From: Ruddington.RegulatoryAffairs <Regulatory.Affairs@quotientclinical.com>
Sent: 24 November 2015 17:16
To: SANTE-D6-GL-GMP-IMP
Cc: Lucy Lawton; Susan Head; Kirsty Dare; Simon Lee; Joanne Slee; Ruddington.RegulatoryAffairs
Subject: "GL on GMP for IMP"

Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014

Dear Sir/Madam,

On behalf of Quotient Clinical Ltd, please find below our comments to the above mentioned guideline.

Name: Quotient Clinical Ltd

Category: Company

Line numbers of the relevant text: Lines 147-149

Comment: Clarity on Transitional Qualified Persons would be helpful as Transitional Qualified Persons have not fulfilled the FULL conditions of qualification set out in Article 49(2) and (3) of Directive 2001/83/EC, cf. Article 61(2)(b) of Regulation (EU) No 536/2014.

We can confirm that our contribution can be directly published with our organisation information (We consent to publication of all information in our contribution in whole or in part including the name of our organisation, and we declare that nothing within our response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).

Please address any queries to Regulatory.Affairs@quotientclinical.com

Yours faithfully,

Quotient Clinical Ltd

Ruddington.RegulatoryAffairs

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Quotient Clinical

The Translational Pharmaceutics Company