Australian Government
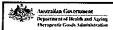Department of Health and Ageing
Therapeutic Goods Administration

**Auditing of Computerised Systems for
Pharmaceuticals and Medical Devices
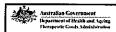Dr Dragana Milic
TGA
ARCS - November 2005**

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

- Regulatory requirements specified in:

- Annex 11 (Computerised Systems) of the Australian GMP Code for Medicinal Products

- Supplementary document: PICS Guidance to Good Practices for Computerised Systems in Regulated "GXP" Environments

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Department of Health and Ageing
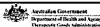Therapeutic Goods Administration

Pre-audit Information

- List of automated/computerised systems and top level review of their functions/interactions with manual systems.

- Validation status of the above systems.

Australian Government
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At the Audit

- Documented evidence of validation is available for review.
- An inventory of all computerised systems, ownership, supplier/developer, functionality, links and validation status.
- A top level site based policy and validation master plan (VMP) for computerised systems.
- Clearly defined responsibilities for the management of all information technology products, systems and projects.
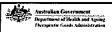

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Site Based Policy

- Comprehensive policies and procedures for:
  - specifications;
  - purchases; and
  - development and implementation of computer systems
  - maintenance,
  - business continuity

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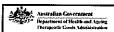Department of Health and Ageing
Therapeutic Goods Administration

At the Audit

- Starting point of every regulatory audit:
  - risk assessment as documented by the user (PIC/S Guidance document 6.3), devices design dossier
  - risk assessment could be part of the VMP

- Auditor's focus:
  - manufacturing – critical processes and control parameters,
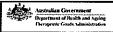 - product (equipment/device) - safety + operational parameters

At the Audit

- Auditors will not and should not review validation of computerised systems in isolation

- Process validation
- Design dossier
- Change control

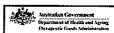## Validation Master Plan (VMP)

- Identify computerised systems that **need** to be validated
- Provide brief descriptions of the validation strategies for different categories of computerised systems as well as other validation activities;
- Outline protocols and related test procedures for all validation activities including computer systems;
- Define reporting requirements to document validation exercises and related results; and
- Identify key personnel and their responsibilities as part of the validation program.

At the Audit

The scope and level of documentation and records needed for GXP related systems will be dependent upon:
- software category + the level of risk associated with its operation;
- the complexity of the system and variables relating to quality and performance;
- the GMP impact areas involved; and
- the need to safeguard product quality, process control and critical records integrity.
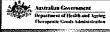

User Requirements

Irrespective of whether the software is purchased or custom built (including in house developed software) system specifications/User Requirement should be the starting point

The URSs should satisfy the following criteria:
- Each requirement should be reviewed, authorised and uniquely catalogued;
- There should be no conflict between requirements.

User Requirements

- Each requirement, particularly mandatory/regulatory requirements, should be testable.
- The URS should be understood and agreed by both user and supplier.
- There should be a clear distinction between mandatory/regulatory requirements and optional features.

User requirements

- URS – information as to where there are important interfaces between system and manual operations
- Documentation describing the computer system(s) should include logic flow or block diagrams, an indication of hardware layout, networks and their interaction.
- These basic schematics should align with the functional specification and be traceable to the URSs.