

MINUTES OF THE MEETING

Meeting Title:	25th General Membership Meeting -		
Date:	June 16-17, 2023	Time:	8am – 5pm
Minutes Taker:	Aurora Caguicla and Maribel Buado (Documentation Committee)	Location:	First Pacific Leadership Academy, Km 27 Sumulong Highway, Antipolo City
Attendees:	PAMDRAP Officers & Members, Engr. Cecile Matienzo (Director, CDRRHR), Mr. Cristan Yang (Country Manager Terumo & Leadership Coach)		

DAY 1: JUNE 16, 2023

I. Opening Remarks and Business Updates

By: Rhoel Laderas
President, PAMDRAP

- The President welcomed the attendees after the singing of the National Anthem and Prayers.
- He welcomed the new members and they took their oath later after presentations by the different committees.
- He presented the PAMDRAP Updates and Advocacies
 - PEMDL is the biggest concern of the industry at present. It basically means that Medical Devices must be listed in the Philippine Essential Medical Device Listing for these to be procured by Government Establishments.
 - Part of the Advocacy is to partner with the US Embassy for concerns, issues of PEMDL, and related topics on Medical Devices to develop Training Programs to help DOH and CDRRHR.
- The second advocacy is Scholarship Program for Pharmacy Students. Currently PAMDRAP is supporting two (2) Pharmacy students.
 - as such, PAMDRAP is the 1st HC Organization that gives this kind of scholarship. It has also partnered with PACOP and as such was invited to the 2023 PACOP Oath Taking of New Officers and Turnover Ceremony.
- Finally, PAMDRAP and Engr. Matienzo were invited to the 2023 PPhA Convention to represent the Medical Device Industry and introduced the MDs as part of the FDA regulated products and that these are part of the Healthcare Industry. Two PAMDRAP members were elected during the PPhA election namely: Maria Lourdes Garganera, Board of Trustees and Jingle Diola, Section Representative for Pharmacy Practice.

II. The different committees led by their Advisors and Chairpersons presented their committees' advocacies, achievements, and their accomplishments:

a. Documentation Committee

Advisor: Charmaine Roson

Chairperson: Jane Krisel Tan

Advocacy/Achievement/Accomplishment: PULSE, Minutes of the Meeting, Disseminating the Presentation of the Speakers

b. Finance Committee

Advisor: Charmaine Roson

Chairperson: Emegrace Milan

Advocacy/Achievement/Accomplishment: ITR/FS Preparation and Submission to BIR, Renewal of Business Permit, Membership with APACMED, Statement of Accounts, SOP and Forms for the Finance Committee, Peso and Dollar SA.

c. Ways and Means

Advisor: Rona dela Rosa

Chairperson:

Advocacy/Achievement/Accomplishment: PAMDRAP Knowledge Sharing, Future Plans of more sharing, Resource Persons

d. Administration and Secretariat

Advisor: Rona dela Rosa

Chairperson: Iza Cruz

Advocacy/Achievement/Accomplishment: Safe-keeping of documents, dissemination Information, currently working for a permanent solution with regards to email errors and cleaning the email database, helped some members with their PPhA Membership Renewal

e. CSR Committee

Advisor: Jingle Diola and Emegrace Milan

Chairperson: Vangie

Advocacy: Education, Social Development, Environmental Protection Conservation. Achievements/Accomplishment: 2022 MOA signing with the Phil. Ass. of Colleges of Pharmacy for scholarship grant, partnered with PACOP, 1st to launch PAMDRAP Pabahay Project, Ilog Clean-up, designing PAMDRAP T-shirt for the PPhA Convention, President Rhoel being one of the speakers, 2nd yr. of scholarship grant recipients firmed up for SY 2022-2023, cash grants to selected students for 3rd and 4th Qtr, selection for grantees for SY 2023-2024, Mentorship Program with PACOP, clean-up drive with tree planting in Batangas, Collaborate with Climate Change Commission as industry partner for RA 11898 Community and Medical Outreach for Indigenous people, provide service and support other committees.

f. Regulatory Intelligence Committee

Advisor: Belinda Gabriel

Chairperson: Liza Pajarillo

Advocacy/Achievement/Accomplishment: Updates members with latest regulations and changes in the regulatory industry. It is committed to daily monitoring of all related regulatory agencies' announcements and issuances. It encourages members to update their email addresses, disseminating related medical device announcements, memos, circulars, etc., released by various government agencies, aids, and responds to queries about medical device concerns.

g. Scientific Committee

Advisor: Jules Obarde

Chairperson: Andrea and Mitsumi

Advocacy/Achievement/Accomplishment: Scouts and prepares venues for PAMDRAP GMMs and related use. It was able to secure PRC units for the GMMs, verify thru <https://cpdas.prc.gov.ph>.

h. Equipment

Advisor: Jules Obarde

Advocacy/Achievement/Accomplishment: Viber Chat for Equipment was created.

i. IVD Committee

Advisor: Jhoanna Gulle

Advocacy/Achievement/Accomplishment: IVD regulation is still in draft, continuous monitoring of FDA issuances regarding IVDs, submitted position papers with APACMED. Regarding draft FDA IVD Regulations, implementation

time was extended from 1 yr. to 3 yrs. In the new draft, RUO's proof of registration was removed from the list of requirements for submission. RUO are not registered anywhere thus, it is impossible to comply with.

j. Membership Committee

Advisor: Grace Virata

Advocacy/Achievement/Accomplishment: Increase in Membership from 179 individual members and 126 member companies in 2021 to 231 individual members and 157 member companies in 2023. Successful increase in membership fee from 5K pesos for new member and 3K pesos for renewal in 2021 to 6,500 pesos for new member and 5,000 pesos for renewal. There is now a permanent office and a permanent secretariat. It supports the 2023 Sports Fest in cooperation with the CSR Committee.

III. OATH TAKING OF NEW MEMBERS C/O MEMBERSHIP COMMITTEE

IV. LEADING WITH IMPACT: UNLEASHING THE POWER OF INTENTIONAL LEADERSHIP

By: MR. CRISTAN YANG

Country Manager Terumo and Leadership Coach

- His topic was about the power of Intentional Leadership. The agenda was about:
 - Definition, style, and dimensions of Leadership
 - His personal journey, struggles, and motivation as a leader
 - Your leadership journey and mindset
- He defined Leadership as the ability to inspire, influence and guide a group of individuals or an organization towards achieving a common goal. It involves taking charge, making decisions, and providing direction to others.
- Differentiated Management from Leadership
- Defined Power according to RACI (responsibility, accountability, consulted, informed). It is the ability to directly make, execute, and implement the action to effect the change that you want to see. But even with power, there is no guarantee of results.
- To lead without authority, we need to build relationships, demonstrate expertise, lead by example, be a problem-solver, effective communication, collaborate and support, be a positive influencer, seek opportunities to lead.
- In closing, let us challenge ourselves to change the world in small ways, in our own way. We may not be able to change what we want to, but we can change ourselves today.
 - Panel Discussion followed to discuss about personal journey, struggles, and motivation as a leader, leadership journey and mindset.

Key Takeaways:

- There is nothing intentional in Leadership.
- You are a leader because people recognize you as such.
- A leader does not need a Title.
- Respect is earned.
- Styles of Leadership depend on the situation and are used in combination.
- A leader must be Focused on the vision, purpose, and task.
- Be a better human to be a better Leader.

V. TEAM BUILDING c/o Membership Committee

Members were group into Teams: Blue, Green, Yellow, Red, and Purple. Teams are made to compete against each other in 4 games prepared by the Committee.

V. FELLOWSHIP NIGHT

Theme: Enchanted Kingdom

Attendees had a night of fun in their theme inspired clothes. Best theme-inspired clothes were given awards.

DAY 2: JUNE 17, 2023

I. Day 2 started with breakfast and Group Photos, Synthesis of Day 1 activities including awarding of winners of Team Building Activities and Feedback from Members.

- Bel Buniel, Joie of Abbot, and Bubbles shared their take of the Synthesis of Day 1 activities.
- 203 individual attendees for the 25th GMM

II. Re-visit Journey of a Medical Device Products: Road Map to Philippine Market

By: Liza Pajarillo and Belinda Gabriel

- The focus was on Registration. Note that Registration refers to CPRs and Licensing is to LTO.
- Definition of MD according to AO 2018-0002 based on the ASEAN Medical Device Harmonized Technical Requirements.
- FC 2021-012 – Licensing Requirements for Retailers of Medical Devices and AO 2018-0002 – New Regulatory Requirements for registration of Medical Devices
- Covered by FC 2021-012 are online sellers, social media platforms like FB, Optical Shops, Drug Outlets retailer outlets of non-prescription drugs.
- Not covered by the Circular are Groceries, supermarkets, convenience store, kiosks, and similar stores. Though LTO is not required, sell only MD that are registered or notified. Source MDs from legitimate distributors.
- Optical Shops required Optometrist under RA 8050 s. 1995 but not FC 2021-021. The FC requires a qualified person who can be the Optometrist.
- FDA Guidelines in CPR Registration / Notification were presented in table format indicating pertinent issuance and its subject.
- Process pathways for Registration of CMDN / CMDR Medical Devices and Bureau of Customs process to release of Medical Devices, Equipment and Ionizing Radiation emitting Devices (ex. X-ray machine) were presented.
- IVD was defined in AO 2018-002. List of regulated IVDs is found in FDA Circular 2014-005 and Memorandum Circular 2018-001.
- Approval/Certificates must be secured from other regulatory agencies (like DENR, DDB, OMB, NRL) in addition to FDA based on the component of the product.
- Process pathway and timeline for In-Vitro MD was presented in flowchart form for easy-to-follow guide.

Key Take Aways:

1. Be knowledgeable of your products
2. Conduct a detailed product assessment
3. expand your medical device knowledge; attend to various trainings
4. Join and participate in PAMDRAP committees

III. FDA – CDRRHR Updates

By: Engr. Ma. Cecilia Matienzo

Director, FDA - CDRRHR

- IVD Regulations and Requirements - the draft regulation is already with DOH, waiting for approval of DOH Secretary
- AO 2018-002 will be amended to include additional regulations for Refurbished Medical Devices. They will have the same regulations as New Medical Devices and will be subjected to Classifications based on Risks.
- Custom - made Medical Devices shall be regulated. When comments are settled, AO 2018-002 will be reissued to avoid confusion, if allowed to do so.
- Labelling will follow AO 2028-002 and its amendments when and if allowed final presentation of Labeling Guideline and subsequent posting will be done.

- IVD – CDRRHR has finally received the Legal opinion regarding WHO Pre-qualification for registration IVD MD. It will be reviewed and if there are no more impediments, it will be passed to DG for approval and signature.
- PMS is now with the DOH adopting the Annex 2 of the AMDD
- Creation of PNRC (Phil. National Regulatory Commission). PNRI's Nuclear Regulatory Division and Radiation Regulatory Division of CDRRHR and DOH shall be reassigned to PNRC as sole regulating body for Ionizing Radiation Emitting Devices. Congress is working on its passage and was approved on the 1st reading. Should it be enacted into law, only ionizing radiation emitting devices for medical use will still be registered with CDRRHR.
- Introduced the new project of DG Zacate for FDA to promote products of local manufacturers, MSME (micro, small, medium enterprises) mostly on Food and Cosmetics manufacturers. Engr. Matienzo is currently pushing for the baby project concerning Medical Devices.
- Support of Bagong Negosyo (BNB)
- Together with DOST, it hopes to boost local manufacture of Medical Devices to support healthcare delivery system in rural areas.
- Variation and Renewal of CMDN - shift from eportal to eservice is being worked-out
- When no type of variation is on the list, it means that it is for initial registration.
- Software – guideline for variation will be out soon

IV. Closing Remarks

By: Juls Obarde