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Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



# Election of AHWP Leadership 2018-2020

22<sup>nd</sup> AHWP Annual Meeting  
4-8 Dec 2017, New Delhi, India

Mr. Bryan SO  
AHWP Secretariat



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# Election of **AHWP** Office Bearers

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# Agenda

- Endorsement/election arrangement for AHWP Chair, AHWP Vice-chair (Regulatory Authority) and AHWP Vice-chair (Industry)
  - Related Requirements in AHWP Terms of Reference (TOR)
  - Voting Procedures
  - Nomination Results

Position	Number of Nominees	For Endorsement	For Election
AHWP Chair	1	✓	
AHWP Vice-chair (Regulatory Authority)	1	✓	
AHWP Vice-chair (Industry)	1	✓	

- Endorsement & Result





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# Requirements in AHWP TOR

In regard to AHWP office Bearers

## According to AHWP Terms of Reference (TOR):

### 1.3 Leadership

**One AHWP Chair** and **two AHWP Vice-chairs** shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all presented Primary AHWP Representatives for a term of office until the next election. The AHWP Chair and one AHWP Vice-chair shall come from Regulatory Authorities while one AHWP Vice-chair shall come from the Industry. The AHWP Chair and Vice-chairs will normally rotate among member economies.





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# AHWP Office Bearers Nomination Results

## Summary of AHWP Office Bearers Nomination Results:

Position	Number of Nominees	For Endorsement	For Election
AHWP Chair	1	✓	
AHWP Vice-chair (Regulatory Authority)	1	✓	
AHWP Vice-chair (Industry)	1	✓	



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# AHWP Office Bearers Nomination Results

- **Post: AHWP Chair**
- Number of nominee: 1
- Information of nominee:

**Mr. Zamane Abd Rahman**

AHWP Primary Representative (Regulatory Authority)

Chief Executive

Medical Device Authority

Ministry of Health

Malaysia



**For Endorsement Y/N?**







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# AHWP Office Bearers Nomination Results

- **Post: AHWP Vice-chair (Regulatory Authority)**
- Number of nominees: 1
- Information of nominee:

**Mr. Gao Guobiao**

AHWP Primary Representative (Regulatory Authority)

Vice Director

Medical Device Registration Department

China Food and Drug Administration

People's Republic of China



**For Endorsement Y/N?**





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# AHWP Office Bearers Nomination Results

- **Post: AHWP Vice-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

**Ms. Quan TRAN**

AHWP Primary Representative (Industry)

Vice President

Regulatory Affairs

Asia Pacific Medical Technology Association (APACMed)

Laos PDR



**For Endorsement Y/N?**







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# Announcement of New AHWP Chair and Vice-chairs





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## New AHWP Chair and Vice-chairs

Position	Name	Affiliation	Member Economy
AHWP Chair	<b>Mr. Zamane Abd Rahman</b>	<b>Medical Device Authority, MOH</b>	<b>Malaysia</b>
AHWP Vice-chair (Regulatory Authority)	<b>Mr. GAO Guobiao</b>	<b>China Food and Drug Administration</b>	<b>People's Republic of China</b>
AHWP Vice-chair (Industry)	<b>Ms. Quan TRAN</b>	<b>APACMed</b>	<b>Laos PDR</b>







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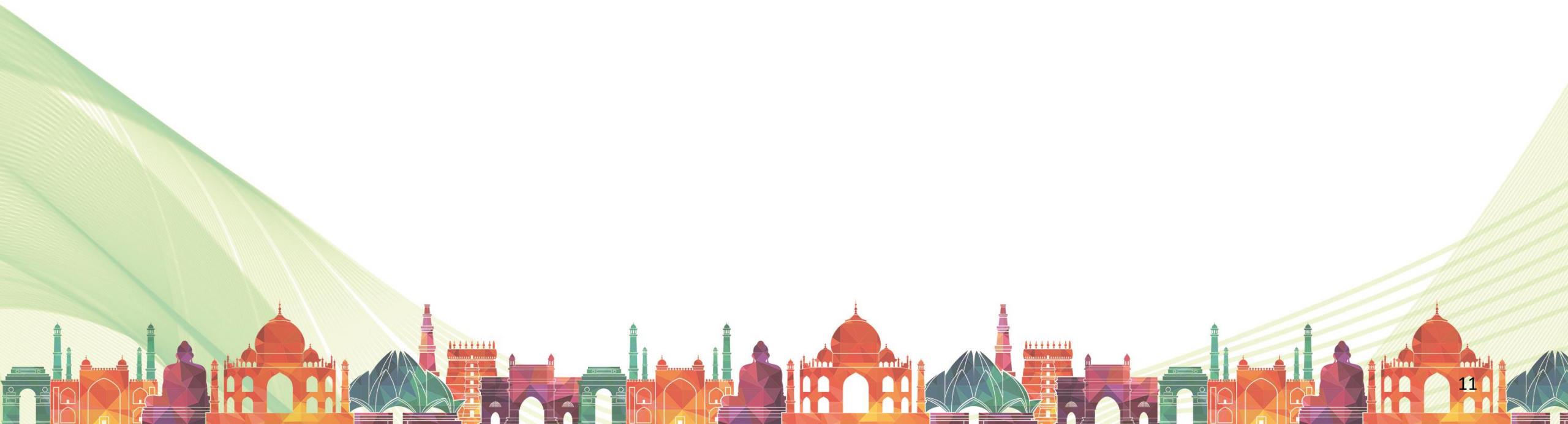


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# Election of AHWP TC Office Bearers

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# Agenda

- Endorsement/election arrangement for AHWPTC Chair, AHWPTC Co-chair (Regulatory Authority) and AHWPTC Co-chair (Industry)
  - Related Requirements in AHWPTC TOR
  - Voting Procedures
  - Nomination Results

Position	Number of Nominees	For Endorsement	For Election
AHWPTC Chair	1	✓	
AHWPTC Co-chair (Regulatory Authority)	2		✓
AHWPTC Co-chair (Industry)	2		✓

- Election & Result







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# Requirements in AHWPTC TOR

In regard to AHWPTC Office Bearers

According to AHWPTC TOR:

## 2.3 AHWPTC Leadership

**One AHWPTC Chair** and **two AHWPTC Co-chairs** shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives at the AHWPTC Meeting that is held in conjunction with the AHWP Annual Meeting. The **AHWPTC Chair** and **one AHWPTC Co-chair** shall come from the **Regulatory Authorities** while **one AHWPTC Co-chair** shall come from the **Industry**.

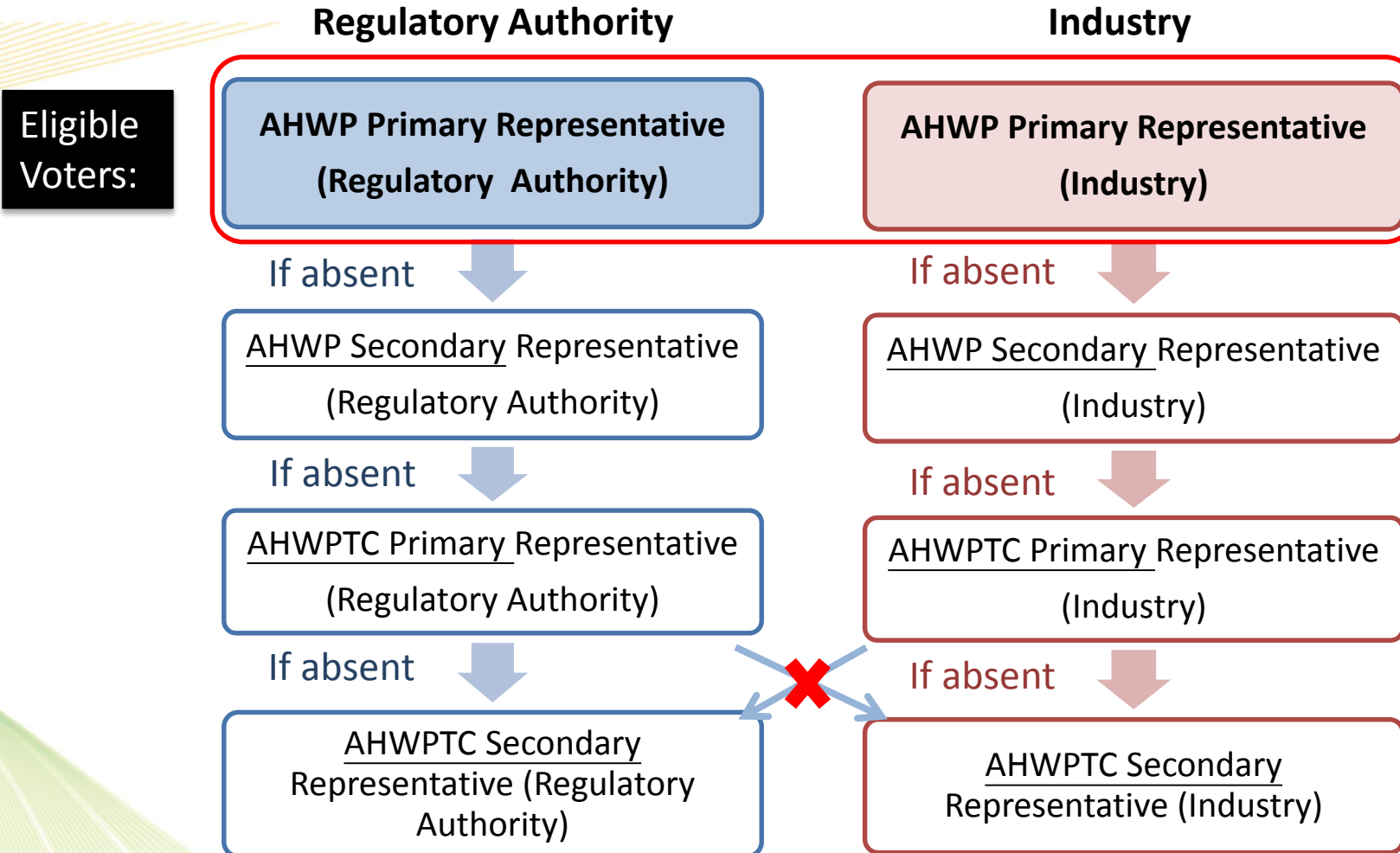


# Eligible Voters

No proxy

According to AHWP & AHWPTC TOR Clause 2.4:

\*Representatives (Industry) cannot take up the voting rights from representatives of (Regulatory Authorities), and vice versa.







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# Voting Procedures





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## Voting Instruction (For Voters)

1. Sign on the “List of eligible voters” against the name printed on the list prepared by AHWP Secretariat
2. Receive the Voting Slip from AHWP Secretariat
3. Select only one candidate by putting a “✓” on the Slip
4. Fold the Slip to conceal the vote
5. Put your Slip into the ballot box at the time of collection
6. A blank Slip will be regarded as “given up”
7. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.\*

\* Adopted from AHWP House Rule Clause 5 on Nominations and Elections of the AHWPTC Chair/Co-chairs.







# Voting Instruction (For Voters)

- The Voting Slip B is designed for the election of AHWPTC Co-Chairs

No proxy



## Voting Slip B

**Application of this Voting Slip**  
This Voting Slip A is designed for the election of AHWP TC Co-chair (Industry) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

**Eligible Voters**  
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWPTC Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulator) and the AHWP Primary Representative (Industry) of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

### Voting Instructions

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

<u>Candidates for AHWP TC Co-chair (Industry)</u>		
Number	1	2
Name		
Member Economy		
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted		

**Remarks**  
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

## Eligible Voters:

**AHWP Primary Representatives**



(if absent):

AHWP Secondary Representatives



(If absent):

AHWPTC Primary Representatives





(If absent):

AHWPTC Secondary Representatives



# Voting Instruction (For Voters)

- **Correct**

<u>Nominated Candidates for AHWP Co-chair (Regulatory Authority)</u>		
Number	1	2
Name	ABC	DEF
Member Economy	ABC Member Economy	DEF Member Economy
Please <u>put a tick</u> "✓" in either one of the box on the right hand side.		





# Voting Instruction (For Voters)

- INCORRECT (Void)

Nominated Candidates for AHWP Co-chair (Regulatory Authority)		
Number	1	2
Name	ABC	DEF
Member Economy	ABC Member Economy	DEF Member Economy
Please put a tick "✓" in either one of the box on the right hand side.	1	



# Voting Instruction (For Voters)

- INCORRECT (Void)

Nominated Candidates for AHWP Co-chair (Regulatory Authority)		
Number	1	2
Name	ABC	DEF
Member Economy	ABC Member Economy	DEF Member Economy
Please put a tick "✓" in either one of the box on the right hand side.	X	







# AHWPTC Office Bearers Nomination Results

Summary of the TC Office Bearers Nomination results:

Position	Number of Nominees	For Endorsement	For Election
AHWP TC Chair	1	✓	
AHWP TC Co-chair (Regulatory Authority)	2		✓
AHWP TC Co-chair (Industry)	2		✓



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# AHWPTC Office Bearers Nomination Results

- **Post: AHWP TC Chair**
- Number of nominee: 1
- Information of nominee:

**Mr. Ali M. Al-Dalaan**

AHWPTC Primary Representative (Regulatory Authority)

Executive Director

Medical Device Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia



**For Endorsement Y/N?**





# AHWPTC Office Bearers

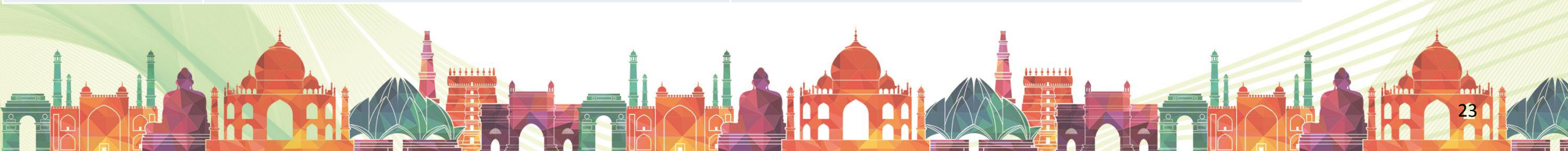
## Nomination Results

- **Post: AHWP TC Co-chair (Regulatory Authority)**
- Number of nominees: **2**
- Information of nominees: (in arbitrary order)

Number	1	2
Name and Affiliation	<b>Dr. Jeong-Rim Lee</b> AHWPTC Primary Representative (Regulatory Authority)	<b>Dr. V. G. Somani</b> AHWPTC Primary Representative (Regulatory Authority)
	Director	Joint Drug Controller
	Cardiovascular Devices Division	Central Drugs Standard Control Organization
	Ministry of Food and Drug Safety(MFDS)	Ministry of Health and Family Welfare (MOHFW)
	Republic of Korea	India



**For Election**





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# Self-introduction by Candidates







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# Please Vote

No proxy

1. Select only **one candidate for each position** by putting a “✓” on the Slip
2. Fold the Slip to conceal the vote
3. Put your Slip into the **ballot box** at the time of collection
4. A **blank Slip** will be regarded as “**given up**”

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**Voting Slip B**

Application of this Voting Slip  
This Voting Slip A is designed for the election of AHWP TC Co-chair (Regulatory Authority) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

Eligible Voters  
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWP TC Meeting. Therefore, the eligible voters are the **AHWP Primary Representative (Regulator)** and the **AHWP Primary Representative (Industry)** of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

Voting Instructions

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

Candidates for AHWP TC Co-chair (Regulator)			
Number	1	2	3
Name	Dr. Jeong-Rim Lee	Ir. Sasikala Devi Thangavelu	Dr. V. G. Somani
Member Economy	Republic of Korea	Malaysia	India
Please put a tick, ✓, in either one of the box on the right hand side. Writing other than a "✓" would not be counted			

Remarks  
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfil the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

-Page 1 of 1 -



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# Distribution of Voting Slips

Voters please **sign** on “Eligible Voters List” Sheet  
&  
**receive Slip B**







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# Collection of Voting Slips



# AHWPTC Office Bearers

## Voting Result

- **Post: AHWP TC Co-chair (Regulatory Authority)**
- Number of nominees: **2**


No.	1	2
Name	<b>Dr. Jeong-Rim Lee</b> <b>Republic of Korea</b>	<b>Dr. V. G. Somani</b> <b>India</b>
Number of Votes		



# AHWPTC Office Bearers Nomination Results

- **Post: AHWP TC Co-chair (Industry)**
- Number of nominees: **2**
- Information of nominees: (in arbitrary order)

Number	1	2
Name and Affiliation	<b>Mr. Alfred Kwek</b> AHWPTC Primary Representatives (Industry)	<b>Ms. Sumati Randeo</b> AHWP Primary Representatives (Industry)
Director	Director	Director
Public Affairs		Global Regulatory Strategy & Advocacy
	Edwards Lifesciences	Abbott Labs
	Laos PDR	India

  
**For Election**



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# Self-introduction by Candidates







# Please Vote

No proxy

1. Select only **one candidate for each position** by putting a “✓” on the Slip
2. Fold the Slip to conceal the vote
3. Put your Slip into the **ballot box** at the time of collection
4. A **blank Slip** will be regarded as “**given up**”



## Voting Slip B

### Application of this Voting Slip

This Voting Slip A is designed for the election of AHWP TC Co-chair (Industry) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

### Eligible Voters

According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWPTC Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulator) and the AHWP Primary Representative (Industry) of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

### Voting Instructions

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

<u>Candidates for AHWP TC Co-chair (Industry)</u>		
Number	1	2
Name	Mr. Alfred Kwek	Ms Sumati Randeo
Member Economy	Laos PDR	India
Please put a tick “✓” in either one of the box on the right hand side. Writing other than a “✓” would not be counted		

### Remarks

The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.



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# Distribution of Voting Slips

Voters please **sign** on “Eligible Voters List” Sheet  
&  
**receive Slip B**







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# Collection of Voting Slips



# AHWPTC Office Bearers

## Voting Result

- **Post: AHWP TC Co-chair (Industry)**
- Number of nominees: **2**

No.	1	2
Name	<b>Mr. Alfred Kwek Laos PDR</b>	<b>Ms. Sumati Randeo India</b>
Number of Votes		





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# Announcement of New AHWP TC Chairs and TC Co-chairs





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## New AHWP Chair and Vice-chairs

Position	Name	Organization	Member Economy
AHWPTC Chair	Mr. Ali M. Al-Dalaan	Saudi-FDA	Kingdom of Saudi Arabia
AHWPTC Co-chair (Regulatory Authority)	Dr. Jeong-Rim Lee	MFDS	Republic of Korea
AHWPTC Co-chair (Industry)	Mr. Alfred Kwek	Edwards Lifesciences	Laos PDR





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# Election of AHWPTC Working Groups/Special Task Groups Office Bearers

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# Agenda

- Endorsement/election arrangement for Chair (Regulatory Authority) and Co-chair (Industry) of Work groups (WG) 1-9.

Post		Number of Nominees	For Election	For Endorsement
WG 1 (Pre-market : General MD)	Chair	1		✓
	Co-chair	1		✓
WG2 (Pre-market: IVDD)	Chair	1		✓
	Co-chair	1		✓
WG 3 (Pre-market: Software as a Medical Device)	Chair	1		✓
	Co-chair	2	✓	







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Post		Number of Nominees	For Election	For Endorsement
WG4 (Post-Market)	Chair	1		✓
	Co-chair	1		✓
WG5 (Clinical Evidence for Performance and Safety)	Chair	1		✓
	Co-chair	1		✓
WG6 (QMS-Audit & Assessment)	Chair	1		✓
	Co-chair	1		✓
WG7 (QMS-Operation & Implementation)	Chair	1		✓
	Co-chair	1		✓
WG8 (Standards)	Chair	1		✓
	Co-chair	2	✓	
WG9 (U&N)	Chair	1		✓
	Co-chair	1		✓





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# Requirements in AHWPTC TOR

in regard to office bearers for WGs

According to AHWPTC TOR:

## 2.4 Working Groups (WGs) and Special Task Groups (STGs)

- A. With the consent of the AHWP Chair, the AHWPTC Chair may create Working Groups and Special Task Groups for carrying out specific tasks and duties of the Technical Committee. Each Group shall have one Chair from the Regulatory Authority and one Co-chair from the Industry.
- B. The AHWPTC Chair may appoint Acting Chairs and Co-chairs to take charge of the newly formed Groups until the next AHWP Meeting in which the Chairs and Co-chairs of the newly formed Groups are elected.





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# Voting Procedures





# Voting Procedures (for voters)

No proxy

- The Voting Slip C is designed for the election for the election of **AHWPTC WG Chairs and Co-chairs**

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**Voting Slip C**

**Application of this Voting Slip**  
This Voting Slip A is designed for the election of AHWP WG1 Chair (Regulatory Authority) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

**Eligible Voters**  
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWPTC Meeting. Therefore, the eligible voters are the **AHWP Primary Representative (Regulator)** and the **AHWP Primary Representative (Industry)** of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

**Voting Instructions**

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

Candidates for AHWP WG1 Chair (Regulatory Authority)			
Number	1	2	3
Name			
Member Economy			
Please put a tick <input type="checkbox"/> in either one of the box on the right hand side. Writing other than a "✓" would not be counted			

**Remarks**  
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

-Page 1 of 1-

## Eligible Voters:

**AHWP Primary Representatives**

(if absent):

**AHWP Secondary Representatives**

(If absent):

**AHWPTC Primary Representatives**

(If absent):

**AHWPTC Secondary Representatives**





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# AHWPTC WG/STG Office Bearers Nomination Results

## Summary of WG Office Bearers Nomination Results:

Post		Number of Nominees	For Election	For Endorsement
WG1 (Pre-market : General MD)	Chair	1		✓
	Co-chair	1		✓
WG2 (Pre-market: IVDD)	Chair	1		✓
	Co-chair	1		✓
WG3 (Pre-market: Software as a Medical Device)	Chair	1		✓
	Co-chair	2	✓	



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Post		Number of Nominees	For Election	For Endorsement
WG4 (Post-Market)	Chair	1		✓
	Co-chair	1		✓
WG5 (Clinical Evidence for Performance and Safety)	Chair	1		✓
	Co-chair	1		✓
WG6 (QMS-Audit & Assessment)	Chair	1		✓
	Co-chair	1		✓
WG7 (QMS-Operation & Implementation)	Chair	1		✓
	Co-chair	1		✓
WG8 (Standards)	Chair	1		✓
	Co-chair	2	✓	
WG9 (U&N)	Chair	1		✓
	Co-chair	1		✓







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG1 – Pre-market: General MD

- **Post: WG1 Chair (Regulatory Authority)**
- Number of nominee: 1
- Information of nominee:

**Mr. Se-il Park**

Assistant Manager

Ministry of Food and Drug Safety

Republic of Korea



For endorsement **Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG1 – Pre-market: General MD

- **Post: WG1 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

**Ms. Kate HyeongJoo KIM**

Director, Regulatory Strategy & Innovation, ASPAC

Johnson & Johnson Medical

Republic of Korea



For endorsement **Y / N**







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG2 – Pre-market: IVDD

- **Post: WG2 Chair (Regulatory Authority)**
- Number of nominee: 1
- Information of nominee:

**Mr. Wen-Wei TSAI**

Technical Specialist

Food and Drug Administration

Ministry of Health and Welfare

Chinese Taipei



For endorsement **Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG2 – Pre-market: IVDD

- **Post:** WG2 Co-chair (Industry)
- Number of nominee: 1
- Information of nominee:

**Mr. Albert POON**

Professor of Practise (Biomedical Engineer)

Hong Kong Polytechnic University

Hong Kong



For endorsement **Y / N**







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG3 – Pre-market: Software as a Medical Device

- **Post: WG3 Chair (Regulatory Authority)**
- Number of nominee: 1
- Information of nominee:

**Dr. Bae Youngwoo**

Deputy Director

Ministry of Food and Drug Safety

Republic of Korea



For endorsement **Y / N**



# AHWPTC WG/STG Office Bearers Nomination Results

## WG3 – Pre-market: Software as a Medical Device (Cont.)

- **Post: WG3 Co-chair (Industry)**
- Number of nominees: **2**
- Information of nominees: (in arbitrary order)

Number	1	2
Name and Affiliation	<b>Mr. Tony YIP</b>	<b>Dr. Shim Hun</b>
	Associate Director	Associate Research
	Regulatory Affairs, Asia Pacific, Grifols (HK) Limited	Wonju Medical Industry Techno Valley (WMIT)
	Hong Kong SAR, China	Republic of Korea



**For Election**







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# Self-introduction by Candidates





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# Please Vote

No proxy

1. Select only **one candidate for each position** by putting a “✓” on the Slip
2. Fold the Slip to conceal the vote
3. Put your Slip into the **ballot box** at the time of collection
4. A **blank Slip** will be regarded as “**given up**”



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### Voting Slip C

**Application of this Voting Slip**  
This Voting Slip A is designed for the election of AHWP TC WG3 Co-chair (Industry) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

**Eligible Voters**  
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWP TC Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulator) and the AHWP Primary Representative (Industry) of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. NO Proxy is allowed.

**Voting Instructions**

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

<u>Candidates for AHWP TC WG3 Co-chair (Industry)</u>		
Number	1	2
Name	Mr. Tony YIP	Dr. Shim Hun
Member Economy	Hong Kong SAR, China	Republic of Korea
Please put a tick “✓” in either one of the box on the right hand side. Writing other than a “✓” would not be counted		

**Remarks**  
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

-Page 1 of 1 -







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# Distribution of Voting Slips

Voters please **sign** on “Eligible Voters List” Sheet  
&  
**receive Slip C**





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# Collection of Voting Slips





# AHWPTC WG/STG Office Bearers

## Voting Result

### WG3 – Pre-market: Software as a Medical Device (Cont.)

- **Post: WG3 Co-chair (Industry)**
- Number of nominees: **2**

No.	1	2
Name	<b>Mr. Tony YIP Hong Kong SAR, China</b>	<b>Dr. Shim Hun Republic of Korea</b>
Number of Votes		



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# AHWPTC WG/STG Office Bearers Nomination Results

## WG4 – Post-market

- **Post:** WG4 Chair (Regulatory Authority)
- Number of nominee: 1
- Information of nominee:

**Ms. Jennifer MAK**

Senior Electronics Engineer

Medical Device Control Office

Department of Health

Hong Kong SAR



For endorsement **Y / N**







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG4 – Post-market

- **Post:** WG4 Co-chair (Industry)
- Number of nominee: 1
- Information of nominee:

Ms. Kitty MAO YiQing

RA Director

GE Healthcare

Singapore



For endorsement **Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG5 – Clinical Evidence for Performance and Safety

- **Post:** WG5 Chair (Regulatory Authority)
- Number of nominee: 1
- Information of nominee:

**Ms. Yuwadee PATANAWONG**

Director of Medical Device Control Division

Food and Drug Administration

Ministry of Public Health

Thailand



For endorsement **Y / N**







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG5 – Clinical Evidence for Performance and Safety

- **Post:** WG5 Co-chair (Industry)
- Number of nominee: 1
- Information of nominee:

**Ms. Sumati RANDEO**

Director Global Strategy Regulatory Affairs  
& Advocacy

Abbott Laboratories

India



For endorsement **Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG6 – Quality Management System: Audit & Assessment

- **Post:** WG6 Chair (Regulatory Authority)
- Number of nominee: 1
- Information of nominee:

**Mr. Abdullah Al Rasheed**

Compliance and Enforcement Executive  
Director

Saudi Food and Drug Authority

Kingdom of Saudi Arabia



For endorsement **Y / N**







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# AHWPTC WG/STG Office Bearers Nomination Results

## WG6 – Quality Management System: Audit & Assessment

- **Post: WG6 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

**Mr. Vincent LAM CHEE-CHOONG**

Senior Product Specialist

TUV SUD Product Service

Malaysia



For endorsement **Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG7 – Quality Management System: Operation & Implementation

- **Post:** WG7 chair (Regulatory Authority)
- Number of nominee: 1
- Information of nominee:

<b>Mr. WANG AI JUN</b>
Director
Center For Food and Drug Inspection
CFDA
People's Republic of China



For endorsement **Y / N**







# AHWPTC WG/STG Office Bearers Nomination Results

## WG7 – Quality Management System: Operation & Implementation

- **Post: WG7 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

**Mr. Ee Bin LIEW**

Owner and Consultant

Access-2-Healthcare

Singapore



**For endorsement Y / N**





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# AHWPTC WG/STG Office Bearers Nomination Results

## WG8 – Standards

- **Post: WG8 Chair (Regulatory Authority)**
- Number of nominee: 1
- Information of nominee:

**Mrs. Salbiah Yaakop**

Senior Principal Assistant Director

Medical Device Authority

Malaysia



For endorsement **Y / N**





# AHWPTC WG/STG Office Bearers Nomination Results

## WG8 – Standards

- **Post: WG8 Co-chair (Industry)**
- Number of nominees: **2**
- Information of nominees: (in arbitrary order)

Number	1	2
Name and Affiliation	<b>Mr. Tony LOW</b>	<b>Ms. Youngjin LEE</b>
	Director of QA/RA and Human Performance	Q&R Senior Manager
	Commissioning Agents International	Philips Korea
	Malaysia	Republic of Korea



**For Election**





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# Please Vote

No proxy

1. Select only **one candidate for each position** by putting a “✓” on the Slip
2. Fold the Slip to conceal the vote
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**Voting Slip C**

**Application of this Voting Slip**  
This Voting Slip A is designed for the election of AHWP TC WG8 Co-chair (Industry) at the 22<sup>nd</sup> AHWP New Delhi Meeting.

**Eligible Voters**  
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website [www.ahwp.info](http://www.ahwp.info) for details), each AHWP Primary Representative shall have one vote at the AHWP TC Meeting. Therefore, the eligible voters are the **AHWP Primary Representative (Regulator)** and the **AHWP Primary Representative (Industry)** of each Member Economy. Only in the absence of the primary representative can the secondary representative of the same side take up the voting rights of the former. AHWP Secretariat would distribute this voting slip to eligible voters according to the record kept by AHWP Secretariat. **NO Proxy is allowed.**

**Voting Instructions**

- Please select ONE candidate only.
- Mark only with Blue or Black ink.
- Fold the paper to conceal your vote, and put it into the ballot box.

<u>Candidates for AHWP TC WG8 Co-chair (Industry)</u>		
Number	1	2
Name	Mr. Tony LOW	Mr. Youngjin Lee
Member Economy	Malaysia	Republic of Korea
Please put a tick "✓" in either one of the box on the right hand side. Writing other than a "✓" would not be counted		

**Remarks**  
The AHWP Chair has the full authority to review the voting rights and validity of voters, and to reject any votes that cannot fulfill the requirements as stated in the Terms of Reference and House Rules of AHWP, and the instructions as stated in this voting slip.

-Page 1 of 1 -



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# Collection of Voting Slips



# AHWPTC WG/STG Office Bearers

## Voting Result

### WG8 – Standards

- Post: WG8 Co-chair (Industry)
- Number of nominees: **2**

No.	1	2
Name	<b>Mr. Tony LOW Malaysia</b>	<b>Ms. Youngjin LEE Republic of Korea</b>
Number of Votes		





# AHWPTC WG/STG Office Bearers Nomination Results

## WG9 – UDI & Nomenclature

- **Post: WG9 Chair (Regulatory Authority)**
- Number of nominee: 1
- Information of nominee:

<b>Mr. Jun LI</b>
Division Director
Medical Device Registration Department, Registration Division II
CFDA
People's Republic of China



For endorsement **Y / N**





# AHWPTC WG/STG Office Bearers Nomination Results

## WG9 - UDI & Nomenclature

- **Post:** **WG9 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

**Ms. Victoria QU**

Director Regulatory Affairs

Abbott China

People's Republic of China



**For endorsement Y / N**







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# Announcement of New AHWP TC WG/STG Chairs and Co-chairs





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## New WG Chairs and Co-chairs

Position		Name	Affiliation	Economy
WG1 (Pre-market : General MD)	Chair	Mr. Park Se-il	Ministry of Food and Drug Safety	Republic of Korea
	Co-chair	Ms Kate HyeongJoo KIM	Johnson & Johnson Medical	Republic of Korea
WG2 (Pre-market: IVDD)	Chair	Mr. Wen-Wei TSAI	TFDA	Chinese Taipei
	Co-chair	Mr. Albert POON	Hong Kong Polytechnic University	Hong Kong SAR
WG3 (Pre-market: Software as a Medical Device)	Chair	Dr. Bae Youngwoo	Ministry of Food and Drug Safety	Republic of Korea
	Co-chair	Mr. Tony YIP	Grifols (HK) Limited	Hong Kong SAR, China
WG4 (Post-market)	Chair	Ms. Jennifer MAK	MDCO, Department of Health	Hong Kong SAR
	Co-chair	Ms. Kitty MAO	GE Healthcare	Singapore







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## New WG/STG Chairs and Co-chairs

Position		Name	Affiliation	Economy
WG5 (Clinical Evidence for Performance and Safety)	Chair	<b>Ms. Yuwadee PATANAWONG</b>	<b>Thai-FDA</b>	<b>Thailand</b>
	Co-chair	<b>Ms. Sumati RANDEO</b>	<b>Abbott Laboratories</b>	<b>India</b>
WG6 (Quality Management System : Audit & Assessment)	Chair	<b>Mr. Abdullah Al Rasheed</b>	<b>Saudi-FDA</b>	<b>Kingdom of Saudi Arabia</b>
	Co-chair	<b>Mr. Vincent LAM CHEE-CHOONG</b>	<b>TUV SUD Product Service</b>	<b>Malaysia</b>
WG7 (Quality Management System: Operation & Implementation)	Chair	<b>Mr. WANG AI JUN</b>	<b>CFDA</b>	<b>People's Republic of China</b>
	Co-chair	<b>Mr. Ee Bin LIEW</b>	<b>Access-2-Healthcare</b>	<b>Singapore</b>
WG8 (Standards)	Chair	<b>Mrs. Salbiah Yaakop</b>	<b>Medical Device Authority</b>	<b>Malaysia</b>
	Co-chair	<b>Mr. Tony LOW</b>	<b>Commissioning Agents International</b>	<b>Malaysia</b>
WG9 (UDI & Nomenclature)	Chair	<b>Mr. Jun LI</b>	<b>CFDA</b>	<b>People's Republic of China</b>
	Co-chair	<b>Ms. Victoria QU</b>	<b>Abbott</b>	<b>People's Republic of China</b>





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# Thank You

