Good Manufacturing Practice

Objectives

- Acknowledge and understand the consequences of inadequate manufacturing practice;
- Analyse such consequences of negligent compounding, esp. in the context of complex compounding (e.g., sterile componding); and
- Understand what a pharmacist is allowed to compound in Australia.

Principles

Rules of engagement are simple

- GMP: compulsory guidance about what, where, who, how etc. of the medicines manufacturing process
- All meds manufactured must follow the GMP
- Compounding is also medicines manufacturing, just smaller scale (typically 1 patient)
- GMP in compounding is used as a guide but not compulsory

Exercise 1: Analysing recalls

1. Check **TGA Recalls** 👉 shorturl.at/x1lly (ex one eye eye why)
2. Query for **01-JAN-2017 – 28-NOV-2017**

What are the three classes of recalls?

Recall actions occurs when the product deficiency is:

- I: potentially *life-threatening* or could cause a serious risk to health;
- II: *could cause illness, injury or result in mistreatment* (but not under Class I);
- III: may *not* post significant hazard to health, but the action may be initiated for other reasons e.g., QC issues.

Exercise 1: Analysing recalls (35 mins)

Objectives

1. Go over the recalls analysis questions
2. Prepare a brief presentation on your selected recall
3. As a group, we'll present to the class