

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/ORL/OPQO HQ, Room #2032 12420 Parklawn Drive Rockville, MD 20857 www.fda.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/5, 09/06, and 09/09 to 09/13/2109
	FEI NUMBER 3003153579

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Jeffrey R. Broadfoot, Senior Director Quality

FIRM NAME Emergent BioSolutions Canada Inc.	STREET ADDRESS 155 Innovation Drive
CITY, STATE AND ZIP CODE Winnipeg, MB, Canada R3T 5Y3	TYPE OF ESTABLISHMENT INSPECTED Contract Manufacturer of Sterile Human Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

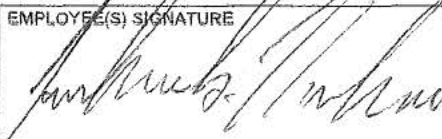
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically, on 09/06/2019, during the filling equipment setup operations for (b) (4) Injection, (b) (4) mg/mL (b) (4) Lot # (b) (4), a Lead Manufacturing Assistant was observed grasping the outside of his sterile boot covers to unfold the vinyl boot soles during the gowning process. The firm's procedures specifically require employees to only place their sterile, gloved hands inside the sterile boot covers, and to only grasp the vinyl boot sole from inside the sterile boot cover in order to unfold the boot cover sole.

JGM 9/13/2019

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jonathan G. Matrisciano, Investigator	DATE ISSUED 09/13/2019
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