29 August, 2020

BiologicALs versus biologics –two letters to FMT

Australia's Therapeutic Goods Administration (TGA) announced earlier this year that Faecal Microbiota Transplant (FMT) would be regulated as biologic**AL**s. FMT products are defined as products which comprise, contain or are derived from human stool **and** are intended for therapeutic use.

In fact, all therapeutics made from, or containing, human cells or human tissues are regulated by the TGA as biologic**AL**s. There are four classes of biologic**AL** therapeutics, with Class 1 capturing low risk biologicals, and Class 4 capturing high-risk biologicals. FMT is considered to fall predominately in Classes 1 or 2

- Class 1 biologic**AL** products do not require to be manufactured under GMP conditions, and are included on the Australian Register of Therapeutic Goods (ARTG) following provision of information, which includes submission of a statement of compliance with relevant standards, via the TGA Business Services portal.
- Class 2 FMT biologic**AL** products, as with those in Classes 3 and 4, require TGA evaluation and approval prior to being included in the ARTG. Applications are submitted via the TGA Business Services portal, and TGA GMP clearance is applicable for relevant manufacturing sites, as is other supporting data.

There are many biologically-derived medicines however, which are regulated by the TGA under the medicine framework. These include recombinant products and plasma-derived products, amongst others, and are commonly referred to as 'biologics'. So therapeutics containing microorganisms known to be present in stool, but are grown in established isolates and then characterised and developed as usual, are regulated as registered medicines under the medicine framework, GMP inclusive.

How to remember the difference between biologic**AL**s and biologics?

Try this: Faec**AL** – Biologic**AL**

Four questions to help with your biologicAL intellectuAL

1. Is the therapeutic listed in Schedule 16 of the Therapeutic Goods Regulations 1990? ⇨ Class 1 biologic**AL** (low risk)
2. Is the biologic**AL** manufactured using minimal manipulation, and intended for homologous use? → Class 2 biologic**AL** (low risk)
3. Is the biologic**AL** manufactured using more than minimal manipulation? → Class 3 biologic**AL** (medium risk)
4. Does the biologic**AL** comprise of or contain live animal cells/tissues/organs, human cells or tissues with modified functionality, or pluripotent cells? → Class 4 Biologic**AL** (high risk)

Do you have a complex Regulatory activity which could value from an experienced Regulatory review? Are you interested in on-line Regulatory Affairs learning or mentoring? Contact Mary on enquiries@enimeraregsplus.com.au for a complimentary and in confidence discussion.