**Facilities for Large-scale Bacteriophage Manufacturing**

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With the rise of antibiotic resistant bacterial strains, therapeutic bacteriophages are emerging as both a potential alternative to antibiotics and as an antibiotic-synergistic treatment of bacterial infections. Bacteriophages are viruses that only infect and replicate in bacteria, often with very targeted infection of specific strains. Emerging therapies require CGMP manufacturing of host bacterial culture in large-scale (10L - 1000L) bioreactors and downstream processes scaled appropriately. Manufacturing at-scale involves examining key process input variables for their effect upon key process outputs for all unit operations. For upstream operations this involves examining such variables as bioreactor temperature, time of infection, multiplicity of infection, and agitation for their influence on such outputs as bacteriophage yield, infection kinetics, and quality of phage. Downstream processes begin with separating the bacterial debris from the newly replicated phage particles through techniques including centrifugation or filtration. Facility design begins with translating optimized net API yield potential to the equipment and processes determined to provide the mass/activity required. Then, prokaryotic culture facility design is established considering such factors as the selected mode and scale of each operation throughout the process train, and such options as the use of either single-use or stainless-steel equipment to implement them.