Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

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

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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:

MRA	FDA	PIC/S	NZ	TGA
49%	9%	6%	6%	14%

International Program

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

China	India	Europe	US/Can	NZ
29	19	7	16	3

Agreements

- Mutual recognition
- Information sharing

- Coverage – 3rd 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