





**From:** Noel.Fraser [mailto:Noel.Fraser]  
**Sent:** 31 December 2013 00:10  
**To:**  
**Cc:**  
InternationalGMP  
**Subject:** RE: Request for information India. [SEC=UNCLASSIFIED]

Dear

Thank you for the update, it's most helpful.

I appreciate your undertaking to provide TGA with the report (when available) and to inform us of the IAG decision(s) regarding any Regulatory actions.

Thank you and kind regards,

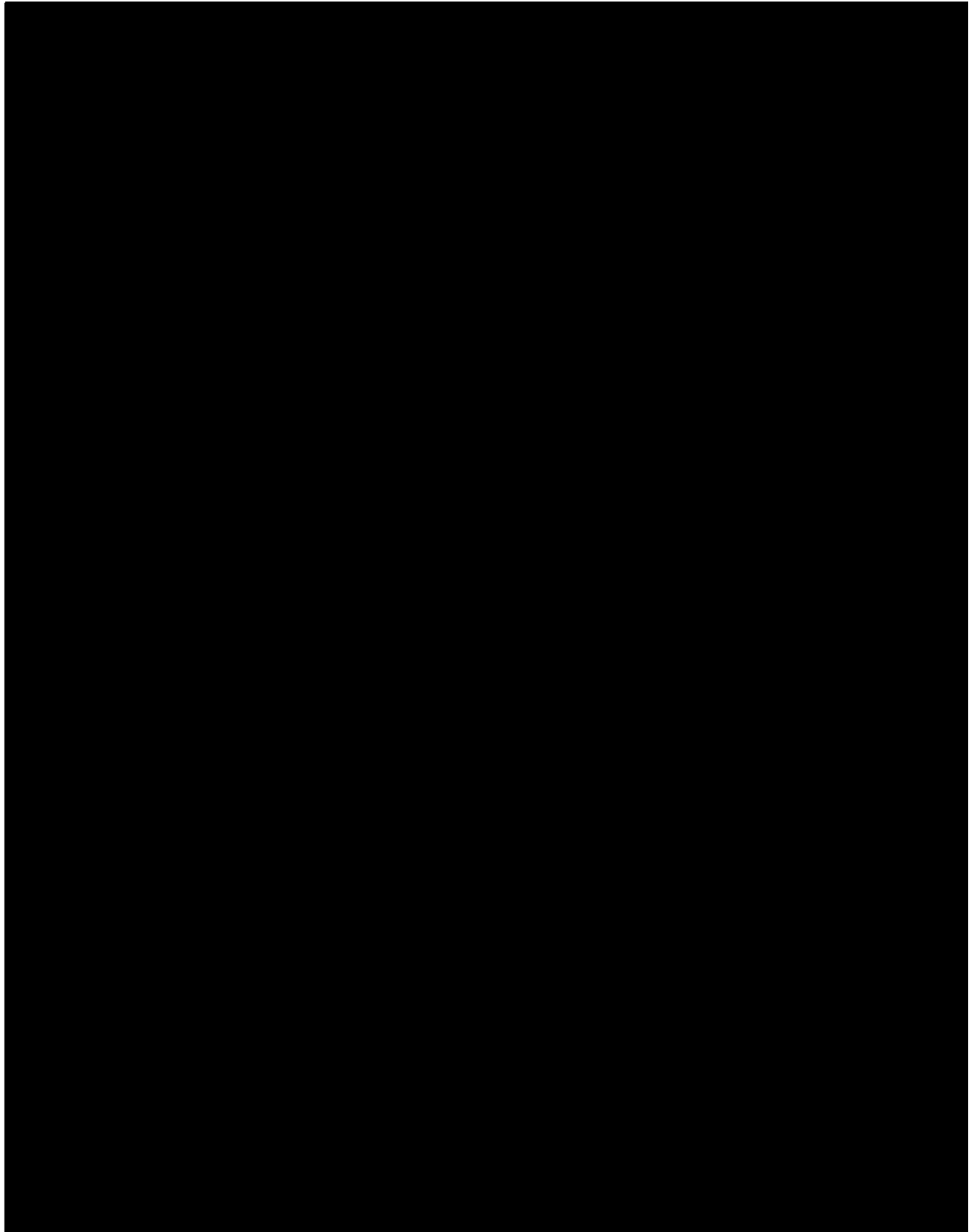
Best wishes for 2014.

Noel.

Noel Fraser  
Inspection Group Manager, Compliance.  
Office of Manufacturing Quality | Monitoring & Compliance Group  
Phone: +61 3 8626 4302 | Email: [noel.fraser](mailto:noel.fraser)

Therapeutic Goods Administration | Department of Health.  
Level 8, 595 Collins St . Melbourne, Victoria,  
Australia. 3000





**From:** Noel.Fraser [mailto:Noel.Fraser] [redacted]  
**Sent:** 20 December 2013 02:01  
**To:** [redacted]  
**Cc:** [redacted] InternationalGMP [redacted]  
**Subject:** RE: Request for information [redacted] India. [SEC=UNCLASSIFIED]

Dear [REDACTED]

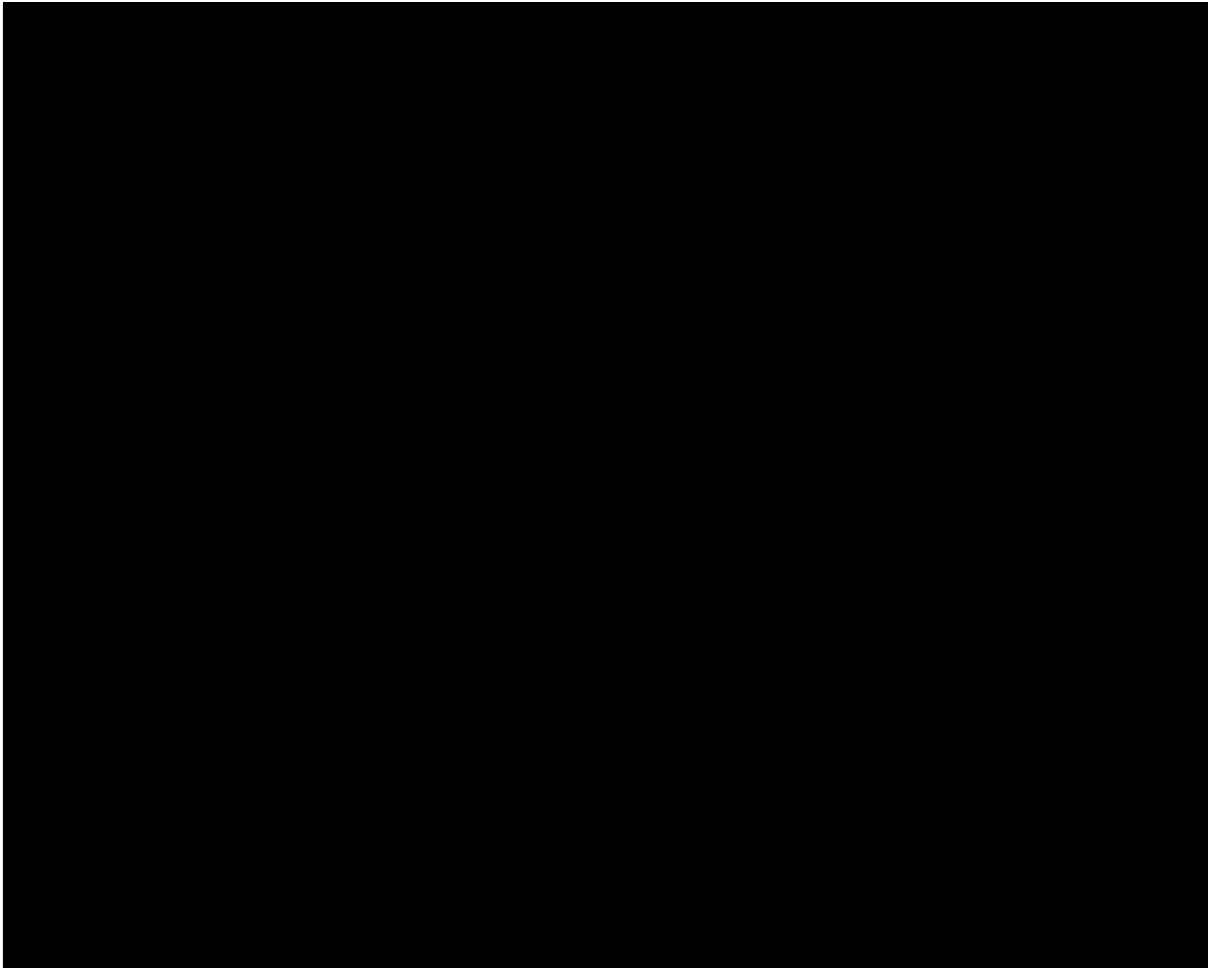
Thank you for your earlier response to Colleen.

Further to your email, I was wondering if there had been any developments to this matter, including as applicable, (1) the results of the regulatory action meeting you referenced and (2) The structured response with report ?

Thank you and kind regards,  
Noel.

Noel Fraser  
Inspection Group Manager, Compliance.  
Office of Manufacturing Quality | Monitoring & Compliance Group  
Phone: +61 3 8626 4302 | Email: [noel.fraser](mailto:noel.fraser) [REDACTED]

Therapeutic Goods Administration | Department of Health.  
Level 8, 595 Collins St . Melbourne, Victoria,  
Australia. 3000  
[REDACTED]



[REDACTED]

**From:** Colleen.Gill [REDACTED] [mailto:Colleen.Gill [REDACTED]] On Behalf Of InternationalGMP [REDACTED]  
**Sent:** 21 November 2013 01:24  
**To:** [REDACTED]  
**Cc:** [REDACTED] Noel.Fraser [REDACTED]  
**Subject:** Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

[REDACTED]

An Australian sponsor has contacted the TGA following the receipt of a MHRA report issued to [REDACTED] indicating serious deficiencies. They have forwarded a copy of this report to the TGA.

In accordance with the cooperative arrangements for the Exchange of Information between the TGA and the MHRA relating to GMP inspections; and to assist TGA's understanding of the MHRA findings and resulting actions relating to [REDACTED] we would like to request a copy of the complete inspection report and any other relevant information relating to this site.

It would be much appreciated if this information could be sent to us as soon as possible.

Alternatively or additionally a teleconference including yourself, the inspectors involved and the TGA could be organised if an open dialogue would better convey your findings and outcomes.

Please contact myself or Noel Fraser ([noel.fraser@\[REDACTED\]](mailto:noel.fraser@[REDACTED])) to arrange.

Thank you in advance for your assistance.

Kind Regards

Colleen Gill on behalf of

International GMP  
Office of Manufacturing Quality

Phone: 02 6232 8156

Fax: 02 6232 8426

Email: [internationalgmp@\[REDACTED\]](mailto:internationalgmp@[REDACTED])

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[REDACTED]

[REDACTED]





