Dear sir(s)

With regard to the proposed Revision to the EU Commission guidelines on Good manufacturing Practice Medicinal Products, and in particular Chapter 6: Quality control. We have a concern regarding the following proposed paragraph:

6.21 Culture media should be prepared in accordance with the manufacturer's requirements unless scientifically justified. The performance of all culture media should be verified prior to use.

This implies that for each batch of culture media that is prepared (eg supplementing DMEM with FBS) needs to be checked prior to use. This is onerous and prohibitively expensive. The manufacturers do grow promotion tests on each manufactured batch of base media and perhaps this can satisfy the requirement for verification prior to use. Also for some micro media that we prepare infrequently we run concurrent growth promotion controls as for low volume testing the requirement to do testing per batch prior to testing would add a delay to the testing for no increase in quality.

Best regards

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