Technical Alert

GMP Clearance Applications Using Health Canada Evidence

GMP Forum

Sports Supplements

GMP Clearance Applications Using Health Canada Evidence

Background

Historically Health Canada (HC) and the TGA have had Mutual Recognition Agreement (MRA) related to Conformity Assessment in Relation to Medicines Good Manufacturing Practice Inspection and Certification between the Government of Canada and the Government of Australia. This means that Australian sponsors using manufacturers in Canada have been permitted to use the HC "Inspection Exit Notice" as evidence to demonstrate compliance in place of a GMP Clearance Certificate. However, this MRA is only applicable to inspections of Canadian manufacturing sites, and when HC inspect outside their borders, there is insufficient evidence in these reports to demonstrate compliance (See the GMP Clearance Guidance for more information about specific requirements). As HC is increasing the number of overseas inspections, this has been causing a backlog of applications for clearance verification and delaying Australian sponsors.

Process and fee changes

The TGA have been working with HC to determine the types of evidence they require to fulfil on the Compliance Verification pathway under the MRA.
As this requires extensive liaison for each application the TGA will be imposing the additional liaison fee *(Obtaining evidence from an overseas regulatory authority)* to all CV clearance applications submitted using HC 'exit notices', including all submitted CV clearance applications that are currently in progress. The announcement of this change is published on the TGA website.

GMP Forum in Melbourne

The 2nd GMP Forum is being held on **21 November 2019** in Melbourne.

The event is hosted by the TGA in conjunction with the Royal Australian Chemical Institute (RACI), Australian Regulatory and Clinical Scientists (ARCS), Parenteral Drug Association (PDA) and the International Society for Pharmaceutical Engineering (ISPE), and will include content relevant to prescription, over-the-counter and complementary medicine sectors.

The TGA encourages personal/consultants employed by sponsors, manufacturers, small to medium size enterprises, who are involved with quality assurance, regulation, and risk assessment of medicines to attend.

Details:

Thursday, 21 November 2019
8:15am - 6:00pm AEDT
Pullman Melbourne Albert Park (the Pullman), 65 Queens Road, Melbourne, Victoria 3004

Registration:

Before Friday 18 October 2019
RACI - ARCS - PDA - ISPE members - $170
Non-members - $200
After 18 October 2019 - $430

Registrations close **Friday 1 November 2019**.

Payment and registration instructions are available on the webpage, along with additional information about accommodation at the Pullman Hotel.

Enquires about this event can be directed to Ms Karen Sivonen of the Manufacturing Quality Branch on 02 6221 6831 (tel), 02 02 6203 1451 (fax) or by email, GMPForum2019@health.gov.au

Sports Supplements

The TGA has published a reminder to owners of sports supplements - including vitamins, minerals, sports nutrition products such as protein powders – that these products could be regulated as either a food or a medicine, depending the form of the medicine, presentation and claims being made. The food-medicine guidance tool can assist sponsors in determining whether a product is a food or medicine.

ENDS

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.