Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Computerised systems (Annex 11)

Technical guidance on the interpretation of the PIC/S Guide to GMP

Last updated: 10 December 2019

Annex 11 has been updated to provide clarification of existing requirements to ensure that computerised systems are managed appropriately, particularly in relation to data management and integrity.

Validation and control of computerised systems

All computerised systems (including commercial off-the-shelf systems) used by licensed manufacturers in the manufacture of medicines should be validated and controlled in accordance with Annex 11 requirements (i.e. GMP computerised systems).

The level, extent and formality of system control should be commensurate with the criticality of the system. Manufacturers should have a good understanding of all the systems used, and the impact and criticality of each system.

In general, the following systems (list is not exhaustive) should be fully validated and controlled, such as those used:

- for the electronic acquisition of quality control data
- to control and monitor the operation of critical utilities, facilities and equipment
- to generate, store or access electronic GMP records
- to generate, process, calculate or monitor data that forms part of the batch processing record, or batch control testing records
- in the place of physical (hard-copy) records, e.g. electronic spreadsheets used to track records or perform calculations, electronic documents used to record data
- to control the status of materials, products, equipment or processes, e.g. Enterprise Resource Planning systems
- to perform the release of materials and release for supply of finished goods
- to track the distribution of products and/or control the reconciliation of products and materials in the case of quality defects or recalls

- to acquire and store environmental data such as temperature, humidity, and differential pressures
- to manage quality investigations and store and track investigation records. For example, deviations, out of specifications, complaints and change control

'Regulated users' definition

The TGA regards 'regulated users' to be the licence or GMP certificate holder responsible for the application of GMP.

'Life-cycle' of a computerised system

The 'life-cycle' of a computerised system includes all stages from the initial concept, design, qualification, validation, and use through to the eventual retirement of the system and archival of all data.

Manufacturers need to manage computerised systems effectively at all stages in the life-cycle to ensure that they function correctly. Therefore, validation not only applies at the initial introduction of the system, but throughout all stages of use. Further guidance regarding the life-cycle management of computerises systems may be found within the PIC/S Good Practices for Computerised Systems in Regulated GXP Environments.