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PAMDRAP
Regulatory Affairs Professionals

Presentation of Result of Survey (CMDN)

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Key Highlights of the result of the survey

Respondents: 57

63% - submitted application for CMDN application (B, C, D)

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COMMON DEFICIENCIES

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Online Application Form

- 1. List down all the accessories and configurations on the "size and codes" portion of the online form.
- 2. Max file size 2MB, FDA cant accept letter with the link of google drive if the file size is more than 2MB. This can supposedly solve the problem if the file is too big.
- 3. Correct the Intended Use- it should start with - "Intended to be used as…", Kindly follow the template when encoding shelf-life: N/A; Service life: XX years

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Legal Requirements

1. Properly classify based on ASEAN Medical Device Directive.
2. Submitted ISO Certificate is from legal manufacturer. Submit valid notarized ISO Certificate for the physical manufacturer.
3. Submit actual photo of your device being registered

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Technical Requirements

1. Submit all raw materials.
2. Submit all test reports.
3. To submit document to justify CE0917 is allowed to affix in the label
4. Submit complete labels with the sticker label attached to know where all the stickers are located. (Even in shipping carton, country specific in all parts (main unit, accessories, peripherals etc)
5. Provide the useful life of the product. On the column for shelf life, kindly put “N/A; Useful Life: (i.e. “N/A: Useful Life: 3 years”

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Evaluator-related issue

1. Same documents for several products (because in other countries considered as one application) have different deficiencies/reasons of denial
2. Interpretation differs on the evaluator who handles the assessment.
   * Some evaluators accept attestation of notary instead of notarized declaration from the manufacturer, some do not.
   * Every NOD has different deficiencies, differ from each NOD.
   * Some evaluators accept attestation of notary instead of notarized declaration from the manufacturer, some do not.

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CONCLUSION

- Industry still have lots to learn during this transition period of the new medical device regulations.
- We also recognize the effort of CDRRHR to implement this new regulations with the least disruption for both agency and industry. We are thankful for the consideration given to us to ensure continuous supply of medical device in the market during transition.
- In order to help FDA, we will develop FAQs for our members that guide our members in their submission and ease pain points for both industry and the agency during this transition.
- We will reach to CDRRHR leadership for input and alignment with respect to content.

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