

Overview of changes requiring an inspection in the GMP area

Area	Change	Must GMDP-krav@dkma.dk be notified about the change?	Does the change require an inspection?
Buildings	New production room (formulation/filling/packaging)	Yes	Yes
	New GMP laboratory	Yes	Yes
	New storage facilities (freeze/cool/ambient)	Yes	Yes
	New access locks (for classified rooms)	Yes	Case-by-case decision
	New changing room (for non-classified rooms)	No	No
	New external storage facilities, e.g. tanks for organic solutions	No	No
	New additional building for receipt control of raw materials	No	No
Equipment	New filling line	Yes	Case-by-case decision
	New packing line	Yes	Case-by-case decision
	New freeze dryer	Yes	Case-by-case decision
	New separator	No	No
	New autoclave	No	No
	New washer	No	No
	New analytical equipment	No	No
Plant	Switch to WFI water by RO	Yes	Yes
	New fermentation line	Yes	Case-by-case decision
	New water plant	Yes	Case-by-case decision
	New ventilation system for classified area	Yes	Case-by-case decision
Product	New medicinal product	Yes	Case-by-case decision
	New biological API	Yes	Case-by-case decision
	New sterile API	Yes	Case-by-case decision
	New chemical API	Yes	Case-by-case decision