

European Biosafety Association
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Summary¹ Break-out Discussion
GMP vs Biosafety

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It was clear from the discussion that there are sometimes conflicting priorities when it comes to balancing GMP concerns vs. biosafety concerns. In GMP systems, the focus is more on protection of the product against contamination, but scenarios where contaminated product is handled (either knowingly as for certain specialty blood products, e.g. HCV hyperimmune globulin, or potentially unknowingly with recombinant manufacturing systems, in the very rare cases of contamination) also require that the operator is protected. Therefore, containment systems that protect both operator and product where necessary should be considered when designing GMP facilities.

¹ This summary reflects the discussion and recommendations as noted by the moderators. While the views expressed in this summary can assist EBSA in determining what further action is possible, they do not necessarily represent EBSA's position on the matter and should not be presented as such.