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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