



**Global Harmonization Working Party**

GHWP Towards Medical Device Harmonization

# Common Evaluation Reliance Practice Special Task Group

Zhang Shiqing  
Acting Chair

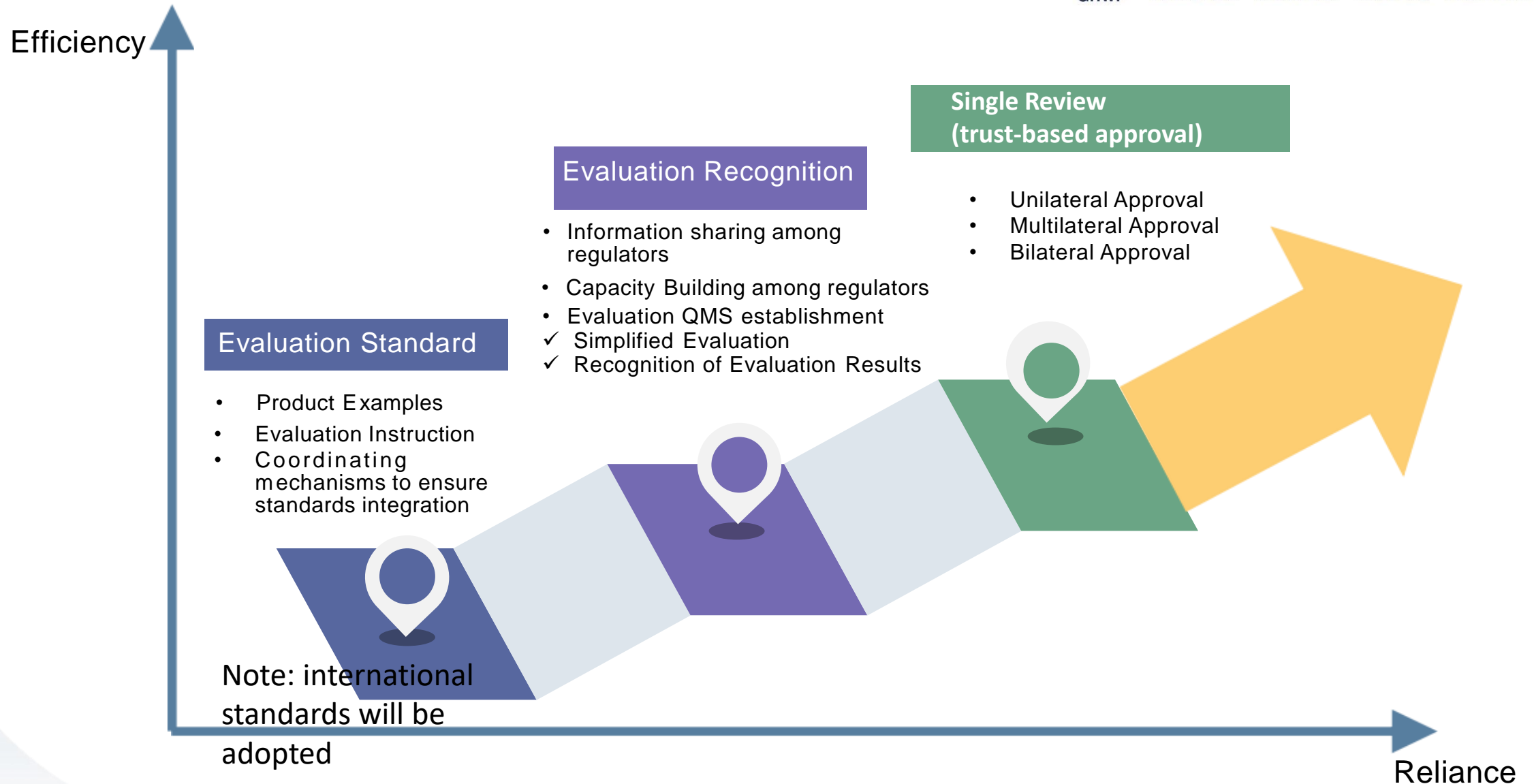
# Part 1 Background

1. Medical devices are related to public health
2. Unbalanced industry development, Inconsistent regulations
3. Repeated evaluation in different countries\regions, waste of resources

# Part 2 Purpose

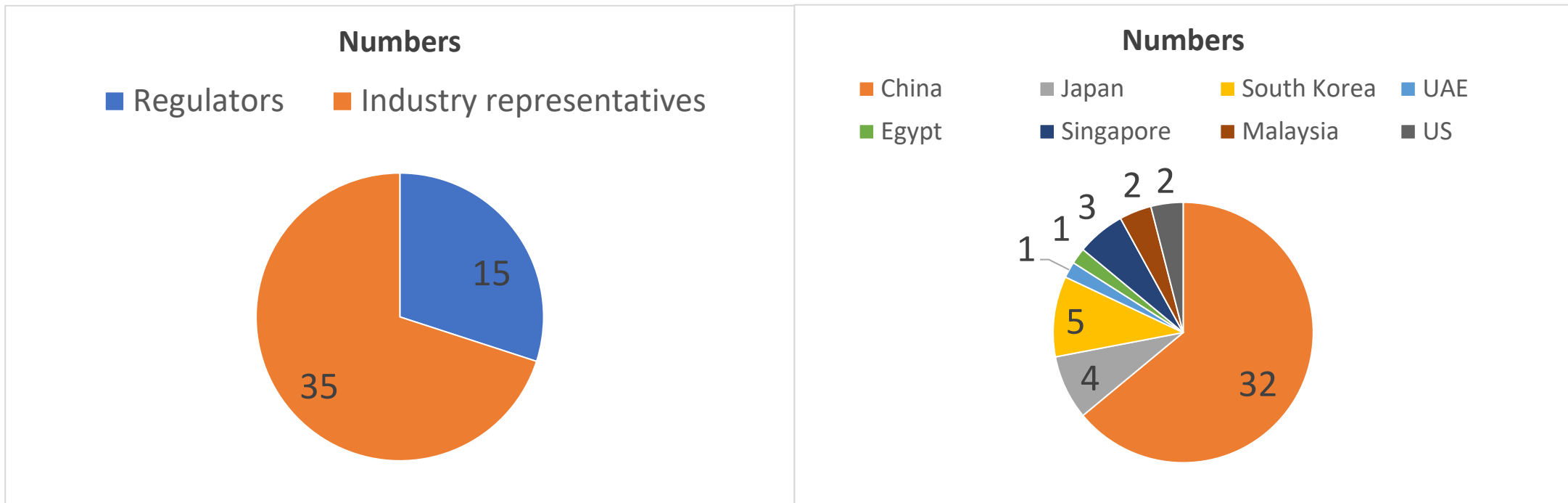
Common Evaluation Reliance Practice(CERP) Special Task Group (STG) aims to achieve the goals of mutual approval and regulatory reliance by developing standards for medical device product registration review, establishing technical review consensus and reducing duplicate reviews.

# Part 3 Program Planning



# Part 4 Work Progress

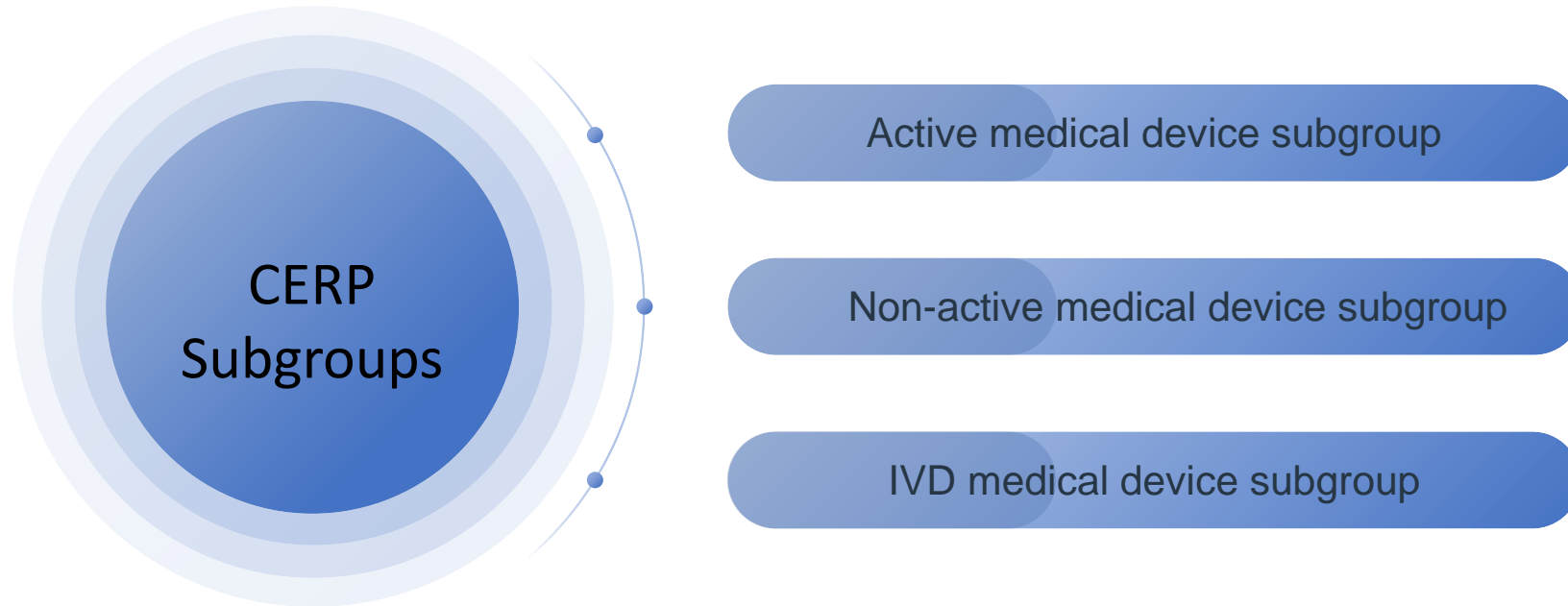
## 1. CERP STG Establishment



currently, CERP has a total of 50 members. Among them, 15 are from regulatory authorities and 35 are from the industry. These members come from China, Japan, the United States, the United Arab Emirates, Egypt, Malaysia, Singapore, and South Korea.

# Part 4 Work Progress

## 1. CERP STG Establishment



# Part 4 Work Progress

## 2. Online meeting



**Global Harmonization Working Party**

Towards Medical Device Harmonization

### CERP First Online Meeting Minutes

发件人: 刘英杰 liuyj@cmde.org.cn

收件人: alicia\_chang alicia\_chang@apacmed.org, asmaa.awad asmaa.awad@roche.com, bo.gao.bg4 bo.gao.bg4@roche.com, doris.guo doris.guo@cordis.com, heba.tork heba.tork@roche.com, hu.jing hu.jing@siemens-healthineers.com, iamlululu iamlululu@fda.gov.tw, inho.dan inho.dan@cordis.com, ishibashi-kenichi ishibashi-kenichi@pmda.go.jp, Joyce Liu joyce\_liu@welllead.com, justin.yea justin.yea@medtronic.com, jyw6 jyw6@itri.org.tw, LiuJing liujing@bluesail.cn, lianghong lianghong@cmde.org.cn, lily.li lily.li@medtecx.com, liqin.li liqin.li@stryker.com, MDR mdr@tmbia.org.tw, minyue minyue@cmde.org.cn, morooka morooka@shimadzu.co.jp, nasreenara.alquaid nasreenara.alquaid@bd.com, qiuyun.zhao qiuyun.zhao@elekta.com, Stevew stevew@scwmed.com, so.eb so.eb@om.asahi-kasei.co.jp, Tammy.steuerwald tammy.steuerwald@roche.com, tiantian.yang tiantian.yang@bsci.com, wangrui wangrui@sinomed.com, wangyu wangyu@cmde.org.cn, xnc xnc@micro-tech.com.cn, yangyx yangyx@cmde.org.cn, yishinlee yishinlee@bioteq.com.tw, yokoyama-yoshimasa yokoyama-yoshimasa@pmda.go.jp, yue.liu yue.liu@olympus.com.cn, zhangj zhangj@cfdi.org.cn, zhangqi zhangqi@cmde.org.cn, zhangsq@cmde.org.cn, zhengjie zhengjie@cfdi.org.cn, zhengljia zhengljia@cdr-adr.org.cn, 1416681688 1416681688@qq.com, cpelou cpelou@apacmed.org

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附件: Attachment 1.docx 下载附件

Attachment 2.docx 下载附件

Dear All,

I hope this email finds all of you in good health and high spirits.

With the successful convening of the CERP First Online Meeting, I would like to send meeting minutes, registration template and other information to everyone.

#### 1.Meeting Minutes(Attachment 1)

#### 2.Registration(Attachment 2 is template)

- Personnel training.** Anyone who wants to share and introduce the regulations of your country at the CERP Online Meeting can contact this email.
- Subgroups of CERP.** Please select the group(s) that best suits you and provide feedback(template) to this email.
- Secretary registration.** For interested members, please fill out the template and provide feedback to this email.
- Advisor registration.** For interested members, please fill out the template and provide feedback to this email.

#### 3.Creation of a Wechat group

For ease of communication, please scan the QR code(Valid for 7 days) to join the WeChat group.



Hold six online meetings

### CERP Second Online Meeting Minutes

发件人: 刘英杰 liuyj@cmde.org.cn

收件人: alicia\_chang alicia\_chang@apacmed.org, asmaa.awad asmaa.awad@roche.com, bo.gao.bg4 bo.gao.bg4@roche.com, cpelou cpelou@apacmed.org, doris.guo doris.guo@cordis.com, heba.tork heba.tork@roche.com, hu.jing hu.jing@siemens-healthineers.com, iamlululu iamlululu@fda.gov.tw, inho.dan inho.dan@cordis.com, ishibashi-kenichi ishibashi-kenichi@pmda.go.jp, Joyce Liu joyce\_liu@welllead.com, justin.yea justin.yea@medtronic.com, jyw6 jyw6@itri.org.tw, LiuJing liujing@bluesail.cn, lianghong lianghong@cmde.org.cn, lily.li lily.li@medtecx.com, liqin.li liqin.li@stryker.com, MDR mdr@tmbia.org.tw, minyue minyue@cmde.org.cn, morooka morooka@shimadzu.co.jp, nasreenara.alquaid nasreenara.alquaid@bd.com, qiuyun.zhao qiuyun.zhao@elekta.com, Stevew stevew@scwmed.com, so.eb so.eb@om.asahi-kasei.co.jp, Tammy.steuerwald tammy.steuerwald@roche.com, tiantian.yang tiantian.yang@bsci.com, wangrui wangrui@sinomed.com, wangyu wangyu@cmde.org.cn, xnc xnc@micro-tech.com.cn, yangyx yangyx@cmde.org.cn, yishinlee yishinlee@bioteq.com.tw, yokoyama-yoshimasa yokoyama-yoshimasa@pmda.go.jp, yue.liu yue.liu@olympus.com.cn, zhangj zhangj@cfdi.org.cn, zhangqi zhangqi@cmde.org.cn, zhangsq@cmde.org.cn, zhengjie zhengjie@cfdi.org.cn, zhengljia zhengljia@cdr-adr.org.cn, 1416681688 1416681688@qq.com

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附件: UAE Regulatory Framework.pptx 下载附件

NMPA Classification of Medical Devices-CERP.pptx 下载附件

CERP Technical Specification and Product List.pptx 下载附件

CERP Internal Management Mechanism(1).pdf 下载附件

Dear All,

I hope all of you are doing well.

As the CERP second online meeting concludes, I am sending you the minutes of this meeting.

**Meeting Date:** May-16th, 2024

**Location:** Zoom Meeting

#### Summary

##### •Personnel training

- 1)Ms.Asmat introduced UAE medical device regulation;
- 2)Ms.Wang Yawen introduced medical devices classification of NMPA.

•**Product list and template introduction.**Ms.Min Yue introduced some products and format of template for discussion.

•**Internal management mechanism introduction.**Ms.Zhang Qi introduced internal management mechanism.

•**Others.** Members can express opinions on product selection, template format and internal management mechanism.

#### Attachment

- UAE regulatory framework
- NMPA classification of medical devices
- CERP technical specification and product List
- CERP internal management mechanism

Looking forward to your idea(s).

# Part 4 Work Progress

## 3. Personnel training

There is always a personnel training session at every CERP meeting. The topic revolves around registration requirements, evaluation requirements, quality management systems, and regulatory regulations in various countries and regions.

### **April** CERP meeting:

1. CERP-STG Introduction.
2. China Regulations Introduction

### **May** CERP meeting:

1. UAE Regulations Introduction.
2. Classification Catalogue introduction.

### **June** CERP meeting:

1. Regulatory reliance in MedTech-The Singapore HSA/Thailand FDA Case Sharing.
2. Introduction to the System of Guidelines for Medical Devices Registration in china.



# Part 4 Work Progress

## 3. Personnel training

### **July** CERP meeting:

1. Introduction of Japan's regulations.
2. Introduction to quality management system.

### **October** CERP meeting:

1. Introduction to medical device regulations in Indonesia.
2. Introduction to the IMDRF Washington Meeting.

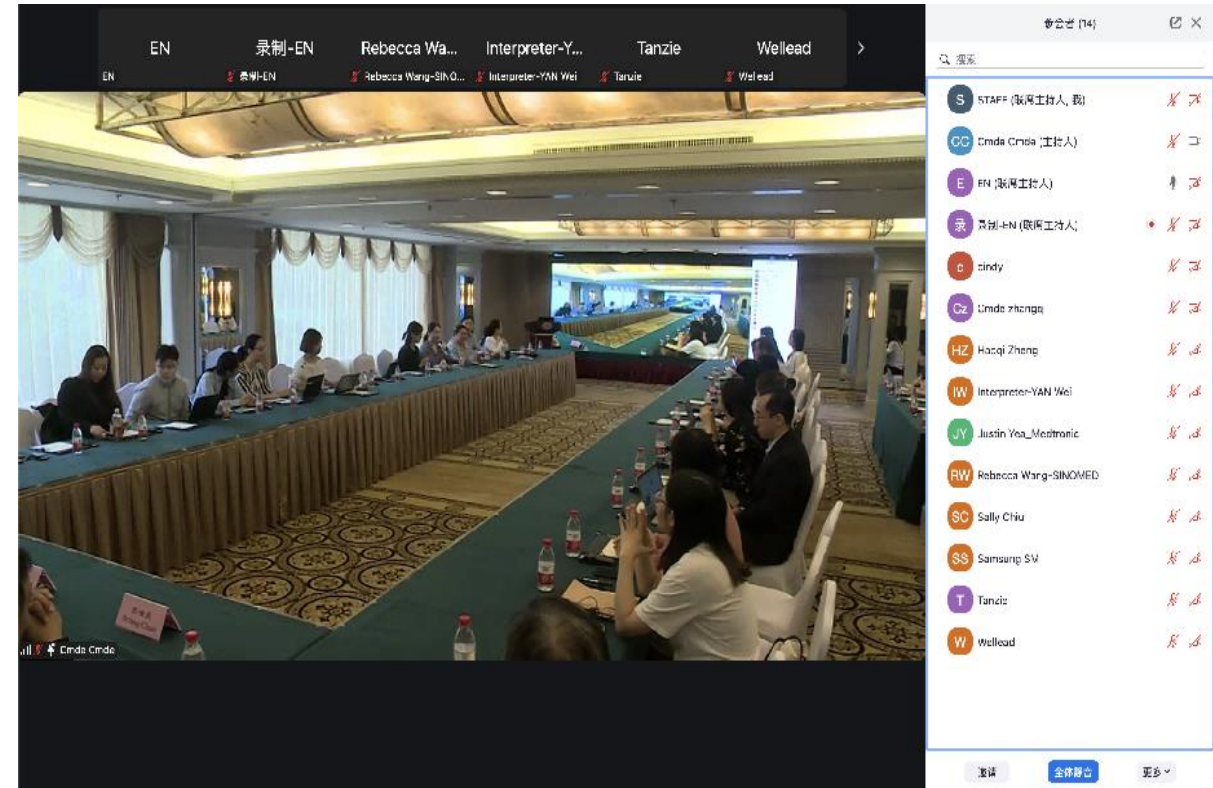
### **November** CERP meeting:

1. Reliance in MEA region - challenges and opportunities.
2. Malaysia Regulatory Overview-Initial Registration.

# Part 4 Work Progress

## 4.Activities

In **September**, a combination of **online and offline** meeting was held. CERP has invited many experts in the industry to give speeches. Besides, CERP also discussed products, evaluation instruction documents and the next work plans.



# Part 4 Work Progress

## 4.Activities

### September CERP meeting sharing

- 1.CERP updates
- 2.Accelerating Patients' Access Through Reliance
- 3.Regulatory Reliance Practice: Development Path from a Global Health Perspective
- 4.Introduction of Reliability to Pre-market Review
- 5.Requirements for Review of Active Medical Devices in China
- 6.Requirements for Review of Passive Medical Devices in China
- 7.Clinical Evaluation for Medical Device
- 8.Regulatory Reliance
- 9.Elements for Success of Regulatory Reliance
- 10.Sharing industry experience Australia Reliance pathways
- 11.Discussed on evaluation instruction document-abutment

# Part 4 Work Progress

## 5. Product examples and evaluation instructions



Infusion Set



Metal Bone Plate



Abutment



Ultrasound Surgical  
Equipment



High Frequency  
Surgical Equipment

Evaluation instruction document of abutment is collecting comments and feedback. Others are about to form draft.



- ◆ Product: Infusion sets for single use with graduated flow regulator
- ◆ Description: Consisting of an infusion set and a flow regulator
- ◆ Indication for Use: Suitable for intravenous infusion of medication. The product flow remains stable and can be set according to the scale
- ◆ Applicable standard : ISO 8536-13:2016, Infusion equipment for medical use-Part 13: Graduated flow regulators for single use with fluid contact)

- ◆ Product: Metal locking bone plate
- ◆ Description: Manufactured by stainless steel, pure titanium and titanium alloy materials, etc. And it is made by machining, heat treatment and surface treatment processes, such as passivation, electrolytic polishing, anodizing, etc.
- ◆ Indication for Use: It is suitable for internal fixation of limbs fracture.
- ◆ Applicable standard : ISO 5832-1, ISO 5832-2, ISO 5832-3, ISO 5832-11, ISO 5836, ASTM F 382, ISO 9269, ISO 9585, etc.



- ◆ Product: Abutment
- ◆ Description: The abutment is a cylindrical or other shaped solid with or without an angle and a hole or thread. Generally adopt titanium, titanium alloy, zirconia, alloy and other materials. Mounted on a dental implant that anchored to the bone.
- ◆ Indication for Use: The abutment is installed on an implant platform anchored to the bone and extends into the oral cavity for connecting, supporting, and/or securing the restoration or upper structure of the implant.
- ◆ Applicable standard : ISO 14801、ISO22674



- ◆ Product: Ultrasound Surgical Equipment
- ◆ Description: Generator, Foot switch, Transducer(Handle), Ultrasound accessories, etc.
- ◆ Intended use: Soft tissue excision and hemostasis during surgical procedures within medical facilities, closure up to 7mm vessels.
- ◆ Applicable standard: IEC 60601-1, IEC 60601-1-2, IEC 61847 (for reference), YY/T 1750-2020 (Chinese industry standard)



- ◆ Product: High Frequency Surgical Equipment
- ◆ Description: Generator, Foot switch, associated equipment, accessories, etc.
- ◆ Intended use: Cut and Coagulation for soft tissue of human during surgical procedures within medical facilities.
- ◆ Applicable standard : IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2

# Part 4 Work Progress

## 6. Evaluation instruction template

Item Number	Title	Description	Regional Requirement
		General	regional
.....	.....	.....	.....
.....	.....	.....	.....

Template

Refer to WHO documents

Evaluation Requirements of Customized abutment (titanium alloy)

RPS 目录 Row ID	标题 Heading	适用情况 Applicable	资料要求 Material Requirements of registration	技术审评要求 Evaluation Requirements
<b>第1章——监管信息 CHAPTER 1-ADMINISTRATIVE</b>				
CHI.4	申请表 Application Form	R	<p>Application Form</p> <p>Fill in the form according to the filling requirements and upload the application form file with the data check code. Upload the Application Form for Priority Approval of Medical Devices (if applicable). Upload the Application Form of Fee Preference for Small and Micro Enterprises (if applicable).</p>	<p>1. Class III passive medical devices, classification code is 17-08-02</p> <p>2. Model and specifications: See CH1.5 product list for details.</p> <p>3. Structure and composition: The product is composed of the main body of the abutment and screws, the repairable part of the upper part of the abutment is processed by CNC machine tools based on CAD/CAM technology, the <u>gingival</u> part of the abutment, the diameter, the height of the crown of the abutment, and the angle of the abutment can be individually designed, and</p>

Sample

# Part 4 Work Progress

## 7. Internal operating mechanisms

1. The organizational structure of CERP includes Chair, Co-chair, Advisors, Secretary, and Members
2. Applying to join CERP requires submitting an application to the GHWP Secretariat and obtaining approval from GHWP TC; Members applying for other positions also need to be approved by TC
3. CERP holds group meeting and arranges personnel training session during each group meeting
4. CERP sets up three subgroups to carry out work: active medical device subgroup, non-active medical device subgroup, and IVD medical device subgroup
5. The evaluation instruction(s) and work plan(s) drafted by CERP must be submitted to GHWP TC with the approval of 2/3 or more members within the group.



# Part 4 Work Progress

## 8. cooperation and communication

1. Countries, such as Japan, South Korea, Malaysia, Saudi Arabia, Indonesia, etc.
2. Organizations, such as APACMed, WHO, etc.

# Part 4 Work Progress

## 8. Joint Evaluation

### Basic Process

First stage: Manufacturers submit registration applications to local regulatory authorities, and reviewers conduct evaluation according to regulatory requirements.

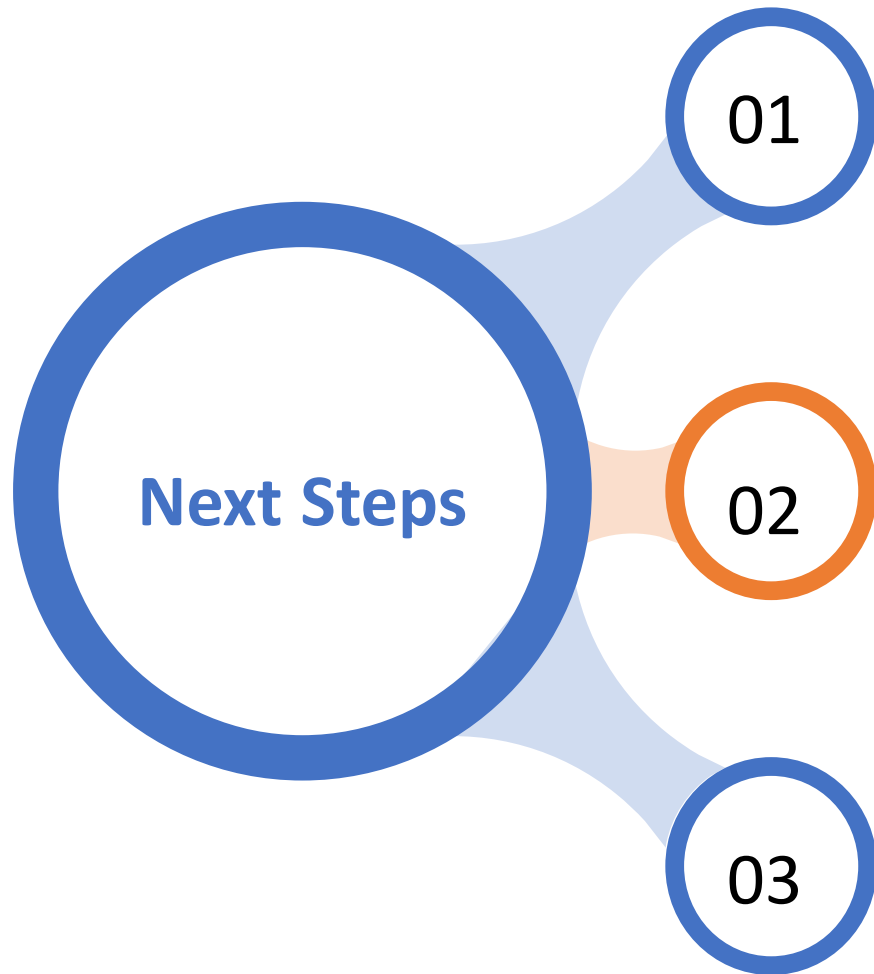
Second stage: Regulatory authorities share evaluation requirements. (the extent of sharing depends on the regulatory authorities).

Third stage: Regulatory authorities jointly discuss product risk and risk control measures.

Fourth stage: Regulatory authorities share evaluation report information.(the extent of sharing depends on the regulatory authorities).

Fifth stage: Regulatory authorities independently issue evaluation conclusions.

# Part 5 Next steps of work



01 Improve the work framework and joint evaluation procedures

02 Increase the intensity of compiling evaluation instruction documents.

03 Promote joint evaluation. Cooperate with more regulatory authorities and carry out pilot work.



**Global Harmonization Working Party**

GHWP Towards Medical Device Harmonization

# Thank all

Zhang Shiqing  
Acting Chair of CERP STG

Tel:86-10-86452951  
E-mail:[zhangsq@cmde.org.cn](mailto:zhangsq@cmde.org.cn)

