

## 美國FDA為因應藥品污染事故公告四項製藥新指導原則



美國食品藥物管理局 (the United States Food and Drug Administration, 以下簡稱FDA) 於2015年2月13日公告四項與藥品製造有關之指導原則 (guidance) 作為補充相關政策執行之依據, 主要涉及藥品製程中, 藥品安全不良事件回報機制、尚未經許可之生技產品的處理模式、藥品重新包裝, 以及自願登記制度中外包設施之認定應進行的程序與要求。

該四項指導原則係源於FDA依據2013年立法通過之藥物品質與安全法 (The Drug Quality and Security Act, 以下簡稱DQSA) 所制定之最新指導原則。因2012年位於麻州的新英格蘭藥物化合物中心 (The New England Compounding Center), 生產類固醇注射藥劑卻遭到污染, 爆發致命的黴菌腦膜炎傳染事故, 故美國國會制定DQSA, 以避免相同事故再次發生。DQSA要求建立自願登記制度 (system of voluntary registration), 倘若製藥廠自願同意FDA之監督, 成為所謂的外包設施 (outsourcing facilities)。作為回饋, FDA即可建議特定醫院向該製藥廠購買藥品。

而本次四項指導原則之內容, 其一主要涉及外包設施進行藥物安全不良事件回報之相關規定, 要求製藥廠必須回報所有無法預見且嚴重的藥物安全不良事件。在不良事件報告中必須呈現四項資訊, 其中包括患者、不良事件首名發現者、所述可疑藥物以及不良事件的類型。同時, 禁止藥品在上市時將這些不良事件標示為潛在副作用。第二份指導原則對於尚未經許可的生技產品, 規定可進行混合, 稀釋或重新包裝之方法; 並排除適用某些類型的產品, 如細胞療法和疫苗等。第三份指導原則涉及重新包裝之規定, 內容包括包裝地點以及如何進行產品的重新包裝、監督、銷售和分發等其他相關事項。而第四份指導原則規範那些類型之藥品製造實體應登記為外包設施。為此, FDA亦指出聯邦食品藥物和化妝品法 (the Federal Food Drug & Cosmetic Act) 之規定裡, 已經要求製造商從事無菌藥品生產時, 必須將法規針對外包設施之要求一併納入考量。

### 相關附件

- [United States Food and Drug Administration, Guidance For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Food, Drug, and Cosmetic Act \[ pdf \]](#)
- [United States Food and Drug Administration, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities \[ pdf \]](#)
- [United States Food and Drug Administration, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application \[ pdf \]](#)
- [United States Food and Drug Administration, Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act \[ pdf \]](#)



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資料來源：



United States Food and Drug Administration, Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf> (last visited Feb. 13, 2015).

United States Food and Drug Administration, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434176.pdf> (last visited Feb. 13, 2015).

United States Food and Drug Administration, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf> (last visited Feb. 13, 2015).

United States Food and Drug Administration, Guidance For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434171.pdf> (last visited Feb. 13, 2015).

文章標籤

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