Australian Government
Department of Health
Therapeutic Goods Administration

Interactive Workshop: Code tables for GMP Clearances

How to avoid validation issues

Rheannon McNeil
Assistant Director, GMP Clearance, Manufacturing Quality Branch
Medical Device and Product Quality Division
Therapeutic Goods Administration
GMP Forum 2021

12/05/2021

TGA Health Safety Regulation

Overview

- Common Validation errors – GMP Clearance application forms
- Common Validation errors – Product applications – GMP clearance section
- Question Time

Common Validation errors

GMP Clearance form

- ‘Other’ selected as reason for extension and more than 100 characters included in the reason field.
- MRA renewal application, site in the United Kingdom unable to validate.

Common Validation errors

Product applications – GMP clearance section

- Group term vs single term (eg eye drop / eye drops)
- Manufacture of diluent not available in GMP clearance application – what do I do?
- Sterilisation for OTC products. My evidence is limited to a specific type of sterilisation, but I need ‘sterilisation as a step to validate in my product application – what do I do?
- Error message that my GMP clearance has expired – I have a valid GMP clearance?
- Error message that the name or address on the ARTG entry does not match clearance

Module 3 information vs ARTG/GMP clearance steps

- Regulators and companies may refer to the same activities using different terminology
- The code tables have a limited number of steps for selection
- Choose the step which most closely aligns with the activity outlined within the Module 3 information
- Evaluators will consider the information provided for module 3 and how this aligns with the GMP Clearance information, where the alignment is unclear or a step has been misunderstood they will seek clarification and you may need to update your GMP Clearance by submitting a variation application

Question time

Contact us

- Email – GMPClearance@health.gov.au
- Phone – 1800 020 653

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