UNIVERSITY OF ARKANSAS

Ralph E. Martin Department of

Chemical Engineering

Seminar Series

Viral Clearance Validation: What is it and how an Innovative Approach can Change Biopharmaceutical Process Development

David Cetlin

Founder & CEO of MockV Solutions, Inc.

Thursday, February 28, 2019

3:30 p.m. – 4:30 p.m.

Cato Springs Research Center (CSRC), room 122

Live-Stream

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Abstract: Viruses can arise during the manufacture of biopharmaceuticals through contamination of exogenous viruses or endogenous expression of viral sequences. Regulatory agencies therefore require “viral clearance” validation studies for each biopharmaceutical prior to approval. These studies aim to demonstrate the manufacturing process’ ability at removing or inactivating virus and are conducted by challenging scaled-down manufacturing steps with a “spike” of live virus. These studies are conducted in BSL-2 facilities and are costly. Due to these hurdles, process knowledge pertaining to viral clearance is limited during development and characterization. The use of an accurate, economical and quantifiable non-infectious viral surrogate would enable downstream purification scientists to study viral clearance throughout process development. Discussed here are proof of concept studies conducted through collaborations with Asahi Kasei and MedImmune in which monoclonal antibody material was spiked with either live Minute Virus of Mice (MVM) or non-infectious Mock Virus Particles (MVM-MVP) and processed through Nanofilters and Anion Exchange Chromatography columns. Process performance and Log Reduction Values are compared.

David Cetlin is the founder and CEO of MockV Solutions, Inc. a company dedicated towards establishing and commercializing a novel series of BSL-1 compatible viral clearance prediction kits. These kits will be designed to benefit downstream purification process scientists as they develop, characterize, and validate their downstream purification processes. Prior to MockV, David was a downstream process development scientist at Human Genome Sciences/GlaxoSmithKline. In this role he helped develop, characterize and validate several monoclonal antibody purification processes and worked with various separation techniques including column chromatography, tangential flow filtration and nanofiltration.

Seminar is free and open to the public. Metered parking is available in Lot 71 across the street from the John A. White, Jr. Engineering Hall and in the Harmon Garage down Duncan Avenue. For information about the department, visit https://chemical-engineering.uark.edu/.