



File note

CONTAINS COMMERCIAL-IN-CONFIDENCE INFORMATION:
PERMISSION FOR DISTRIBUTION REQUIRED FROM US FDA PRIOR TO
RELEASE OR DISSEMINATION OUTSIDE TGA

TRIM Reference: 2013/019857

[REDACTED]
Attendees: Noel Fraser, Hongxia Jin, Matt Davis

Date: 1/10/13 at 11.30 -12.15

Background

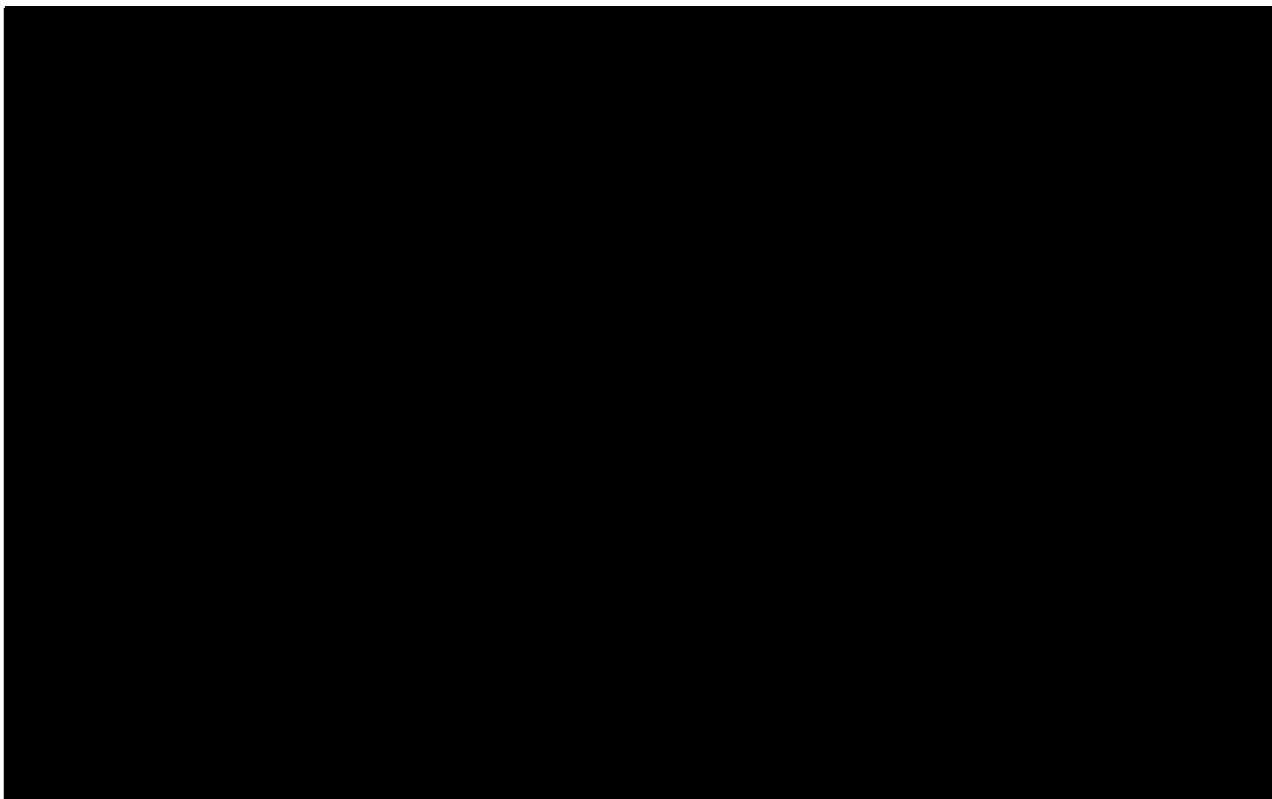
OMQ TGA has planned inspections of [REDACTED] manufacturing sites at [REDACTED] and [REDACTED] for October 2013. The inspections were to take 2.5 days and 3 days respectively, with two (2) inspectors in attendance at each site. In addition, the inspection trip was to include inspection of [REDACTED]

[REDACTED] Following the notification, the TGA participated in a teleconference with FDA, MHRA, WHO, EMA and IMB in order to establish the nature of the FDA's concerns and reconsider TGA's inspection plans relating to [REDACTED], in light of the meeting outcome. The teleconference was held 27 September 2013 with Noel Fraser (TGA) and Jenny Hantzinikolas in attendance.

TGA discussion 1 October 2013

An internal TGA discussion was held on the 1/10/13 between Noel Fraser, (Compliance Manager), Hongxia Jin, (Senior Inspector Med Team C), Matt Davis (A/g Senior Inspector Med Team B).

- [REDACTED]
- 3) A number of products are supplied to Australia from these sites; a number of API's are made at [REDACTED] and subsequently formulated in-to product for Australia, and several solid dosages are made at [REDACTED]
 - 4) The TGA has not visited either the [REDACTED] sites; previous GMP clearances have been issued based on clearance verifications.



The meeting members then discussed the options available to TGA regarding [redacted] sites.

- 1) The planned inspection to India by Maurice Makdessi and Julia Kubiak was to cover [redacted]
- 2) The current inspection plan allocated [redacted] 3 days to [redacted] and 2.5 days to [redacted].
- 3) [redacted] it was determined that the duration for the [redacted] should be increased to accommodate additional time for a focused review of issues, particularly in the context of products supplied to Australia.
- 4) [redacted]
- 5) [redacted], TGA determined that it would be prudent and diligent to allow additional time to fully evaluate areas of concern, in order to provide the best possible assurance of product quality.
- 6) It is recognised that the TGA has not planned an inspection of the [redacted] however, the group determined that the risk associated with the manufacture of [redacted] could be reduced through the thorough evaluation of materials approval and management at the [redacted]
- 7) The group determined that the focus of the [redacted] inspections should include greater emphasis on:
 - a) Vendor assurance, material sampling, testing, approval and use. [redacted]



- b) Establishing the potential or real impact of [REDACTED] products supplied to Australia, as to whether further action is warranted.
- c) Management of investigations into issues.
- 8) The group also determined that [REDACTED] should be asked to present to the inspectors their actions taken at a corporate level to address the range of issues identified at [REDACTED]. The aim of this presentation would be so the inspectors could gain insight and hopefully confidence in the corporate ownership of the issues and their commitment to implementing effective, timely and lasting change to the culture of the organisation.
- 9) On initial review of the scope of each inspection, it was determined that the duration of each [REDACTED] inspection should be increased to allow additional time to review and consider each site's GMPQ compliance, in light of the [REDACTED].
 - a) The inspection at [REDACTED] to be extended from 2 inspectors for 3 days, to 2 inspectors for 4 days. (33% increase in time)
 - b) The inspection at [REDACTED] to be extended from 2 inspectors for 2.5 days, to 2 inspectors for 4.5 days. (80% increase in time)
 - c) The actual times allocated will have to be discussed with the LI, (Maurice Makdessi) and the team are conscious of the reduced timeframe in which to rearrange travel arrangements.

Outcome

The team ~~decided~~ recommended:

- 1) The currently planned trip to India by MM & JK was to be amended to [REDACTED] and increase inspection duration for [REDACTED]
- 2) Matt Davis to communicate with LI (MM) regarding changes.

Further Action

- 1) Meeting to be held with inspection team prior to departure and during preparation to brief team of the specifics of [REDACTED]
- 2) Risk assessment to be developed by the LI to determine the areas of focus for the inspection, and to determine which areas of the QMS can be given low-priority for the upcoming inspections.

Appendix A - Product List

