Australian Government
Department of Health
Therapeutic Goods Administration

# Guidance on licensing/certification inspections

## Version 1.0, April 2013

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## Appendix 2: Examples of medicine inspection deficiencies



### Critical deficiency

Examples of critical deficiencies include the following where it can be reasonably expected that the definition in this Guidance will be met. A critical deficiency is a serious situation that will result in regulatory action being considered.

- Lack of sterilisation validation (relevant to all sterile products)
- Inadequate segregation of manufacturing of high risk products, such as penicillins, cephalosporins, cytostatics, steroids, hormones, resulting in a risk of contamination (relevant to prescription medicine manufacturers but critical deficiency also if possibility of cross contamination to any other product)
- Evidence of gross pest infestation (relevant to all manufacturers)
- Falsification or misrepresentation of analytical results or records(relevant to all manufacturers)
- Raw materials not tested (including proper identification testing) to ensure compliance with specifications (relevant to all manufacturers)
- No master batch documents (relevant to all manufacturers)
- Absence, falsification or misrepresentation of manufacturing and packaging records (relevant to all manufacturers)
- Water system for sterile products not validated (for manufacturers of sterile products)
- Grossly unsuitable premises so that there is a significant risk of contamination (relevant to all manufacturers)
- Release of materials or finished product for a Registered medicine not meeting specifications. (For Listed medicines the assignment of a critical classification should first be discussed with the relevant regulator.)

- Release of blood or tissue product without acceptable mandatory test results (relevant to manufacturers of blood or tissue products)
- Incorrect labelling of blood or tissue product (relevant to manufacturers of blood or tissue products)
- No separation of quarantined and released blood or tissue products (relevant to manufacturers of blood or tissue products)
- No evidence that mandated recall processes have been complied with. (relevant to all manufacturers)

## Major deficiency

Examples of major deficiencies include the following:

- Lack of validation of critical processes (applicable to all medicines, but could be critical for low dose/high potency products; particularly sterilisation processes for sterile devices)
- No or grossly inadequate air filtration to minimise airborne contaminants (applicable to all medicines manufacturers - could be critical if possible contaminants are a safety concern and critical for sterile medicines)
- Cleaning program not followed and evidence of dirty premises/equipment or non-validated cleaning procedures (may be critical if resulting contamination is a safety concern)
- No data available to establish the shelf-life of registered medicines (relevant to all manufacturers of registered medicines as it is their responsibility. This should be referred to the relevant product regulator)
- No data available to establish the shelf-life of sterile medical devices, medical devices that incorporate medicinal substances, biological materials or an energy source. (may be relevant to other manufacturers of medical devices as it is their responsibility. This should be referred to the relevant product regulator)
- Damage (holes, cracks, peeling paint) to walls/ceilings in manufacturing areas where product is exposed
- Design of manufacturing area that does not permit effective cleaning
- Insufficient manufacturing space that could lead to mix-ups
- No raw material sampling area for medicine manufacturers (could be classes as 'other' if adequate precautions are taken)
- Sanitary fittings not used on liquid/cream manufacturing equipment
- Stored equipment not protected from contamination
- Individuals in charge of QC/production not qualified by education, training and experience
- Inadequate initial and ongoing training and/or no training records
- Cleaning procedures not documented and/or no cleaning records
- Production equipment cleaning procedures not validated
- Reduced QC testing of raw materials without data to certify suppliers
- Incomplete testing of raw materials

- Test methods not validated
- Complex production processes for non-critical products not validated
- Unapproved/undocumented changes to master batch or equivalent documents
- Deviations from instructions not approved
- No or inadequate internal inspection program
- No proper release for supply procedure
- Product reworked without proper approval
- No system/procedures for handling complaints or returned goods
- Inadequate testing of packaging materials
- No ongoing stability program and/or stability data for all products not available
- Insufficient lighting in production or inspection areas
- Temporary devices used for equipment repair
- Containers from which samples have been taken not identified
- Equipment not properly maintained
- The temperature of critical temperature controlled storage areas not monitored and alarmed

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