



Australian Government

Department of Health and Ageing  
Therapeutic Goods Administration

# Ensuring Efficient & Effective GMP Compliance (in Challenging Times)

*ISPE Australasia Conference 2009  
14 September 2009*

Michel Lok  
Head of Office, Manufacturing Quality  
Therapeutic Goods Administration





# Ensuring Efficient & Effective Compliance

- Manufacturing Landscape
- Expectations of Regulators
- Effective Compliance
- Risks & Challenges
- What TGA is doing





# Manufacturing Statistics

310 Licences

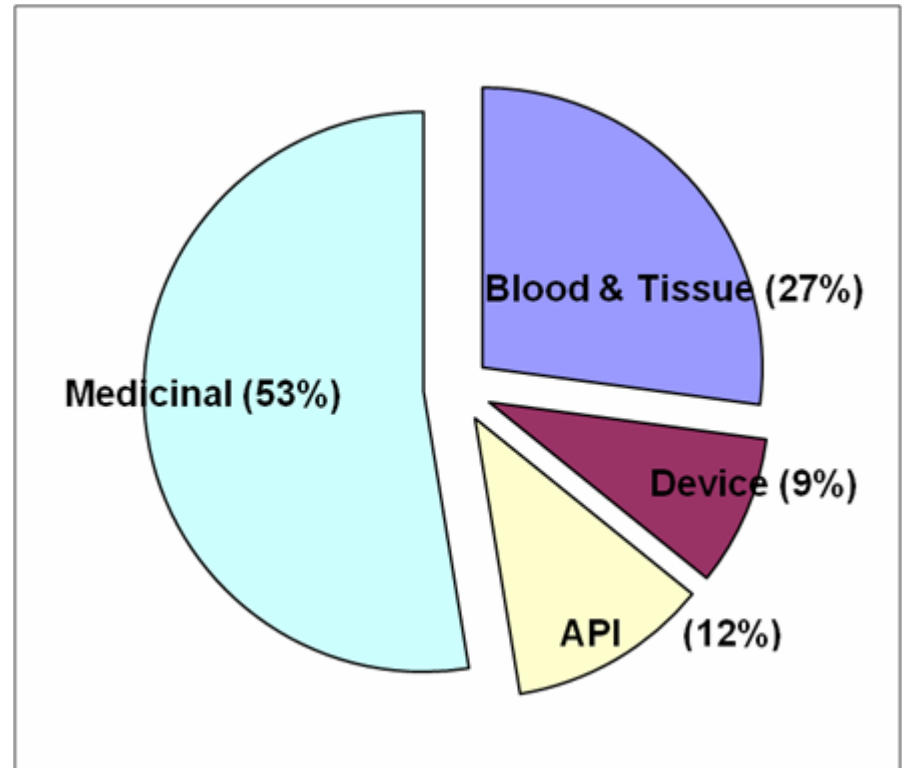
462 Sites

312 audits

77% Good/Avg

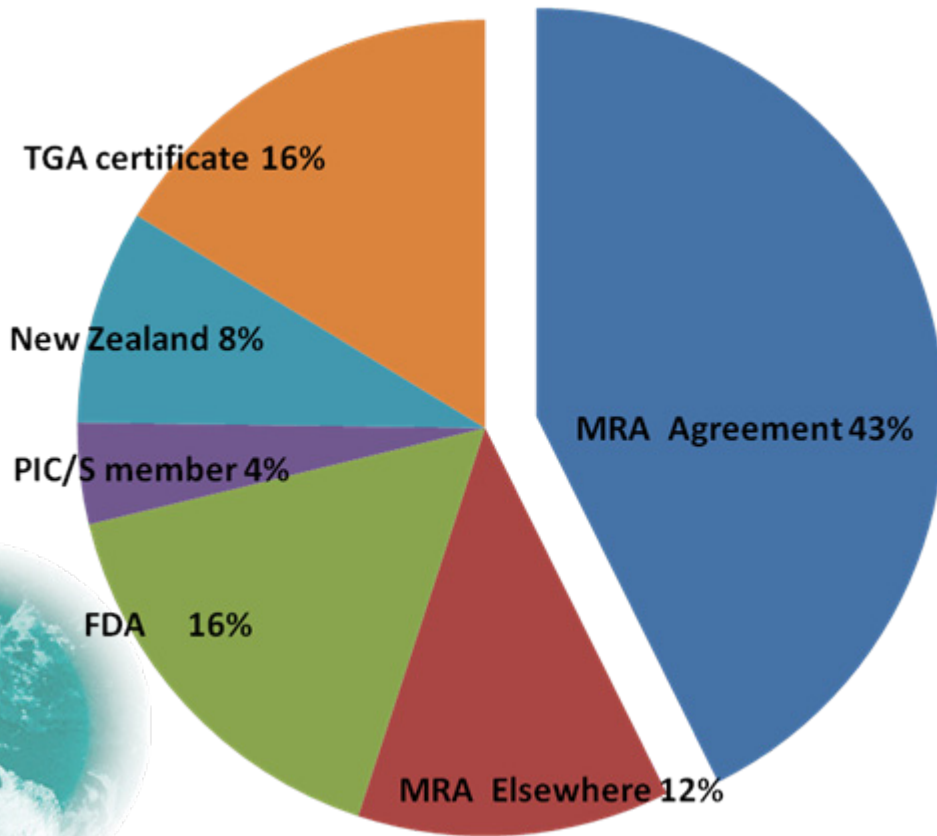
3%

Unacceptable





# Manufacturing Statistics



1,549

Manufacturers

2,288 Sites

3,188

clearances

123 audits

77% Good/Avg

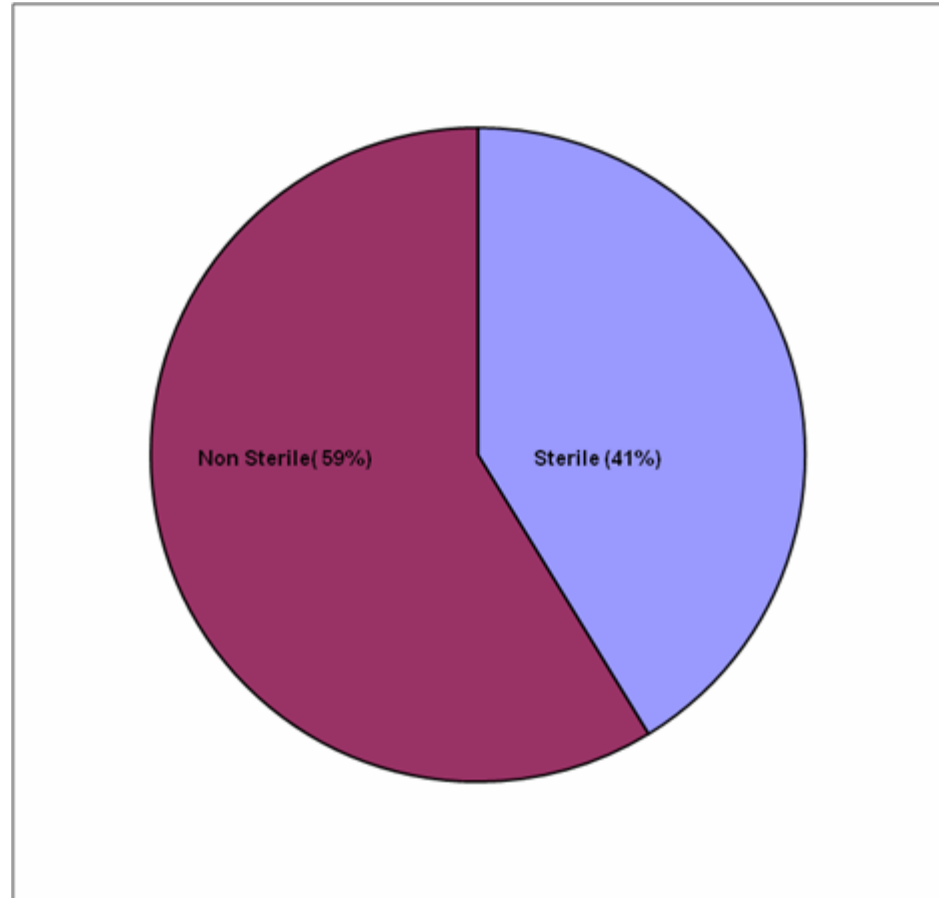
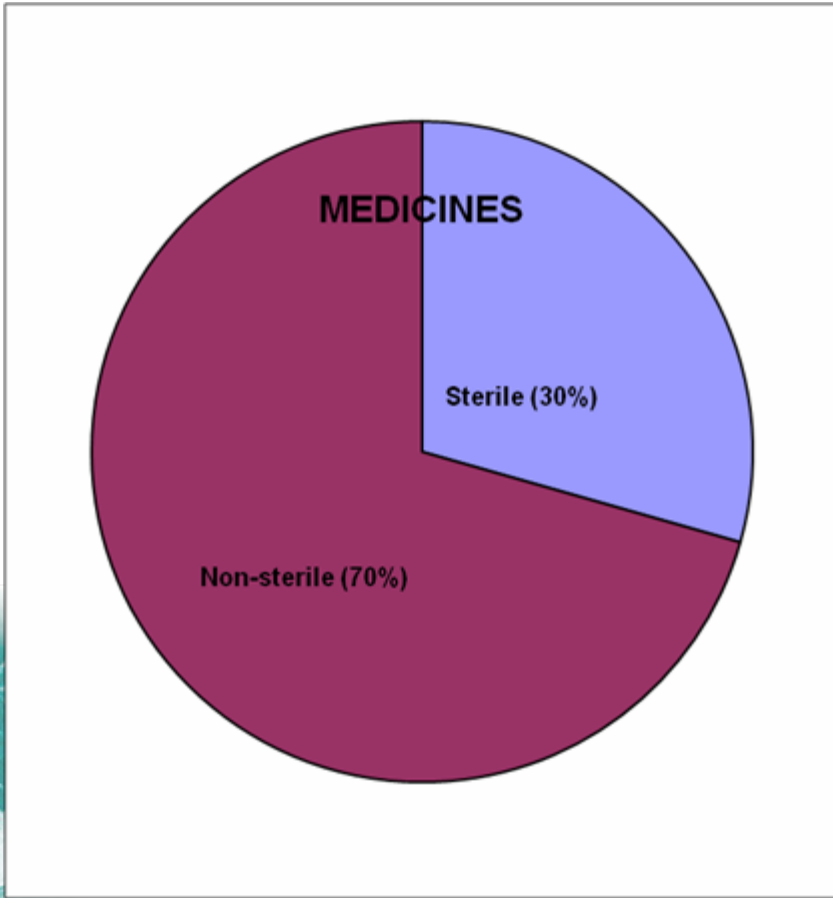
7%

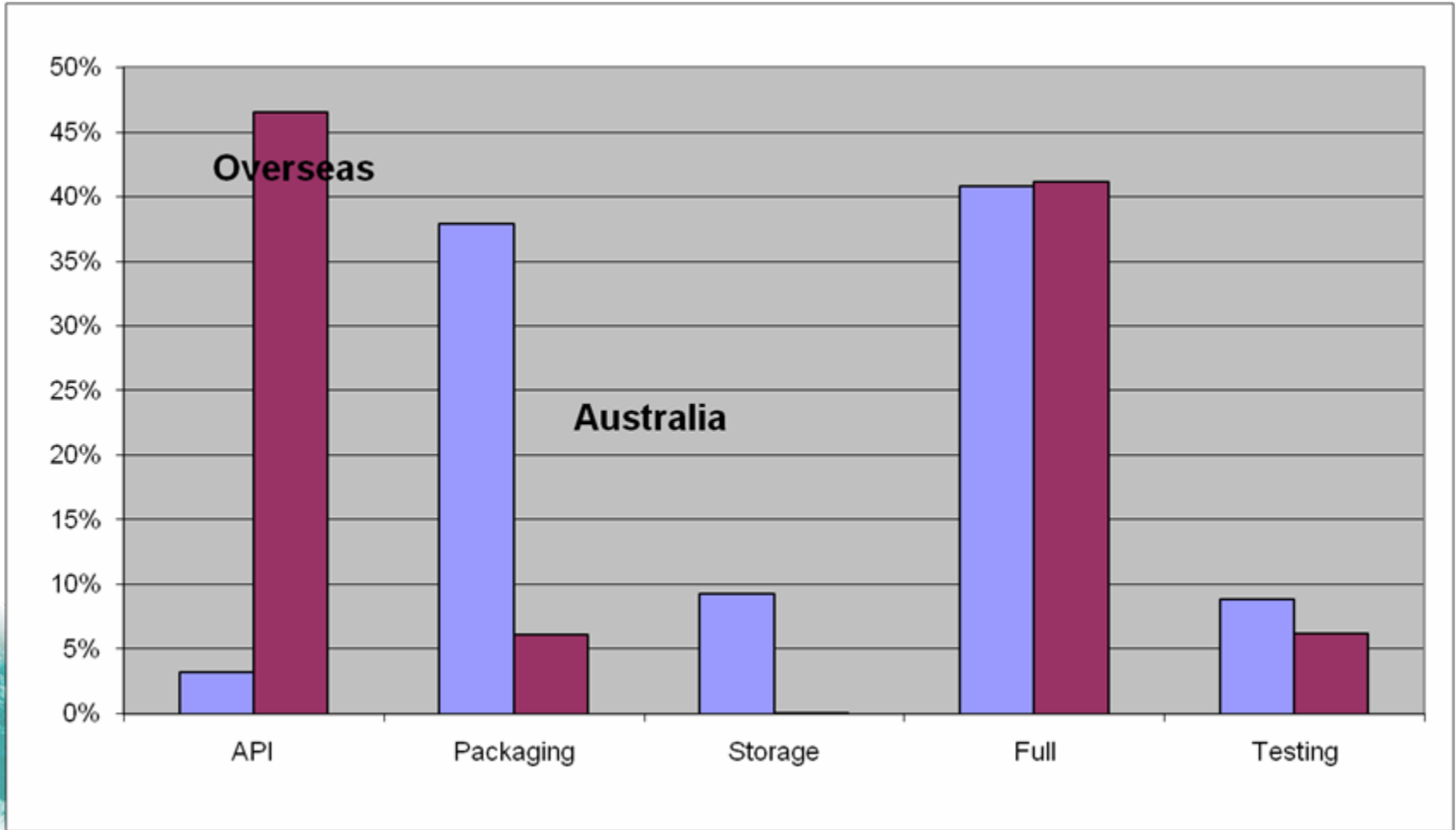
Unacceptable



# Manufacturing Statistics

AUSTRALIA OVERSEAS







# Expectations

Transparency

Good decision making

Consumer protection

Public responsibility

Avoid trade impediments

Undue regulatory burden

Consistency

Timely performance



Resources

Risk management



# Effective Compliance

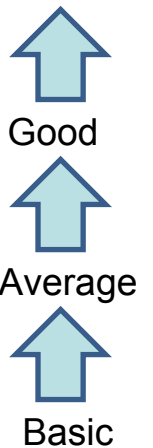


- participate
- visibility
- responsibilities
- communicate
- take action
- management review
- continuous improvement
- commit resources

- quality policy
- responsibilities
- control plans
- Procedures
- resources
- Training
- QC testing
- contractors
- internal audit
- management review

- TG Act & Regs
- scope of licence
- conditions
- nominees
- Manufacturing Principles
- cGMP / ISO
- Registration / Listing
- TG Orders

- Co-operate onsite
- Recognise improvements
- Assess root cause
- Prompt and effective responses to close-out





# Effective Compliance

Legislation,  
Standards  
and  
Guidelines

Effective  
Quality  
Management  
System

Risk  
Management  
Framework

Stakeholder  
Engagement

- authoritative / lawful
- Internationally harmonised
- requirements communicated
- requirements understood
- self assessment

- quality policy
- training & qualification
- consistent application of requirements
- internal audit
- management review
- External accountability

- risk policy
- audit planning
- re-audit schedule
- international cooperation
- o/s clearances
- audit review panels
- measured action

- engage on compliance framework
- Reporting of compliance status\*
- communicate compliance priorities\*
- Feedback\*
- Recognise limits





# Challenging Times



Risk Management





# Risks and Challenges



Global  
Financial  
Crisis

- *Risks*
  - *Reduced resources for quality*
  - *Loss of manufacturers/products*
- *Action*
  - *Minimise regulatory burden*
    - *Continuously review processes*
    - *Review fees model*
    - *Harmonised standards*
    - *Rationalise regulation (one on one off)*
  - *Monitor change in manufacturer profile (essential medicines)*



# Risks and Challenges



Consistency

- *Risks*
  - *Incorrectly accept unacceptable practice*
  - *Over regulation; cost implications*
  - *Compliance expectations poorly understood*
- *Action*
  - *Controlled procedures*
  - *Investment in training*
  - *Audit review*
  - *Stakeholder feedback*
  - *Benchmarking (database development)*





# Risks and Challenges



Overseas  
Manufacture

- *Risks*
  - *Capacity - large number of sites*
  - *Quality - incompatible regulatory frameworks*
  - *Standards - level playing field*
  - *Diminished Australian manufacturing base*
- *Action*
  - *Mutual Recognition Agreements*
  - *International cooperation and collaboration*
  - *Harmonised international standards*
  - *Risk based compliance verification or audit*





# Risks and Challenges

New  
Technolog  
y

- *Risks*
  - *Requirements that stifle innovation*
  - *Regulator not equipped*
- *Action*
  - *Engage international bodies*
  - *Adopt international standards*
  - *Permit alternative approaches (supported by risk assessment)*
  - *Invest in training*
  - *Engage with industry , ISPE & others*





# Risks and Challenges



Supply  
Chain

- *Risks*
  - *Unknown manufacturers and brokers*
  - *Temptation –supplier and contractor control*
  - *Counterfeit product penetration*
  - *Harm, injury, death*
- *Action*
  - *International engagement and information sharing*
  - *New code Good Wholesale Practice*
  - *Development of a national GDP strategy*
  - *Regulatory options for overseas supply chain*



# TGA Action

## International Cooperation

- Maintain our MRA's
- Fully utilise MoU agreements
- Engage in cooperative planning (API Pilot)
- Information sharing, including audit reports
- Joint inspections

### Benefits:

- Efficiency (cost effective, capacity enhancement)
- Effectiveness (coverage of sites, increased exchange of regulatory information)





# TGA Action

## Overseas GMP clearance

- Based on inspection by equivalent regulators
- Clarify guidance, streamline documents
- Clear rules for acceptance, conditions and approval
- Manufacturer master files and letters of consent
- Unacceptable applications --> certification audits

## Benefits:

- Efficiency (cost effective, low regulatory burden)
- Effectiveness (based on evidence and inspection)





# TGA Action

## Risk based audit practices

- Internal review of audit practice
- Understand the risks, options to use alternate approaches
  - ‘surveillance’ audits
  - ‘targeted’ audits, using questionnaires
  - Use of manufacturers QRM based systems
- Create incentives for compliance
- Compliance priorities communicated

## Benefits:

- Efficiency (lower regulatory burden)
- Effectiveness (target risks, reward compliance)





Australian Government

Department of Health and Ageing  
Therapeutic Goods Administration

# Thank You

*Questions ?*

Michel Lok

Head of Office, Manufacturing Quality  
Therapeutic Goods Administration

