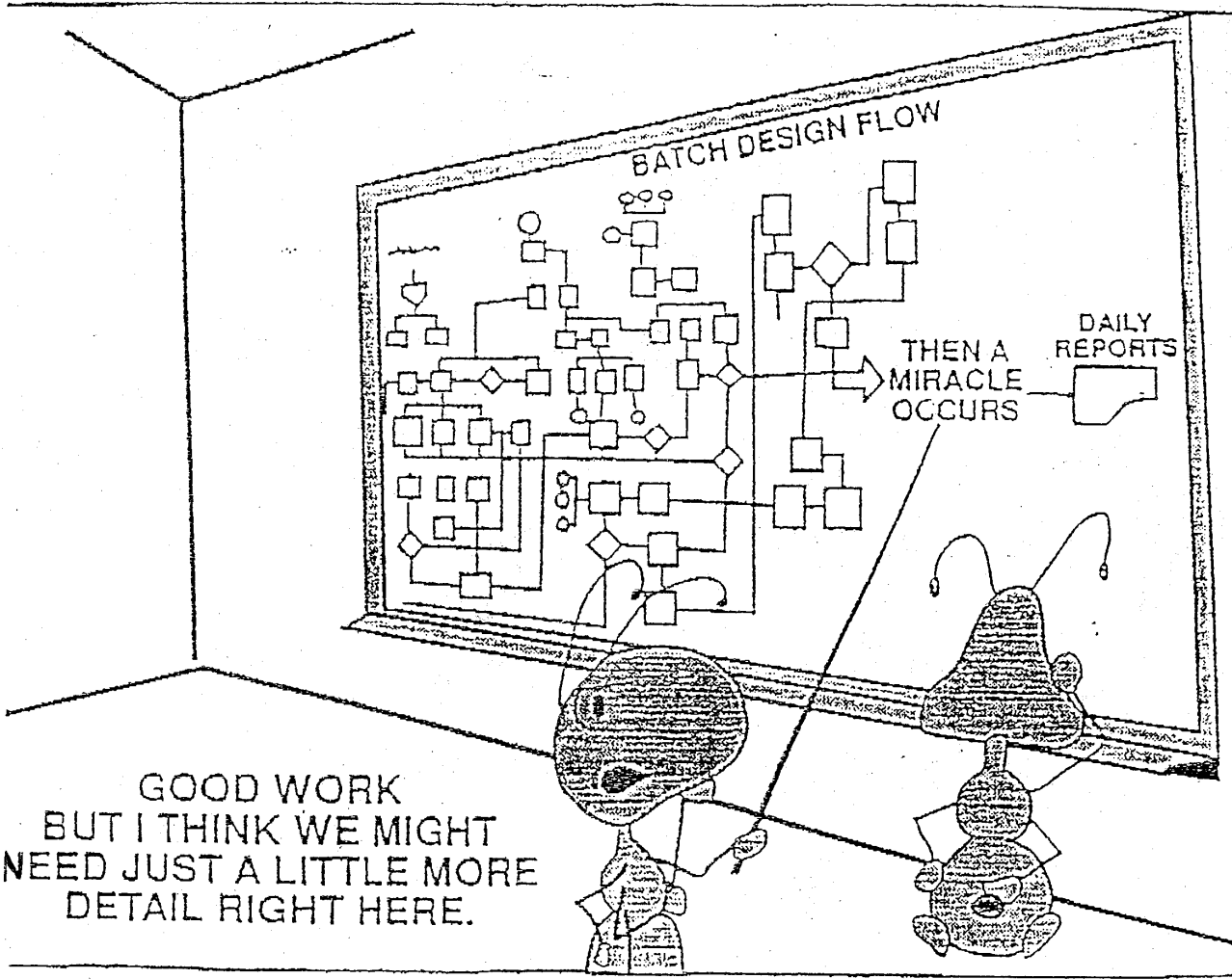
Wrap Up

Summary of the key thoughts.

Outsourcing – WRAP UP

- Supplier evaluation may “make or break”
- You need to be able to work with them as well as get the result - most cases a medium to long term relationship so you need be aligned technically as well as culturally
- Don't trust them get them to prove it
- If they don't write it down they don't do it – plenty can talk about Doc control, Change Control etc. but do they do it??
- Accreditation is king

Non Accredited Supplier – Should you really use them??



Thank You.



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