

biotech facilities

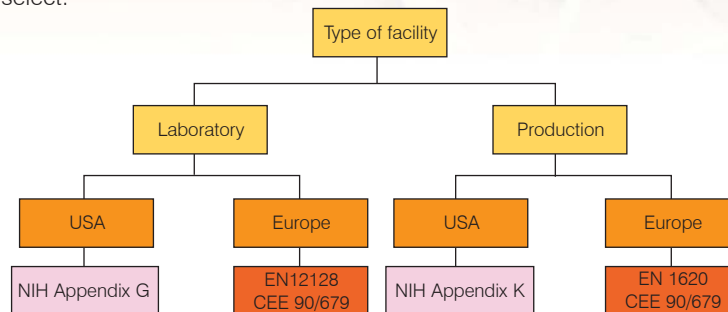
HVAC AND BIOLOGICAL CONTAINMENT



At all stages of a biopharmaceutical process, the possible release of pathogenic or altered organisms into laboratories or the environment poses a significant concern. Luca Arrighi, head of HVAC in our Milan-based Steril Manufacturing Division, discusses the role of the HVAC in providing biological containment.

Regulations

Organizations such as the Federal Drug Administration, European Commission, European Committee for Standardization, National Institute of Health and the World Health Organization have developed rules and guidelines that the design team must follow. Some national agencies have developed guidelines, but in their absence, US and European regulations are generally used worldwide. The flowchart below indicates which guideline to select.



Analyzing Risk

The guidelines require a risk analysis to evaluate the risk of release and the level of containment required to mitigate that risk. One of the most critical design items is the HVAC system which must satisfy both good manufacturing practice and safety requirements. Initially, the quantity and quality of the biological agent is ascertained. Quantity is defined as large-scale (production) or small-scale (laboratories), and quality is defined as:

Hazard group 1: unlikely to cause human disease

Hazard group 2: can cause human disease, unlikely to spread to community

Hazard group 3: can cause severe human disease and serious hazard to community

Hazard group 4: can cause severe disease, no effective prophylaxis

Containment

Depending on the level of containment required, the HVAC system design must incorporate specific features. Primary containment protects the operator in the work area and secondary containment confines potential release within the working area.

