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90 W. EYKAMP 5.1 Background and need  
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442 Downstream Processing For each  
processing step, the effectiveness of  
removal or inactivation must be  
validated by the biomanufacturer using  
virus challenge or spiking studies, in  
which representative and/or model  
viruses are added at known high titers  
then tracked through each step of the  
process typically via infectivity assay.

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4 DOWN STREAM PROCESSING 4.1 INTRODUCTION Industrial fermentations comprise both upstream (USP) and downstream processing (DSP) stages (Fig. 4.1). USP involves all factors and processes leading to and including the fermentation and consists of three main areas: the producer organism, the medium and the fermentation process.

## **4 DOWN STREAM PROCESSING - Microbiology**

As discussed in Chapter 4, a high level of process-related impurities and cell

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debris requires greater efforts during recovery and purification as they might have detrimental effects on the recovery and/or purification steps, leading to a higher cost of the downstream process.

## 32.5.2. Basics of Downstream Process Development

### **Downstream Process Design, Scale-Up Principles, and ...**

Downstream processing operations are discussed in some depth in Chapter 8 . This discussion is limited to factors that must be considered in developing any economically viable product purifi ...

### **(PDF) Strategies in Downstream Processing**

M. Cheryan, in Encyclopedia of Microbiology (Third Edition), 2009. Downstream Processing. Downstream processing refers to the series of unit operations used to isolate, purify, and concentrate the product. Downstream processing often determines the economic feasibility of the process. The

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first operation is cell separation, which can be done by cross-flow microfiltration.

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Downstream processing is now routinely found to be the bottleneck in biopharmaceutical manufacturing because its capacity has not kept pace with upstream production (1). In some cases, the lack of downstream processing capacity can seriously affect the profitability of a new pharmaceutical product and even result in its failure.

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