VAL-195 Maximum Safe Carry-Over (MSCO) Determination

Appendix A: Biologicals Area Cleaning Validation New or Changed Product, Process and Equipment Assessment

1. Introduction

This form is to be utilised for recording new product details and/ new process details that may have impact on the applicability of existing cleaning procedures on the biological production area.

2. Purpose and Scope

This form will be utilised for assessment of new product/process and equipment risk in both blending and antigen production areas. The form will guide the user to supply appropriate product and equipment information so that the impact of the new product material components and process can be assessed in regard to existing or future cleaning validation documentation.

3. New or Modified Product/Process Material

Product Name:_____

Product Type (Circle): Vaccine / Sterile Pharmaceutical / Antigen (Bacterin) / Antigen (Toxoid)

Is the product aqueous or non- aqueous? (Circle): Aqueous / Non - Aqueous

Instruction	Component Description	Component Concentration
List the Active Pharmaceutical Ingredients (APIs) that are of a biological origin.	1.	
	2.	
	3.	
	4.	
	5.	
	6.	
List the Active Pharmaceutical Ingredients (APIs) that are of a chemical origin.	1.	
	2.	
	3.	
	4.	
	5.	
	6.	
Attach the Product Formulation Sheet or the Finished Product Specification containing the product component specifications	Sign/Date	
Attach Solubility Data for all APIs (typically available in the raw material MSDS	Sign/Date	

Appendix A: Biologicals Area Cleaning Validation New or Changed Product, Process and Equipment Assessment

4. New or Modified Product/Process Material

Instruction	Component Description	Component Concentration
List the Excipients in the Product Formulation	1.	
	2.	
	3.	
	4.	
	5.	
	6.	
	7.	
	8.	
	8.	
	10.	
	11.	
	12.	
Attach material data for all Excipients (typically available in the raw material MSDS)	Sign/Date	

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5. New Equipment or New/Modified Equipment Train

I. Is there new equipment required for processing the new product, or is new equipment being utilised?

a. If **Yes** Proceed to (2)
b. If **No** Proceed to (4)

II. Enter details of the new equipment to be utilized (Strikethrough N/A if Not Applicable)

New Equipment 1 ID

a. Equipment Name:	
b. Equipment Purpose:	
c. Height:	
d. Width:	
e. Diameter:	
f. Length:	
g. Circumference:	
h. Internal Surface Area:	
i. Working Volume	
j. Mainpac Entry	No / Yes – ID#_____

New Equipment 2 ID

k. Equipment Name:	
l. Equipment Purpose:	
m. Height:	
n. Width:	
o. Diameter:	
p. Length:	
q. Circumference:	
r. Internal Surface Area:	
s. Working Volume	
t. Mainpac Entry	No / Yes – ID#_____

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III. Is the new equipment intended to be dedicated? **(Yes / No)**

IV. Enter all product contact equipment in the process list below, in order from commencement of manufacture to the completion.

a. MEDIA PREPARATION EQUIPMENT

IV.a.1	
IV.a.2	
IV.a.3	
IV.a.4	
IV.a.5	
IV.a.6	
IV.a.7	
IV.a.8	
IV.a.9	
IV.a.10	

b. ANTIGEN AREA EQUIPMENT

4.2.1	
4.2.2	
4.2.3	
4.2.4	
4.2.5	
4.2.6	
4.2.7	
4.2.8	
4.2.9	
4.2.10	

c. BLENDING AREA EQUIPMENT

4.3.1	
4.3.2	

4.3.3	
4.3.4	
4.3.5	
4.3.6	
4.3.7	
4.3.8	
4.3.9	
4.3.10	

6. Are the cleaning operation intended to be covered by an existing SOP? If Yes, please specify

Equipment	SOP with Cleaning Instruction	Equipment	SOP with Cleaning Instruction

Submitted By:_____ **Sign / Date**:_____