附件：

壹、《醫療器材管理法》草案第十三條

草案條文	衛生福利部食品藥物管理署說明
第十三條 醫療器材製造業、維修業及輸入醫療器材知販售業者，應視醫療器材類別，聘用技術人員。 前項醫療器材類別、技術人員資格及其管理辦法，由中央主管機關。	1.參考藥事法第三十二條制定醫療器材製造業、維修業及輸入醫療器材知販售業者，依醫療器材類別，聘用技術人員。 2.第二項授權技術人員資格及其管理於子辦法訂定之。 3.參考歐盟草案 Article 13 <Person responsible for regulatory compliance> 之要求，製造商和歐盟授權代表皆被要求要設置至少一名 person responsible for regulatory Compliance.本條文要求輸入醫療器材之販賣業者（指輸入醫療器材登錄者或許可證持有者），需設置管理人員，負責管理輸入之產品能符合國的相關法規。 4.子法規：醫療器材技術人員管理辦法

貳、現行藥事法第三十二條暨其施行細則第二十三條條文

《藥事法》第三十二條

醫療器材販賣或製造業者，應視其類別，聘用技術人員。

前項醫療器材類別及技術人員資格，由中央衛生主管機關定之。

《藥事法施行細則》第十三條

醫療器材製造業者依本法第三十二條規定應聘技術人員之醫療器材類別及其技術人員資格，依左列規定：

一、製造一般醫療設備、臨床檢驗設備及生物材料設備者，應聘國內公立或立案之私立專科以上學校或經教育部承認之國外專科以上學校理、工、醫、農等相關科、系、所畢業之專任技術人員駐廠監製。

二、製造隱形眼鏡鏡片消毒藥水（錠）、移植器官保存液、衛生材料、衛生棉條業者，應聘專任藥師駐廠監製。

參、歐盟醫療器材法規草案《*Proposal for a Regulation of the European Parliament AND OF THE Council on medical devices, and amending Directive 2001/83/EC, (EC) No 178/2002 and Regulation (EC) No 1223/2009*》第十三條條文：

Article 13

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation~~,~~ ~~at~~ least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:

   (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognized as*** equivalent ~~course of study, in natural sciences,~~ ***by the Member State concerned, in*** medicine, pharmacy, engineering or another relevant ***scientific*** discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~medical~~ devices;

   (b) five years of professional experience in regulatory affairs ~~or~~ ***related to devices including experience*** in quality management systems ~~relating to medical devices~~.

   Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

1a. ~~This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by~~ ***Micro and small enterprises within the meaning of*** Commission Recommendation 2003/361/EC ***are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal***.

2. The ~~qualified~~ person ***responsible for regulatory compliance*** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately ~~assessed~~ ***checked in accordance with the quality management system under which these devices are manufactured*** before a ***product*** ~~batch~~ is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(***ba***) ***that the post-market surveillance obligations in accordance with Article 8(6) are complied with;***

(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;

(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

3. The ~~qualified~~ person ***responsible for regulatory compliance*** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties***, regardless of whether or not he is an employee of the organisation.***

4. Authorised representatives shall have ~~available within~~ ***permanently and continuously at*** their ~~organisation~~ ***disposal*** at least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses expert knowledge regarding the regulatory requirements for medical devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognised as*** equivalent ***by the Member State concerned,*** ~~course of study,~~ in ~~law, natural sciences,~~ medicine, pharmacy, engineering or another relevant ***scientific*** discipline***,*** and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.