This does need to be more prescriptive in relation to the implementation of Annexes 1 and 2 into this structure. I have picked out a few questions to respond to.

Q3; In order to mesh with the JACIE system in the NHS environment, some thought must be given to the Quality System in relation to personnel. The JACIE accreditation system has a personnel structure that is clinically based, rather than GMP based. The Production Facility Director (JACIE) can also be named the Head of Production (GMP) as this is functionally equivalent, and the Quality Manager in the JACIE program could also be the Head of Quality for the purposes of GMP. Where the Quality Manager is not a member of laboratory personnel, this may have to be remedied by additionally appointing a laboratory based Quality Assurance Manager.

Q18; Many labs, especially those currently governed by JACIE and the HTA may not currently have access to a QP and would have to do so.

Q22; Yes, I agree that the manufacturer's responsibility would be limited to validation of the reconstitution process (with supply of this information to the end user) plus the supply of detailed information about the reconstitution process to users. It would be also useful for the manufacturer to be available for questions or additional information where required for this activity.

Q23; Where reconstitution is thawing, I agree that this should not be GMP governed as this would be frequently carried out at the bedside or in clinics in the NHS setting. Where reconstitution is more complex, involving diluting, where the procedure is open rather than docked, this should be GMP governed, at least in relation to being carried out in an appropriate environment, with appropriately trained staff according to EU GMP Vol. 4, Part 1 (chapters 1-6) and Annexe 1.

Q24; Reconstitution should be defined as the activity of addition of another substance to an ATMP product where not in a closed system, requiring a Grade A environment.

G25; It would suit most users very well to say that the quality of automated devices be the responsibility of the manufacturer but insisting that all such devices come validated for the particular use of the laboratory may be prohibitive to all. There must be some flexibility to allow local validation of devices where not available from the manufacturer.

Kind regards

Tammy

Tamara Elston
Cellular Therapy Unit Quality Director
Department of Haematological Medicine/CRF
2nd floor, CTU
King's College Hospital
Denmark Hill
SE5 9RS