

重大變更清單 List of Major Changes

製造廠房、設施及生產線

Manufacturing buildings, premises, facilities and production lines

變更類型 Types of Change	變更內容 Description of the activities carried out	變更狀態 Status of Change	涉及本署核定之劑型/ 品項/作業內容 Relevant to the dosage forms/products/operations approved by TFDA	涉及輸台產品 Relevant to products exported to Taiwan	檢送文件 Supporting documents
<input type="checkbox"/> buildings <input type="checkbox"/> premises/facilities <input type="checkbox"/> production lines <input type="checkbox"/> others		<input type="checkbox"/> 已實施, 完成日期 <u>日期</u> <input type="checkbox"/> 進行中, 預計完成日期 <u>日期</u> <input type="checkbox"/> Implemented, done on <u>date</u> <input type="checkbox"/> Ongoing: proposed date of completion <u>date</u>	<input type="checkbox"/> 是, 涉及劑型/品項/製造作業內容 <input type="checkbox"/> 否 <input type="checkbox"/> Yes, the change is relevant to <u>dosage forms/manufacturing processes</u> <input type="checkbox"/> No	<input type="checkbox"/> 是, 涉及輸台產品 (已主動申請/報備文號) <input type="checkbox"/> 否 <input type="checkbox"/> Yes, the change is relevant to <u>products exported to Taiwan (Previous Submission No)</u> <input type="checkbox"/> No	<input type="checkbox"/> 變更前後平面圖 (如附件____) <input type="checkbox"/> 當地主管機關核准文件或說明管理方式(如附件____) <input type="checkbox"/> comparison of layouts before and after the change. (see attachment ____) <input type="checkbox"/> local authority approval or description of the regulation by local authority (see attachment ____)

簽名 (含簽署日期):

Signature (including date of signing) : _____

(職稱/Title)