DNV GL醫療器材驗證服務現況說明

TMBIA簡報

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廠商常見缺失說明

Risk management plan/report cannot meet ENISO14971 requirement

Example:

- ✓ The definition of probability is not clear. there is not clear how the Probability matrix is to be understood ?
- ✓ What is the subject of frequency? Is it per device / per procedure?
- ✓ there is not defined that how often Probability of occurrence is happened?
- ✓ As required in ISO 14971:2012, no risk benefit analysis of individual risks or overall risk benefit analysis for the product are presented in the risk management report
- ✓ Whole life-cycle of the device is not covered in risk management process.

Clinical evaluation cannot meet MEDDEV 2.7/1, Rev. 4 requirement

Example:

- ✓Rev.3 cannot be accepted
- ✓Equivalence is not demonstrated. The tables comparing the equivalent products is not very detailed. For instance intended use is not the same for all equivalent devices, all relevant aspects is not compared, for instance thickness, ability to absorb fluid, is the equivalent products material identical?
- ✓Can indications and contraindications be found in clinical evaluation report?
- ✓The manufacture has not clearly presented literature relating to clinical safety , performance of the device.

PMS/PMCF plan/data is not completed, not be sufficient in technical documentation

Example:

- ✓According to MEDDEV 2.12, manufacturer should have system to identify pattern of adverse events or incidents reporting that are usually excluded from individual reporting. This is to monitor severity and frequency of the known adverse events. Therefore, it is expected that manufacturer have established procedures to proactively collect and scrutinizes trends in all complaints and incidents occurring with their devices. Among other activities this should also include training of not only their own employees but also the user on necessity to report incidents and adverse events of both known and unknown nature. MEDDEV 2.12 requires a robust, proactive post marketing surveillance system (PMS).
- ✓PMS plan and PMCF plan lack all the details as required in meddev 2.12 -1 and -2

Test report is not completed, not be sufficient in technical documentation

Example:

- ✓ISO 10993-1 evaluation, ISO 10993-X test report, per final product
- ✓Sterilization report, routine monitoring, initial validation, re-validation, per product
- ✓Shelf life/ Life Time/ Storage/ Transportation … stability report
- ✓Harmonized standard test report

Labeling/packing/IFU is not completed, not be sufficient in technical documentation

Example:

- ✓Customer web site cannot be confirmed that these devices are home care devices but this is not the same information in the IFU
- ✓The storage conditions are not included in the IFU as required by ER 13.6a.
- ✓There is no graphical symbol for Operating and Storage Temperature on the Labels as specified in the Specifications of devices.

Declaration of conformity is not completed, not be sufficient in technical documentation

Example:

- ✓Declaration of Conformity does not consist a statement that the declaration is issued under the sole responsibility of the manufacturer. This document also does not have any space to mention number identifying the product and this number does not need to be unique to each product but it could refer to a product, batch, type or a serial number allowing traceability.
- ✓The product name, type, models of the device is missing in the DOC. It should be consistence in draft certificate

Essential requirement checklist is not completed, not be sufficient in technical documentation

Example:

- ✓Essential requirement check list is not detailed. This list does not include the standards manufacturer claims compliance with to be compliant with relevant requirement or internal procedures ensuring their compliance.
- ✓It is not full traceability in ER to referred reports/documents, including unique name/version numbers.

Others_ cross directive/IFU compliance

Example:

- ✓There is no reference to RoHS Directive. The requirements of RoHS Directive 2011/65/EU is not declared in active device.
- ✓List of devices: Please include information regarding if the devices is delivered in non-sterile, but it need to be sterilized before use/reuse, there is no cleanliness/sterile validation report, according to IFU.

醫材公會會員廠提問釋疑

MDD指令與MDR法規(EU 2017/745)的差異，以及變化的方向？

- Common Specification (Article 9), a set of technical and/or clinical requirements
- MDR強調系統的概念，譬如品質管理系統(Article 10), 上市後監督系統(Article 83),風險管理系統(Article10, Annex I), UDI系統(Article 27)
- 製造商須建立施行符合MDR的QMS, 執行趨嚴的MDR Annex I GSPR, 臨床評估, 上市後臨床追蹤, 上市後監督。 歐盟會導入UDI and EUDAMED, 增強追溯, 辨識, 器材註冊, 通報作業和各會員國之間的溝通。
- 明定製造商, 經銷商, 進口商, 歐體代表責任義務，須以Economic operator 概念, 作器材申請和上市後監督

IVDD指令與IVDR法規的差異，以及變化的方向？

- DNVGL Presafe is not intend to apply IVDR_NB, so it is exclusive in current NB activity

現行廠商須優先執行MDR改版的重點項目？

- https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en
- Follow EU document

- 廠內品質系統在施行醫材設計, 製造, 銷售, 服務等與醫材生命週期有關的活動, 須符合MDR的條文要求, 參考CEN/TR 17223:2018.
- 導入Economic operator 的概念，組成合適的製造商, 經銷商, 進口商, 歐體代表, 每個角色都須符合MDR資格要求，再依MDR要求作器材申請和上市後監督。
- 完成GSPR Checklist and DOC per MDR，了解廠內需改善的差異。

上市後監督(PMSR, Post Market Surveillance Reports)頻率，以及將須該報告回饋MDR那些文件，頻率該如何訂立? (續下頁)

	PMS report	PSUR Periodic Safety Update Reports			
Class of device	Class I	Class IIa (category)	Class IIb (generic group)	Class IIa, IIb Implantable	Class III
Content 內容	Summary and conclusions of surveillance data analysis 監督資料分析的總結和結論				
	Rationale and description of any preventive and corrective actions 任何預防和矯正措施的理由和描述				
	-	Volume of sales of device and estimate evaluation of the size and other characteristics of the population using it, where practicable usage frequency of the device 在可行的器材使用頻率下，器材的銷售量，和估計評估使用它的人數規模，和其他族群特徵			
	-	Main findings from PMCF 來自PMCF的主要發現			
	-	Conclusions of risk-beneift determination 風險-效益判定的結論			
Periodicity of revision 更版週期	as needed, based on new input 必須的,基於新的輸入	as needed, at least biennially 必須的,至少每2年	at least annually 至少每年	at least annually 至少每年	at least annually 至少每年

醫療器材安全監視定期安全性報告(PSUR, Periodic Safety Update Reports)的執行頻率，以及內容方向？ (接上頁)

	PMS report	PSUR Periodic Safety Update Reports			
Class of device	Class I	Class IIa	Class IIb	Class IIa, IIb Implantable	Class III
Available to Notified body 通告機構可取得	For Is, Im, Ir 一類滅菌，量測，可重複使用手術器械	Part of Annex III Documents 附件III 的部分	Part of Annex III Documents 附件III 的部分	By means of EUDAMED	By means of EUDAMED
Available to Competent Authority 對主管機關可取得	Upon request 依據要求	Upon request 依據要求	Upon request 依據要求	By means of EUDAMED	By means of EUDAMED
Review by NB 通告機構審查	During PA –Is, Im, Ir 定期稽核	During PA 定期稽核	During every PA at least 至少定期稽核	During every PA at least 至少定期稽核	During every PA at least 至少定期稽核
Evaluation report by NB 通告機構評估報告		Part of surveillance audit 監督稽核的部分	Part of surveillance audit 監督稽核的部分	Upload to EUDAMED	Upload to EUDAMED

轉換新法後，會發生reclassification情形嗎？或，還是依照現行MDD指令的分類施行管理？

- MDR醫材分類由18 類變成22類，新增許多內容，故須重新審視廠內器材的歸於22類中的那一類? 那種Class?

- 此外，無醫材用途但具有醫材風險的器材也將納管，譬如Laser除毛器, 無度數的彩色隱形眼鏡片, 抽脂器材...等。

Class IIa以下的產品，臨床評估若無類似廠商授權，仍須執行臨床評估嗎？或是Class IIb以上風險產品才須要臨床評估?

- 所有Class的醫材產品，無論是否有類似廠商授權，都需執行臨床評估。

台灣DNV-GL可啟動受理申請MDR and/or IVDR 稽核的時間為何？

- 台灣DNVGL, 關於MDR的最新情況，預計第4季(10月)，可取得發證權和受理申請。
- 台灣DNVGL, 目前未規劃受理IVDR的案子。關於IVDR的最新情況_ 可以參考 Presafe Denmark A/S website

Thank You!