Comments from contributor wishing to remain anonymous

Comments:

Line 118. Is this point applicable only to deviations relating to the modification steps or does it apply from the beginning of manufacturing? It is unlikely that visibility of deviations in GMP will be available if the product is:

- An unauthorised AMP, but licenced in another member state or 3rd country
- Or if the product is authorised and purchased via an agent/distributor

Line 122. Does this point relate only to the raw materials and packaging components used during the modification step? Visibility of the source of raw materials and packaging will not be visible if the product is:

- An unauthorised AMP, but licenced in another member state or 3rd country
- Or if the product is authorised and purchased via an agent/distributor

Line 130 & 131. Is visibility of the supply required only from the point at which the AMP leaves the custody of the Marketing Authorisation Holder? Visibility of the supply chain will not be available to the Sponsor for the entire supply chain of the medicinal product.