2024年9月6日

OMETA-Qualtech ウェビナー2024

事前質問の解説

OMETA

質問- 1

インドの規制について：

FAQの下記の記載があります。

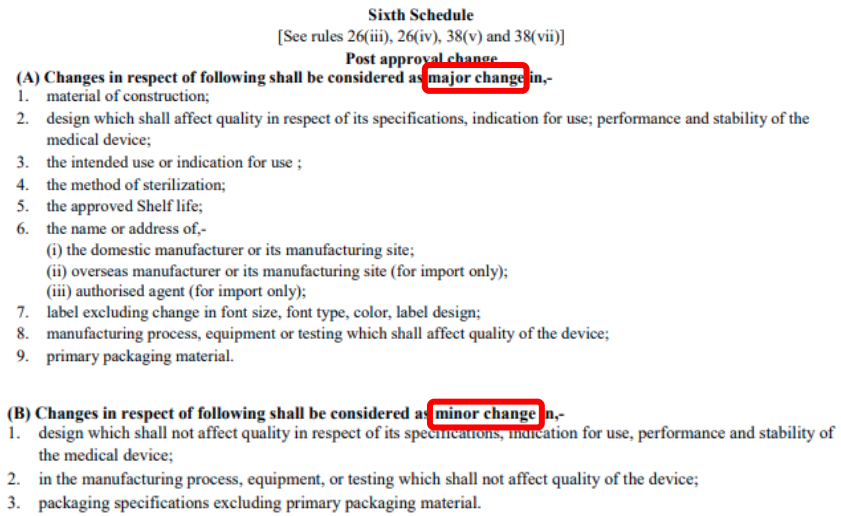
たとえば、包装のシンボルマークの変更などもMajor Changeに該当しますか？

かなり広い範囲で変更申請が必要に思えます。

38. Whether any change in labeling need to be notified to Licensing Authority ?

- *Yes. The Changes in respect of label excluding change in font size, font type, color, label design shall be considered as major change as per Sixth Schedule of MDR-2017.*

解説：



Sixth Schedule

[See rules 26(iii), 26(iv), 38(v) and 38(vii)]

Post approval change

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device;
3. the intended use or indication for use ;
4. the method of sterilization;
5. the approved Shelf life;
6. the name or address of,-
   (i) the domestic manufacturer or its manufacturing site;
   (ii) overseas manufacturer or its manufacturing site (for import only);
   (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

(B) Changes in respect of following shall be considered as minor change in,-

1. design which shall not affect quality in respect of its specifications, indication for use, performance and stability of the medical device;
2. in the manufacturing process, equipment, or testing which shall not affect quality of the device;
3. packaging specifications excluding primary packaging material.

According to Six Schedule of MDR-2017
If the symbol mark is not related to the change affecting efficacy, intended use, stability of device, then it will be minor change.

(シンボルマークが、デバイスの有効性、使用目的や性能、安定性に影響を与える変更に該当するかどうかで判断)

質問- 2

インドの規制について：

CEの要求事項とインドの要求事項で異なる項目はありますか？
どちらの方がハードルが高いでしょうか？

解説：

The requirements for submission dossier is similar to CE requirements.

You may refer to the checklist for the imported device with predicate device in India.

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/14MD.pdf

However, current EU MDR requirements is more difficult than Indian requirements.

(申請資料はCEの要求事項に類似。
EU MDRの要求事項の方がハードルが高い。)

質問- 3

インドの規制について：

MDR Chap1, Article 3に医療機器の定義がありますが、規制対象となる最新の医療機器リストは、2020年9月に発行された理解でよいでしょうか？

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Final%20Classification%20of%20MD.pdf

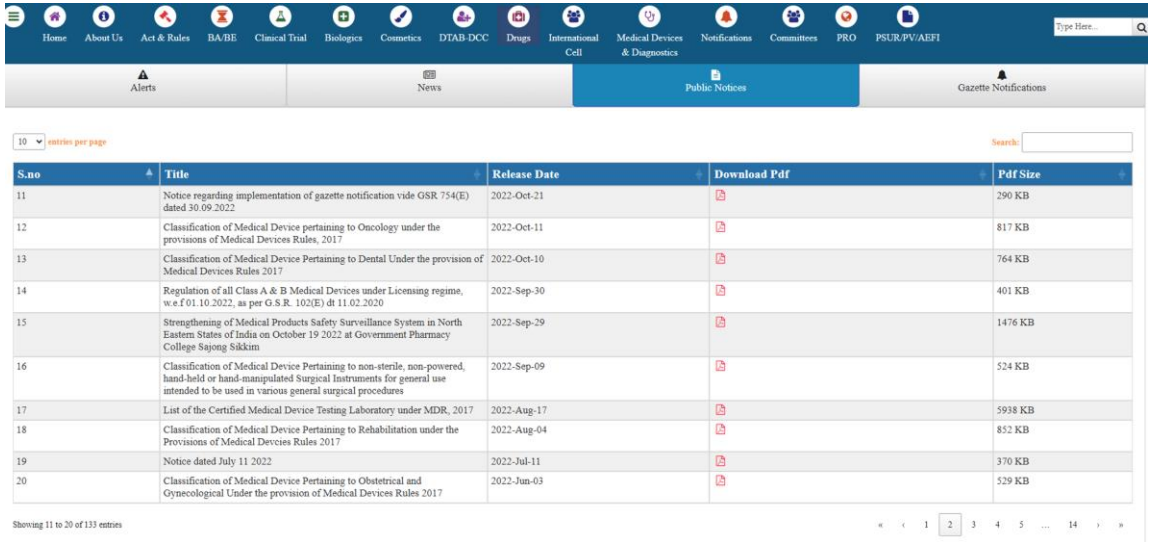
解説：

Yes, it is correct.

You may refer to the updated risk class for each category from CSDCO Public Notice published on official website from this link.

https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/

(ご理解の通りです。)



質問- 4

インドの規制について：

クラスA～Dの平均的な審査期間を教えてください。

解説：

CDSCO will issue a Registration Certificate through online portal. [MDR, 2017, Article 36 (1)]

Registration approval for Class A or B with predicate device, it might take 5-6 month after submission.

Registration approval for Class C of D with predicate device, it takes about 9-10 months after submission.

(Class A/B: 5-6ヶ月、Class C/D: 9-10ヶ月)

※先行品有りの場合

質問- 5

フィリピンの規制について：

フィリピンで医療機器をキット化し、海外へ出荷する場合であり、フィリピン国内で販売しないケースであっても、輸入ライセンス申請は必要となりますか？

解説

The company must have a license or LTO(License to Operate) as medical device exporter and manufacturer (a. If manufactured in the Philippines fully, the LTO must have main activity as manufacturer, b. If only repackaged in the Philippines, the LTO must have repacking as an activity in the license.)

CMDN/CMDR must be applied first but must indicate that it is for export purposes only.

PFDA is generally more lenient/relaxed in the evaluation of products which are intended for export market. Full technical requirements are expected and dependent on risk classification.

(CMDN/CMDRが必要です。)

質問- 6

オーストラリアの規制について：

TGA　第1章第3項に定義されている
スポンサーの役割について確認したい。

定義

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

解説：

An Australian TGA sponsor plays a vital role in device registration process and post market compliance.

Before commercialization of the products, the sponsor will register the goods with the TGA and also assist to encounter the audits.

The Sponsor maintains the track on Regulatory updates, to help the manufacturing companies meet the updated Regulatory requirements, by maintaining the technical documents recommended by the Agency.

The Sponsor shall also maintain the distributor records from the manufacturer.

スポンサーの役割

-市販前の製品登録、監査対応の支援
-規制更新の確認、製造業者が更新された規制要件を満たせるよう、規制当局が求める技術文書の適切な維持管理の支援
-ディストリビューターの維持管理(販売記録の管理)

質問-6-①

オーストラリアの規制について：

日本での製造販売業者、製造業者、販売業者の役割を「スポンサーが一手に引き受けられる」という理解で良いか　？

解説：

The role of MAH in Japan is similar as Sponsor in TGA.

However, a Sponsor may be different from a Distributor.
Aside from the Sponsor (holder of the ARTG entry), the Manufacturer can also authorize other Distributors to import the product.

A Sponsor is the Australian entity responsible for the supply of the medical device in Australia. The Sponsor's responsibilities include ensuring that the medical device complies with regulatory requirements, maintaining records of the device's performance, and cooperating with the TGA in case of post-market monitoring or audits. The Sponsor must also ensure that the device is included in the Australian Register of Therapeutic Goods (ARTG) before it can be legally supplied in Australia.
A Distributor in Australia is responsible for the actual distribution and sale of the medical device within the country. While they must ensure that the products they distribute are legally included in the ARTG, they are not typically responsible for regulatory compliance—that responsibility falls to the sponsor.

スポンサーの役割は日本の製造販売業者に類似
但し、スポンサーはディストリビューターとは異なる場合がある。
製造業者はスポンサー以外のディストリビューターに製品の輸入を許可することもできる。

スポンサーは、オーストラリアにおいて医療機器の供給に責任をもつ事業体。
スポンサーの責任:
①ARTGに機器が登録されていることの確認、②医療機器が規制要件に準拠していることの確認、機器の性能記録の維持、③市販後監視や監査の際に TGA へ協力

ディストリビューターは、オーストラリア国内での医療機器の流通・販売を担当し、流通・販売する製品が ARTG に登録されていることの確認
※規制遵守の責任は通常負わない。その責任はスポンサーにある。

質問-6-②

オーストラリアの規制について：

欧州などの「法定代理人の役割を担う」という理解で良いか　？

解説：

The role of a sponsor in Australia under the Therapeutic Goods Administration (TGA) is somewhat similar to the role of an authorized representative in Europe under the Medical Device Regulation (MDR), but there are some key differences.

(欧州法定代理人の役割に類似)

Similarities:

Representation: Both roles involve representing the manufacturer in the respective regulatory jurisdictions (Australia for the sponsor, and Europe for the authorized representative).

Regulatory Compliance: Both the sponsor and the authorized representative are responsible for ensuring that the medical device complies with local regulatory requirements, including device registration and post-market surveillance.

Point of Contact: Both act as the point of contact between the regulatory authorities (TGA in Australia, and national competent authorities in Europe) and the manufacturer, especially for communication regarding compliance and any necessary corrective actions.

類似点

-製造業者の代理としての役割

-規制要件準拠の確認責任

-規制当局に対する連絡窓口

質問-6-②

オーストラリアの規制について：

欧州などの「法定代理人の役割を担う」という理解で良いか　？

解説：

Differences:

Owner of the license:

The sponsor in Australia is the applicant/owner of Australian Register of Therapeutic Goods (ARTG) Listing. While European authorized representative is not the applicant/owner of CE certificate. Manufacturer including overseas ones will be the owner of CE certificate.

Scope of Responsibility:

The sponsor in Australia has broader responsibilities, including legal liability for the device on the Australian market. In contrast, while the authorized representative also shares some liability in Europe, the manufacturer remains primarily responsible.

Market Introduction:

In Australia, the sponsor is also responsible for including the device in the Australian Register of Therapeutic Goods (ARTG) before it can be marketed, a role that is typically handled by the manufacturer or authorized representative in Europe through CE marking under the MDR.

Overall, while both roles are crucial for market access and compliance in their respective regions, the specific obligations and the extent of responsibility can differ based on local regulations.

相違点

-ライセンスの保有者: オーストラリアでは申請者/保有者

-責任の範囲: オーストラリアでは欧州代理人に比べ、機器の法的な責任を含むより広い責任を持つ

-市場への導入: オーストラリアのスポンサーはARTGへの製品の登録責任

※上記について、具体的な責務や責任の範囲は異なる場合がある

質問-7

その他：

接液原材料が変更されたら、各国にて変更申請ルートがありますか？
もしくは、再度新規申請をする必要がありますか？

Sixth Schedule

[See rules 26(iii), 26(iv), 38(v) and 38(vii)]

Post approval change

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
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   (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

解説：

[India] Raw material changes could be applied the major change application according to Six Schedule of MDR-2017.

変更申請ルート有り。Major changeに該当する可能性。

[AUS] Yes, a change application is required if a raw material that will contact body liquid has changed.

In fact, any changes that may affect product safety, quality, performance, or effectiveness is required to apply for change application.

However, if the change is so critical or serious that may alter the device's risk profile, TGA may be considered it as a new product. In this case, a new application is required.

変更申請ルート有り。変更申請要。(変更内容により新規申請の可能性有り)

[Philippines] Raw material changes are usually required for change application.

Whether new application is required or not needs to be judged by each medical device.

変更申請ルート有り。新規申請の可能性については医療機器毎に判断。