



**AusBiotech2011**

AUSTRALIA'S BIOTECHNOLOGY CONFERENCE



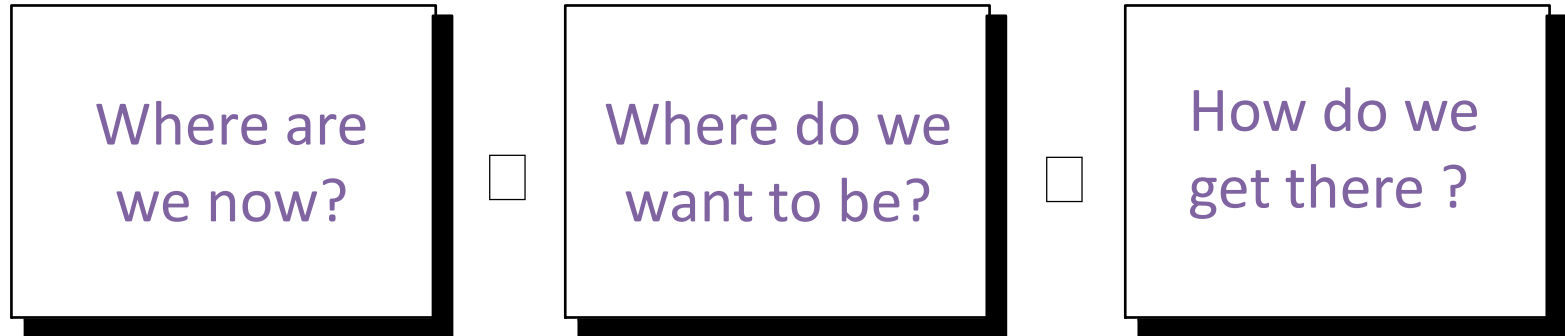
**REGULATORY  
PLAN**

**Foundation for Success**

David Harrison, General Manager

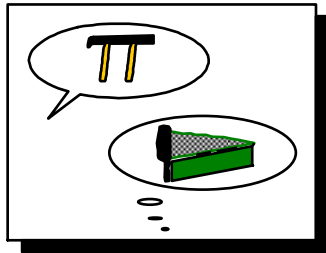


## Traditional Planning Approach

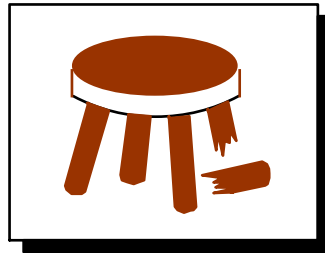


Source: The Positioning Group

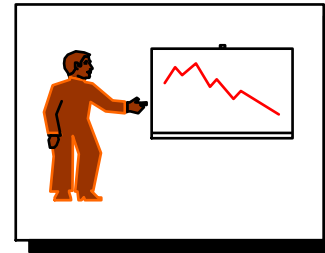
# Why Products Fail



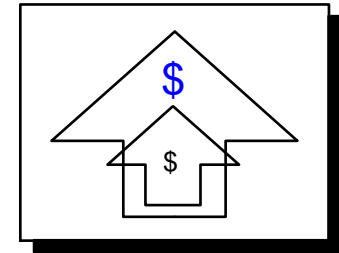
Misunderstood  
Requirements  
45%\*



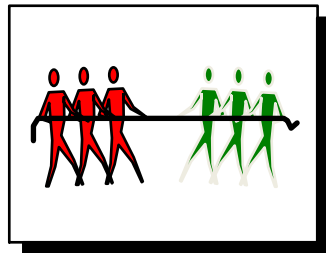
Product  
Problems  
29%\*



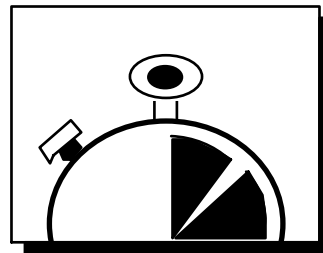
Poor  
Marketing  
25%\*



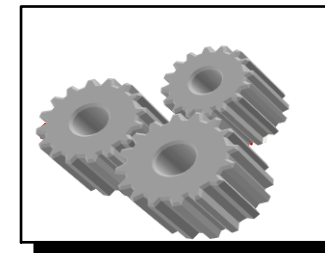
High Product Costs  
19%\*



Competitive  
Action  
17%\*



Poor  
Timing  
14%\*



System  
Problems  
12%\*

\*Multiple Choice

Source: "Winning at New Products", R.G. Cooper, 2001

# *Customer* - “Anyone or anything impacted by your project mission”

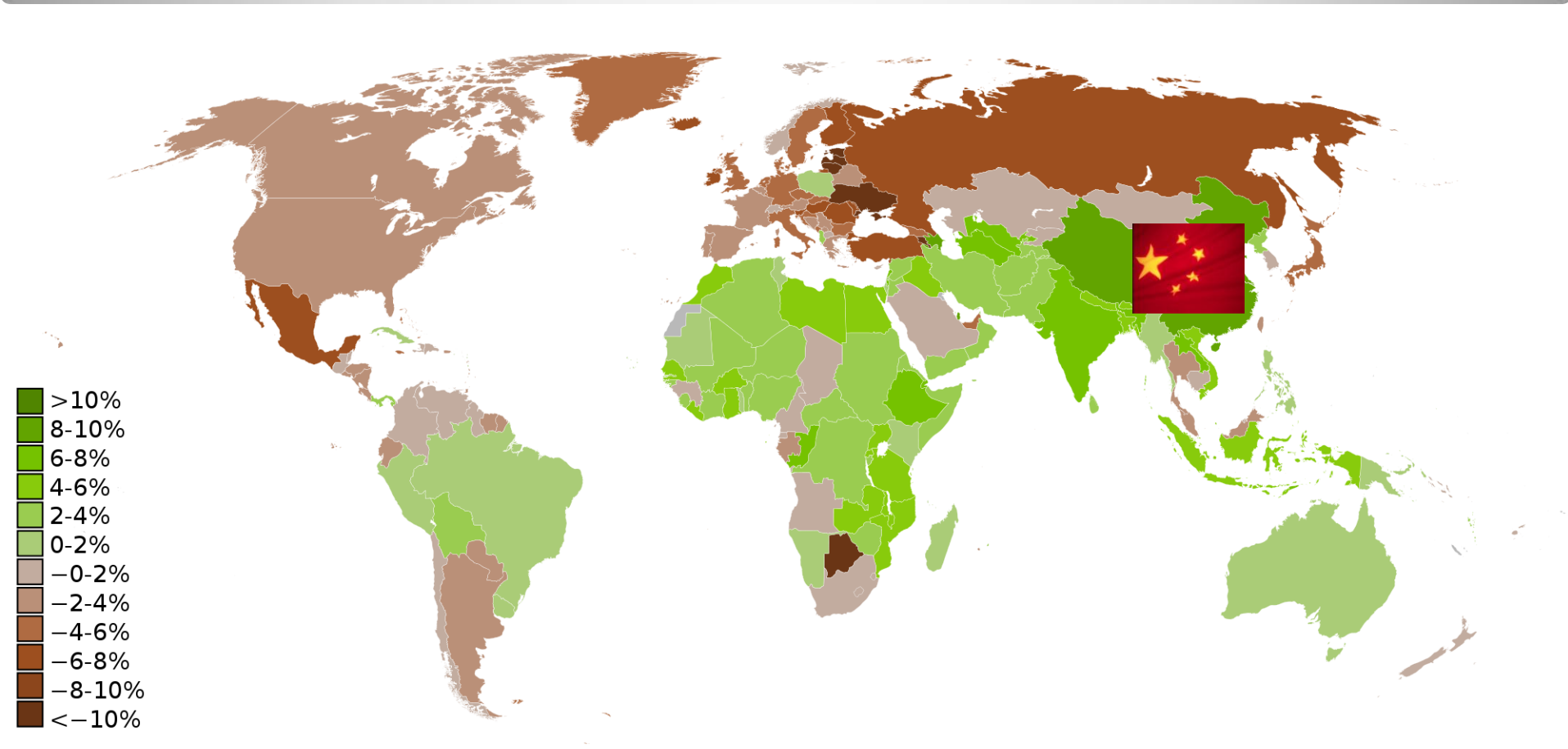
Includes:

- both people and processes
  - internal and external
  - stakeholders, suppliers, distributors
  - regulators / competent authorities
  - multiple levels
- All must be at least **satisfied** (*delighted* is preferred!)

# *The Usual Focus....*



# *GDP Growth Rate 2009/10* (CIA Factbook)



# China Price Comparison (2010)

	Australia	China
Medtronic Insync III Triple Chamber Pacemaker Model 8042	A\$12,480	A\$21,667
CYPHER Select Plus Sirolimus Eluting Coronary Stent	A\$3,450	A\$3,250
Medtronic Capsurefix Novus Model 5076 Pacing Lead	A\$1,248	A\$883

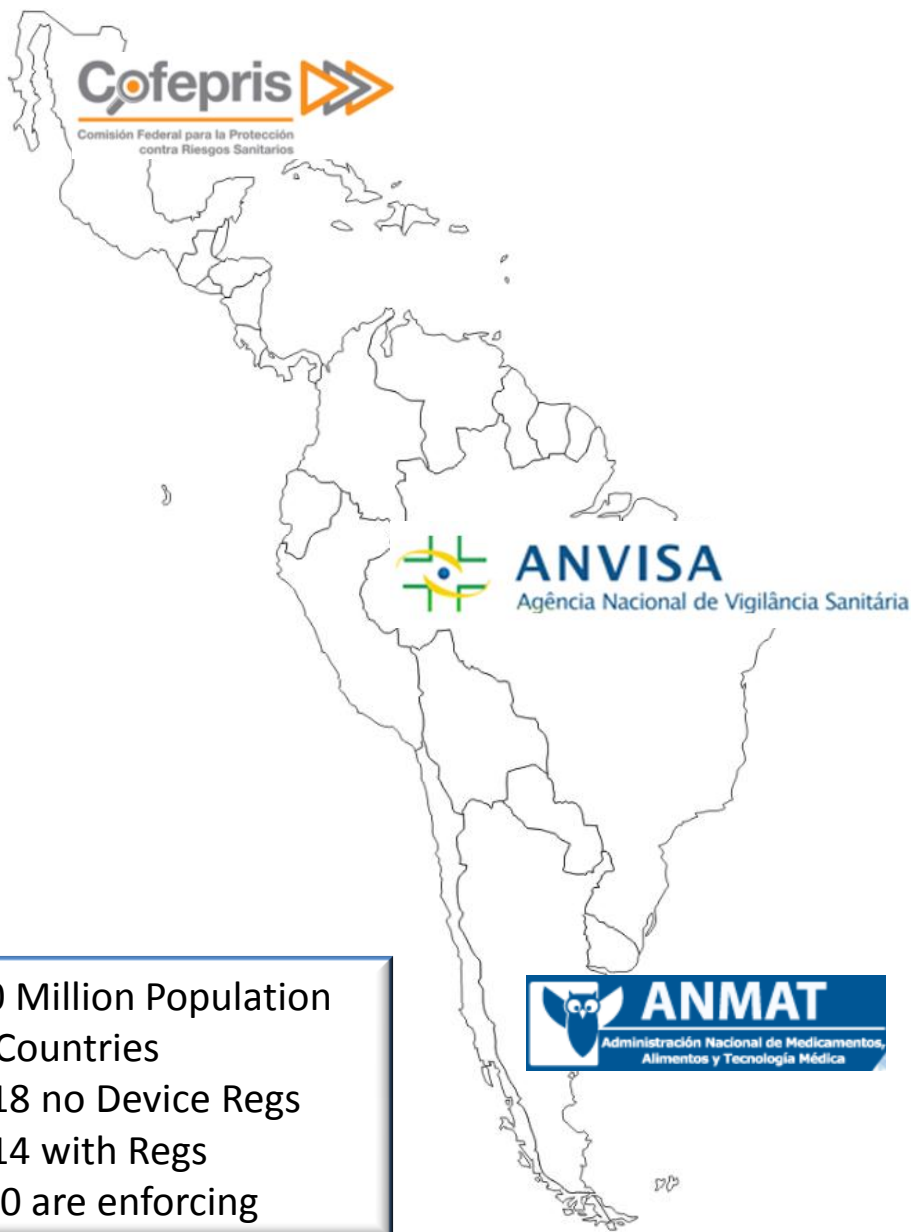
# Regulatory Trends in Asia Pac



2012/4	ASEAN countries harmonize regional IVD registration format
2012	India Medical Devices
2010	HK Medical Devices Australia IVD Registrations
2009	Korea High-risk : Tougher regs
2008	HK IVD Voluntary Product Listing Singapore Mandatory Registration
2007	Major Regulation Change in China, effective Jun 1, 2007
2006	Malaysia Voluntary Product Listing
2005	New Japan PAL
2004	Hong Kong Established Medical Device Registration – but exclude IVD. Singapore Voluntary Product Listing
2002	China Mandatory Product Registration

\* Thailand, Indonesia, Philippines, prior to 2002 already have registration requirement in place





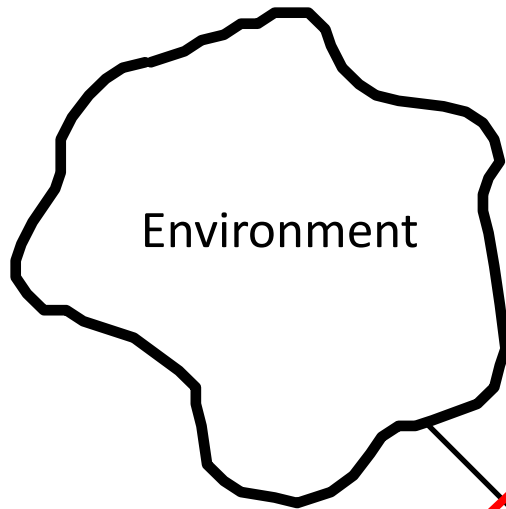
600 Million Population  
32 Countries

- 18 no Device Regs
- 14 with Regs
- 10 are enforcing

# Latin America

- 2010 “Equivalence Agreement” for US and Mexico. But reality is little change.
- 2004 Mercosur Regulations No. 3801/04 and 3804/04. Some aligned technical standards, but country-specific filings.
- 2000’s: Limited GHTF involvement and little ‘regional block’ harmony. Devices not in NAFTA scope
- 2001 Brasil RDC 185
- 1999 Venezuela DM-001 0-99
- 1995: GATT agreements -> WTO -> Some Sanitary and Phytosanitary Measures alignment

*What is the 5<sup>th</sup>  
Biggest Country?*



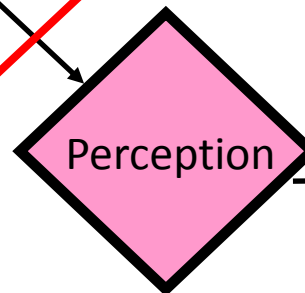
**ANVISA**

Agência Nacional de Vigilância Sanitária

Surveillance  
Filter

Mentality  
Filter

Power  
Filter



**Regulatory  
Plan!**



Source: Dr I Ansoff

# *Why are Regulatory Requirements so “Difficult” in many Emerging Markets?*

History # 1:

*Dumping*



*Solution?*

**केन्द्रीय उत्पाद एवं सीमा शुल्क बोर्ड**  
**Central Board of Excise and Customs**

*Item, at the time of its import, should have a valid shelf life of not less than 60% of original.*

# *The Regulatory Plan*



## *Must:*

- Be drafted and approved “Early”!!
- Include Advanced *and* Emerging Markets: which / why / when / how
- Consider
  - Regulatory Pathway – which jurisdictions first?
  - More than a Registration submission – what else might be needed?
  - Manufacturing and Supply Chain
- Be Detailed

For example.....

# *The Regulatory Plan*



*e.g. an Optical Electronic Medical Device*

- *Manufacture*
  - Needs significant amount of high skilled manual labour steps
  - High volume, will need economy of manufacture
- *Target Markets*
  - Launch in Developed markets? Yes, want CE Mark and Clearance in US; can this be leveraged for other markets?
  - China – but how can registration burden be eased there?
  - Can't sell it in Australia for commercial reasons
- *Logistics*
  - Need fast efficient global transport to meet client service targets

What recommendation drops out in our ***Regulatory Plan?***

# The Regulatory Plan



e.g. an *Optical Electronic Medical Device*

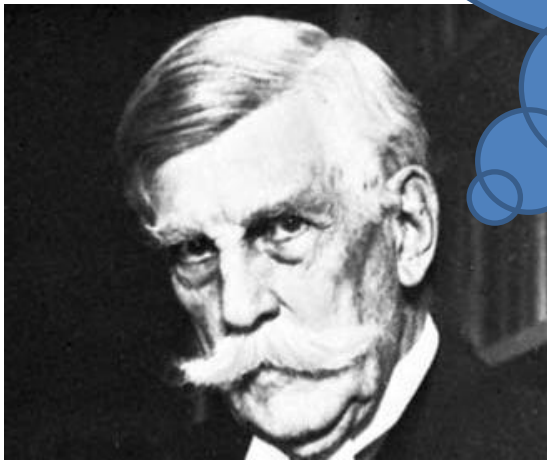
- Recommend manufacture in Wuhan, Hubei Province. Why?
  - *East Lake High-Tech Development Zone*; China's largest centre for optical-electronics. Huge skilled labour pool.
  - *Frequent cargo air services*: Wuhan (with Shanghai, Beijing, Guangzhou) are the four transport hubs of China.
  - *Medical Device Manufacturer establishment incentives*
  - *CE Mark, 510(k) and PMA success incentives*
  - *Domestic manufacturer advantages when registering in China*
  - *Can sell in China and Taiwan, because registered in country of manufacture*
  - *Business-aware and supportive provincial FDA* with strong track record assisting manufacturers

# How to make good decisions in the Regulatory Plan?



- *Upfront*: think global
- *Core competencies Focus*: don't try to 'know it all'
- *Seek/Buy what you need*: Get it first, before investing via:
  - *Regulators*: meet with them
  - *Regulator Groups*: AHWP Working Parties
  - *Industry Groups*: AusMedtech, AdvaMed, EDMA
  - *Consultants*: with a track record in emerging markets
  - *Trade Fairs*: Medica, China Medical Devices Fair etc
  - *Social Networking*: LinkedIn Groups
  - *National Commercial Groups*: Chambers of Commerce, Austrade

The young man knows the rules,  
but  
the old man knows the exceptions.



Oliver Wendell Holmes  
*Supreme Court Justice*