Fall 11-2-2015

Considerations for an incubation chamber for continuous viral inactivation

Raquel Orozco
Bioprocess Engineering, Boehringer Ingelheim Fremont Inc.CA USA, raquel.orozco@boehringer-ingelheim.com

Nancy Guillen
Cell Culture, Boehringer Ingelheim Fremont Inc. CA USA

Loleta Chung
Clinical Supply, Boehringer Ingelheim Fremont Inc. CA USA

Scott Godfrey
Bioprocess Engineering, Boehringer Ingelheim Fremont Inc. CA USA

Jon Coffman
Bioprocess Engineering, Boehringer Ingelheim Fremont Inc. CA USA

CONSIDERATIONS FOR AN INCUBATION CHAMBER FOR CONTINUOUS VIRAL INACTIVATION

Raquel Orozco, Bioprocess Engineering, Boehringer Ingelheim Fremont Inc.CA USA
raquel.orozco@boehringer-ingelheim.com

Nancy Guillen, Cell Culture, Boehringer Ingelheim Fremont Inc. CA USA
Loleta Chung, Clinical Supply, Boehringer Ingelheim Fremont Inc. CA USA
Scott Godfrey, Bioprocess Engineering, Boehringer Ingelheim Fremont Inc. CA USA
Jon Coffman, Bioprocess Engineering, Boehringer Ingelheim Fremont Inc. CA USA

Key words: viral inactivation, continuous bioprocessing

Continuous bioprocessing offers numerous benefits that have been highlighted recently in the literature. While substantial research efforts have allowed for relevant developments in continuous cell culture processes, downstream challenges, such as continuous viral inactivation, have not been addressed. The purpose of this work is to design a chamber that incubates a continuous product stream for a desired incubation time, typically for 1 hour. Since plug-flow cannot be achieved at typical incubation times and flow rates, one of the biggest challenges is to address dispersion of the product stream. Since several logs of viral clearance should be achieved during a virus removal step, the restriction is that only 1-10ppm of the original product should exit the chamber before the specified time. In this work, an initial design is chosen such that the incubation chamber is easy to handle, has a small footprint, and there are no pressure concerns at the desired flow rates. Pulse response experiments have been performed to generate cumulative residence time distribution functions. The average residence time distribution function was used to find the time at which 1 ppm of the original tracer concentration passes through the chamber. An orthogonal method should be used to verify that the diluted tracer concentration falls under the predicted value at the desired time. Thus, the starting tracer solution must be concentrated enough such that a concentration of 1 ppm can be measured by a highly sensitive technique. In this work, a tracer solution and a method of detection were selected. Preliminary results of chamber design will be shown and current challenges will be shared.