Global Manufacturing Update
Issues and Opportunities

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OMQ “Mission”

“Providing the community with confidence about the quality of manufactured therapeutic goods available in Australia”
OMQ Structure and Resources

- Current total staffing of 43
  - 25 qualified auditors
  - 13 clearance, licensing and audit support staff
  - 5 administration staff (incl QMS)
- Recruiting 11 additional auditors
- 4 medicines audit teams (incl clearance)
- Total operating budget of $7.8m
Global Manufacturing Update
Issues and Opportunities

International Program Arrangements

• Statistics
• Agreements
• Collaboration
• Harmonisation
International Program

Clearance of overseas manufacturers (TG Act, Part 2)

- Initial registration or listing of a product (s.25, s.26 and s.26A)
- Continuing condition of entry on ARTG (s.28 and s.31)
- MRAs clearances, desktop assessments and overseas audits
International Program

• 1,312 active overseas manufacturers (320)
  - covering 2,085 sites (458)

• 2,374 clearances approved in last 12 months
  - Clearances are granted for each sponsor
  - 24 rejected (1%)
International Program

• 356 Desktop applications
  - 53 pending
  - 65 in-process (14 currently with auditors)

• All clearances:

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<tr>
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<th>MRA</th>
<th>FDA</th>
<th>PIC/S</th>
<th>NZ</th>
<th>TGA</th>
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<tbody>
<tr>
<td>Percent</td>
<td>49%</td>
<td>9%</td>
<td>6%</td>
<td>6%</td>
<td>14%</td>
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International Program

• 97 overseas audits in 2007-08 (327)
  – 74% average/good compliance (73%)
  – 12% basic compliance (23%)
  – 6% unsatisfactory (2%)

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<thead>
<tr>
<th>Country</th>
<th>China</th>
<th>India</th>
<th>Europe</th>
<th>US/Can</th>
<th>NZ</th>
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<td>19</td>
<td>7</td>
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Agreements

- Mutual recognition
- Information sharing
- Coverage – 3\textsuperscript{rd} Country
- Confidence building
- Maintaining confidence
- Fulfilling obligations
Collaboration

• API Cooperative Inspection Pilot
  - FDA, EMEA(EC), TGA
  - Planning, Reliance, Scope and Joint audits
  - Increased coverage, reduced duplication
  - 61 ‘mutual interest’ sites in pilot for TGA
  - India (29) and China (13)

• SmartGMP Initiative
  - Canada, Swissmedic, HSA, Medsafe
Collaboration

• Multi-lateral Engagement
  - International Medical Products Anti-Counterfeiting Taskforce (IMPACT)
  - PIC/S participation

• Regulatory Capacity Building
  - Assistance for countries with less developed regulatory systems
  - Benefits for recipient country and for Australia
Standards

• International Conference on Harmonization (ICH)
  - Global Cooperation Group

• Pharmaceutical Inspection Co-operative Scheme (PIC/S)
  - Expert Circles
    • chair: Computer Systems; Blood and Tissue
    • participate: API and Pharmacy Compounding
Standards

- PIC/S GMP Guide has been updated several times since 2002
- Amendment of the Manufacturing Principles current in progress - there will be consultation
- Key changes
  - Risk management in Chapter 1 and new Annex 20
  - Regular product review and on-going stability program
  - Several changes to Annex 1 (Sterile manufacture)
  - New Annex 13 (Investigational medicinal products)
  - New Part 2: ICH Q7 for API manufacture
Thank You