

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Christopher Downey, Ph.D., Director of Division of Biotechnology Manufacturing US Food & Drug Administration, Office of Pharmaceutical Quality-OPMA-DBM 10903 New Hampshire Avenue, Bldg. 22, Silver Spring, Maryland 20993 OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/10-12, 15-19/2024
	FEI NUMBER 3013702557

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Robert Wessman, CEO and Chairman (robert.wessman@alvotech.com)

FIRM NAME Alvotech Hf	STREET ADDRESS Sæmundargata 15-19
CITY, STATE AND ZIP CODE Reykjavik, Iceland 102	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

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

**OBSERVATION 1:**

Your environmental/personnel monitoring for Building (b) (4) RABS Filling Line (Rm. (b) (4)) is not adequate. Specifically,

a. On January 15, 2024, during (b) (4) RABS (b) (4) RABS) setup activities, the first-air operator was observed sanitizing (b) (4) multiple times during each of the (b) (4) RABS interventions' operations (b) (4) the (b) (4) RABS filling line to have (b) (4) monitored via (b) (4) (for critical (b) (4) RABS interventions). Frequent sanitization of operators (b) (4) during critical (b) (4) RAB operations may impact microbial data collection and analysis.

b. RABS (b) (4) monitoring is performed for only (b) (4) of the RABS (b) (4) RABS (b) (4) may be used (b) (4) at multiple RABS (b) (4) should be monitored as they are used.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael R. Shanks -S <small>Digitally signed by Michael R. Shanks -S Date: 2024.01.19 10:58:52 Z</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Michael R. Shanks, Senior Biologist Ben Du, Senior Staff Fellow Scott Lute, Senior Biologist	DATE ISSUED 01/19/2024
	Bingchen Du -S <small>Digitally signed by Bingchen Du -S Date: 2024.01.19 06:54:07 -05'00'</small>		
	Scott C. Lute -S <small>Digitally signed by Scott C. Lute -S Date: 2024.01.19 06:08:02 -05'00'</small>		