**MINUTES OF THE MEETING**

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| **Meeting Title:** | **20th General Membership Meeting -** | | |
| **Date:** | 19 February, 2021 | **Time:** | 7:00 am – 12:30pm |
| **Minutes Taker:** | Aurora Caguicla  (Documentation Committee) | **Location:** | Virtual GMM |
| **Attendees:** | Engr. Ma. Cecilia Matienzo, PAMDRAP Officers & Members | | |

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| **Topic** |  |  |
| **General** | Registration started at 7:00 am. Opening prayer, singing of the National Anthem, and opening remarks and on to the presentation proper. Good Regulatory Practice were presented by Bella Rozanna Buniel, Jaymie Gulle and Rhoel Laderas. It was followed by the presentation of the New Medical Device Regulations, FDA Updates by Engr. Matienzo. The new members took their oath followed by the presentations on the 2021 plans of each Committee Chairs. |  |
| **TOPIC I: Product Life Cycle & Good Regulatory Practice (GRP)**  **By: Rhoel Laderas, Bella Rozanna, Buniel, Jaymie Gulle** | | **Remarks / Comments** |
| Research & Development Phase  by: Bella Rozanna Buniel  Pre-Market Phase  By: Rhoel Laderas | Regulatory officers must consider:  1) Regulations & Standards – Comprehensive knowledge of Standards to be able to provide strategic and technical guidance in target markets 2) Product Testing – consists of market trial, clinical evaluation, biocompatibility, risk management, risk classification of the product, and be mindful of change control for accurate profile. A good R.A must be able *sort* and make sense of these documents in order to build a good dossier.  3) Dossier Development – correct, complete and compliant 4) Support Files and Maintenance – review of documentation to ensure this to be clear, consistent and complete. Conclusions are explicit.  The Regulatory Officer must be prepared to do the following to register the product before it goes to the market; Dossier Compilation & Review, Submission Strategy, Regulatory Communications Negotiations, and Tracking & Key Performance Indicator (KPI).  Considerations in preparing a dossier includes Planning, Understanding of Requirements, Use of Checklists, Inputs from CFT, Format, Review / Recheck, Completeness and Consistency with emphasis that creation of a strong dossier is dependent on the knowledge of requirements.  To summarize GRP;  1. GRP is a collection of best practices.  2. A strong knowledge of the regulatory environment is a key to a successful GRP.  3. Adopt a compliance mindset. |  |

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| Post Approval Changes  By: Jaymie Gulle | 4. Complete, Correct and Compliant dossier ensures MoH approval. 5. Always put yourself in the regulator’s position.  6. Be professional at all times.  Post Approval Changes are inevitable. These changes must be identified, and these changes require FDA approval prior to implementation. Changes that require FDA approval are stated in the Notarized Application Form (NAF) that is part of the dossier submitted to the FDA in the Pre-Market Phase. The List of Requirements for each type of change is in the FDA Citizen’s Charter.  There should also be a Risk Management Plan for any eventualities. This vigilance activity is aimed to identify, characterize, prevent or minimize risks to health products and assess the effectiveness of the interventions. A Field Safety Corrective Action (FSCA) is an action taken by the product owner to reduce the risk of death or serious deterioration of health due to the use of the device. These include recall (Bureau Circular No.8 S.2001, FDA Circular 2016-012), Device modification, device exchange, device destruction, and advice of device owner on the use of the device. Complaints should be investigated and documented. Equipment installation, maintenance, and servicing must be done by qualified and trained personnel in accordance with the manufacturer’s procedures.  Good Distribution and Warehousing must be observed from Manufacturer’s site to the Distributor’s Site onto the User warehouse including transporting conditions particularly for those that require specific handling and storage conditions. All risks related to importation, distribution, storage promotions and sales of products must be identified and managed. |  |
| **TOPIC 2: FULL IMPLEMETATION OF THE NEW MEDICAL DEVICE REGULATIONS & FDA UPDATES BY : ENGINEER CECILIA MATIENZO**  **Director IV, CDRRHR** | |  |
| **UPADATE ON**  **IMPLEMENTATION OF 2018- 002, FDA CIRCULAR 2021- 002** | **Medical Devices Timeline of Implementation**  1) Sept. 2020  - Preparation & Approval of Issuance of the Phase  Implementation.  2) 2021 – Full Implementation of 2018-002. FDA Circular 2021-002 is issued on.  3) On-going Activity  - Registration of Medical Devices (MD) in the List as per FDA Circular 2020-001. Validity: 5 years  - Notification of Class A MD. Validity: 5 years  4) March 2021 – Notification of Class B, C, and D. Validity: 2 years 5) March 2023 – Registration of Class B, C, and D. Validity: 5 years |  |

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|  | **IVD Timeline of Implementation**  1) Sept. 2020  - IVD Medical Devices Update of List of Registrable IVDs (FDA Circular)  2) On-going Activity  - Registration of IVD in the List. Validity: 5 years  3) 1st Sem. 2021 – Approval of new A.O for IVD  4) January 2022  - Notification of Class A IVD. Validity: 5 years  - Notification of Class B, C and D IVD. Validity: 2 years 5) January 2024 – Registration of Class B, C and D IVD. Validity: 5 Years  **Phases of Implementation**  **Phase 1: March 20,2021 – expected implementation**  - Notification of Class B, C and D of Non-registrable MD in FDA MC 2014-005;  - List of Medical Devices in Annex A of FDA Circular 2020-001 supersedes FDA MC 2014-005  **Phase 2:**  - Registration of Class D. Notification of Class D ceases. **Phase 3:**  - Registration of Class B, and C. Notification of Class B & C ceases. ***\*Phases 2 and 3 will be implemented at the same time.***  **Once Implemented:**  Application Procedures for Notification of Class B, C, and D shall be the same as Notification Application of Class A.  Classification of MD that are not included in the Annex A of 2018-002 and its amendments shall follow the classification rules of AMDD as stated in AO 2018-002 Item 2, Section V. General Guidelines.  Class B, C and D that are not in Annex A of AO 2018-002 shall have until March 2022 to file for Notification and shall be allowed to import and distribute their devices. However, on April 01, 2022 only those with CMDN and pending application shall be allowed to import and distribute. | **Notes:**  To issue the New List of IVDs that  will be  required to be  registered  listed in the FDA MC  2014-005  plus those  that will be identified  by DOH  programs.  (No New  List  received to date) |

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| **UPDATE ON COVID RELATED PRODUCTS**  **UPDATE ON MEDICAL**  **DEVICE REGULATORY**  **UPDATE** | Three (3) months prior to expiry of CMDN, companies must file for the CMDR Application of Class B, C and D.  Application of Notification for Class B, C and D is thru e-portal. Validity is 2 years and payment to be generated is for 2 years. Requirements are the same as those for Class A Notification.  **Distribution of CoVID Test Kit per Category – as of Jan. 2021** PCR – 287  Serological – 404  Antigen – 96  Others – 43  **2020 2021**  Total Applied 2153 53  Approved 762 25  Disapproved 1363 31  As of January 22, 2021  **Type of PPE Local Manufacturer No. of Reg. Products**  Face Masks 22 22  Gloves 2 1  Coverall 2 11  The Percentage of Approved Applications against received applications for CMDN is 15% (320/2072). The Center lost Php 13, 140, 000.00 in possible revenues if only those received application were all approved. Of the 320 approved application, the Center was able to gather an income of Php. 2.4M.  With CMDR, only 177 of 715 (25%) applications were approved. It lost Php. 4,035,000 in potential income. The higher approval percentage was due to less application as compared to CMDN.  Application Procedures for Initial Registration, as well as Sample Checklist for Pre-Assessment of Class B was discussed.  All legal documents must be valid.  Notarized/Apostille documents dated before the issuance of 2020- 026 (September 2020) are still acceptable as long as they are still valid.  Relevant Essential Principle and Methods used to demonstrate conformity (with Template) is a mandatory requirement. If the product does not have documentation for this, it will be disapproved. |  |

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**Reminders:**

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1. Send only applications to the assigned email address

2. One (1) Application, one (1) email

3. Do not send Compliance to cdrrhr@fda.gov.ph.

4. There are delays in sending soft copy as compared to LTO, remember that this is just being accommodated due to the pandemic.

5. For follow-up email to cdrrhr.lrd@fda.gov.ph

6. Time of submission of application is from 8AM-5PM only on the assigned day.

7. Intended use must be consistent on the application form and technical documents

8. E-signature is still acceptable with the attached company ID of the person who signed.

9. In the application form, the brand name and medical device name should be different.

10. If there are lots of product codes, provide a separate page for the codes. Don’t put them all in the application form.

11. Don’t change the format of the application form.

\***Evaluation process “Approved/Disapproved” during evaluation and not pre-assessment is not yet implemented. CDRRHR will release list of major and minor deficiencies to decide if the application is approved or disapproved. Maybe for minor deficiency it will be emailed to the company. It is still under discussion and negotiations.**

**Timeline based on Revised Citizen Charter**

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| **Type of Verification** | **Timeline (working days)** |
| CMDN Initial | 20 |
| CMDL | 7 |
| Initial CMDR Class B | 60 |
| Initial CMDR Class C & D | 90 |
| Renewal All Types | 20 |
| CFS | 10 |
| App. for Compassionate Permit | 7 |
| IVD CPR- Initial | 90 (LRD processing only) not including Performance Testing Timeline (NRL) |
| IVD CPR- Renewal | 24 (LRD processing only) not including Performance Testing Timeline (NRL) |
| Sales Promo Permit – Initial | 7 |
| Sales Promo Permit - Amendment | 7 |
| Healthcare Waste CPR- Initial | 40 |
| Healthcare Waste CPR- Renewal | 20 |

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|  |  | Healthcare Waste CPR- Turned Initial | 40 |  |  |
| Water Purification  Devices/System CPR - Initial | 42 |
| Water Purification  Devices/System CPR – Renewal | 20 |
| Water Purification  Devices/System CPR - Turned Initial | 40 |
| CPR Variation – MD & IVD | 30 |
| **ISSUES & CONCERNS** | | | | | |
|  | **Q**. Do equipment installed prior to the Circular need to be applied for CMDN?  **A. No need especially if it is already end of life.**  **Q.** Do stand-alone accessories that have to be imported to be used for repairs, parts services, parts replacement have to be applied for CMDN?  **A. Yes, if they are sold independently and there is continuous selling or distribution.**  **Q.** How to register equipment as a system with accessories/spare parts?  Is there a need for a separate registration for the accessories/spare parts that may be imported later for replacement or repair purposes?  **A. Accessories in a system shall each have their own Technical File. They are declared as part of the system and they shall be registered as a system. If these accessories are sold separately, each has to be**  **registered. Take note that e-portal does not support single application, multiple CPRs, so apply separately and follow the latest guideline on registration. No limit on the number of applications for CMDN.**  **Q.** Is FDA 2018-002 applicable to IVD products? How about those not included in the List under Annex A?  **A. IVD Registration of IVD in the List in FDA MC 2014-005 & 2014- 005A is on-going and shall have a validity of 5 years. However, Approval of the new AO on IVD is expected to be on the 1st semester of 2021 which may include an updated list of IVD. Refer to IVD Timeline of Implementation.**  **Q.** Is FDA Circular applicable to IVD products? There are IVDs not found in the List (Annex A), what is applicable to these? **A. Not applicable. Refer to IVD timeline of implementation.** | | | |  |

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|  | **Q.** Will FDA issue Certifications for non-regulated products for BOC and/or Tenders?  **A. No. One time Circular issued is enough.**  **Q.** If a product is given up before the expiry of its validity, can you get a refund for the unused validity?  **A. No.**  **Q.** Will there be a Kapihan or similar avenue before the new regulation takes effect?  **A. Not in the program right now but it will be considered. This avenue is already helpful.**  **Q**. What is the validity of COE for Class B,C and D? It is not identified in the MD Timeline of Implementation.  **A. It will be included in the succeeding issuances. However, it will likely be a one (1) year validity.**  **Q.** For Radiation-emitting devices, do we follow the current CFCR guidelines for every shipment?  **A. It was not answered. Overlooked.**  **Q.** When applying for CMDR 3months prior to expiration of CMDN validity, will the initial registration be shorter or will it follow the regular registration?  **A. A regular initial will be followed.**  **Q**. Does AO 2021-002 already include machines and software? **A. Yes**  **Q.** Granting that COE validity of Classes B, C, and D is clearly identified, can a company apply/submit COEs of Classes B,C and directly as CMDR, to lessen redundancy of submission & requests of documentation?  **A. No. We will only be opening the CMDN for Class B, C and D for now. We are not allowing submission of CMDR for those not yet in the list.**  **Q.** Will the registration number change from CMDN to CMDR? What about the labels, is there a grace period to exhaust?  **A. Yes**. **I suggest to do stickering while in CMDN since it is not yet the official registration number.**  **Q**. For products with small labeling be exempted from printing and label sticker the National labeling requirements?  **A. No. At least the registration number is printed or in the label sticker.** |  |

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| **Other Concerns &**  **Responses to Comments and Questions.** | **Q**. Who are allowed to apply sticker on the machines being assembled in the hospitals?  **A. Somebody from the company or the installer should be the one to apply the sticker. It is up to the company where to put. Q.** What is the impact of the standards in hierarchy? This will be included in the letter. Is there an impact in the Declaration of Conformity?  **A. DoC has nothing to do with the hierarchy of the standards. DoC is where you can find the standards used by the manufacturer.**  **Q.** Can we use brochures or drawings instead of actual picture of the product especially to machines?  **A. Make sure the product applied is in the brochure. Identify the product in the brochure.**  **Q.** CDRR automatic renewal as announced by ARTA – automatically approved. Will this also take effect on CDRRHR’s automatic renewal? **A. With CDRRHR, there is no longer an automatic renewal. We still see incomplete documents.**  **Q**. Clarification on summons regarding Covid Test Kits. **A. If summon comes from FDA ODG, it is because the company did not submit the technical documents on time and not because you don’t have yet the results from RITM or failure to submit samples to RITM.**  **Q.** Clarification of CFCR, will this be amended?  **A. CFCR may not be needed after transition.**  **Q.** Clarification on Apostille, Authenticated Documents. **A. If still valid, apostille. authenticated documents prior to and until Sept. 2020 are accepted. Beyond Sept. 2020, use the Manufacturer’s Declaration. It should indicate that it is true and correct.**  **Q.** Will there be CDRRHR QPIRA scheduled this year?  **A. No schedule. It may even be scrapped. If ever to be pursued,it may not be mandatory. Licensing seminar is mandatory.**  **Q**. Is it possible to attach the corresponding fee for the application in the issued Acknowledgement Receipt, as we are having problems with the issuances of Official Receipts?  **A. CDRRHR will coordinate with Dr. Rosuman.**  **Q.** Can we include the Letter of rejection in re-applying for the Registration of products?  **A. Yes.** |  |

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|  | **Q.** Can we already apply for CMDR instead of CMDN of Class B, C and D.  **A. No. It will automatically be disapproved. Follow the timeline of the phases of the implementation.**  **Q.** If the IPO application is still in process, will that be considered in the product application?  **A. We will only allow if you already have the letter from the IPO stating that your trademark is already ok to use and for publication.**  **-Humidifier is not registrable.**  **-If there is no shelf-life. Provide letter of explanation. -For repackaged product, as to who is the manufacturer will depend on the process flow of the agreement.**  **-SRP is never in the label. It is included only in the Initial Application.**  **- A System includes all accessories in the Product and is applied as a single product. But if its accessories are sold and as stand alone, then they are registrable accessories must be registered individually. Then, include these CPRs in the application of the system.**  **- Software is not Class A only. It is either Class B, C or D. But for now, it is for Notification.**  **- Specific Rule Classifications for IVD will be less complex as there are few groups of IVDs unlike non-IVDs.**  **-Spare parts are not medical devices.**  **\*A new committee for medical machines/equipment is organized. Jules Odarbe is the assigned Chair.**  **- end -** |  |
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\*Disclaimer: Minutes of the meeting, the questions and answers are based on what the minutes takers have heard and captured. Those written shall not deemed as final.

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