Dear Sir / Madam

Please find below comments relating to the Consultation document “Good Manufacturing Practice for Advanced Therapy Medicinal Products”. The comments are being submitted on behalf of Bioquell UK which is a manufacturer of biodecontamination systems and fits the criteria of a SME.

General Comment:

This guidance document needs to align with and reference ISO 18362:2016 Manufacture of cell based healthcare products – control of microbial risks during processing

Detailed comments:

Section 2.3.2 line 259 – this section does not appear to align with Section 11 of ISO 18362, which itself references Section 11 of ISO 13408-1. Section 11 states that sterility testing should be carried out for each batch of product.

Section 4.2.2 – reference should be made to the ISO 13408 series of standards

Section 4.2.2 line 506 – a “closed system” is defined in note 5 at the bottom of the page. The definition should align with the ISO 11139 Terminology standard which defines a closed system as a system preventing the egress of hazardous agents and the ingress of extrinsic contamination.

Section 4.2.2 line 508 – there is much confusion within the industry as to what is and what is not an isolator, a closed system, etc. This section should refer to ISO 14644-7 and / or ISO 13408-6.

Section 9.5 Aseptic manufacturing – this section should reference ISO 18362, the ISO 13408 series of standards and the ISO 14644 series of standards (particularly ISO 14644-7).

Yours sincerely