

Election of AHWP Leadership 2015-2017

19th AHWP Annual Meeting
18-21 Nov 2014, Seoul, Republic of Korea

Mr. Bryan SO
AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Election of **AHWP** Office Bearers

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)	2		✓
AHWP Vice-chair (Industry)	1	✓	

Requirements in AHWP TOR

In regard to AHWP office Bearers

According to AHWP Terms of Reference (TOR):

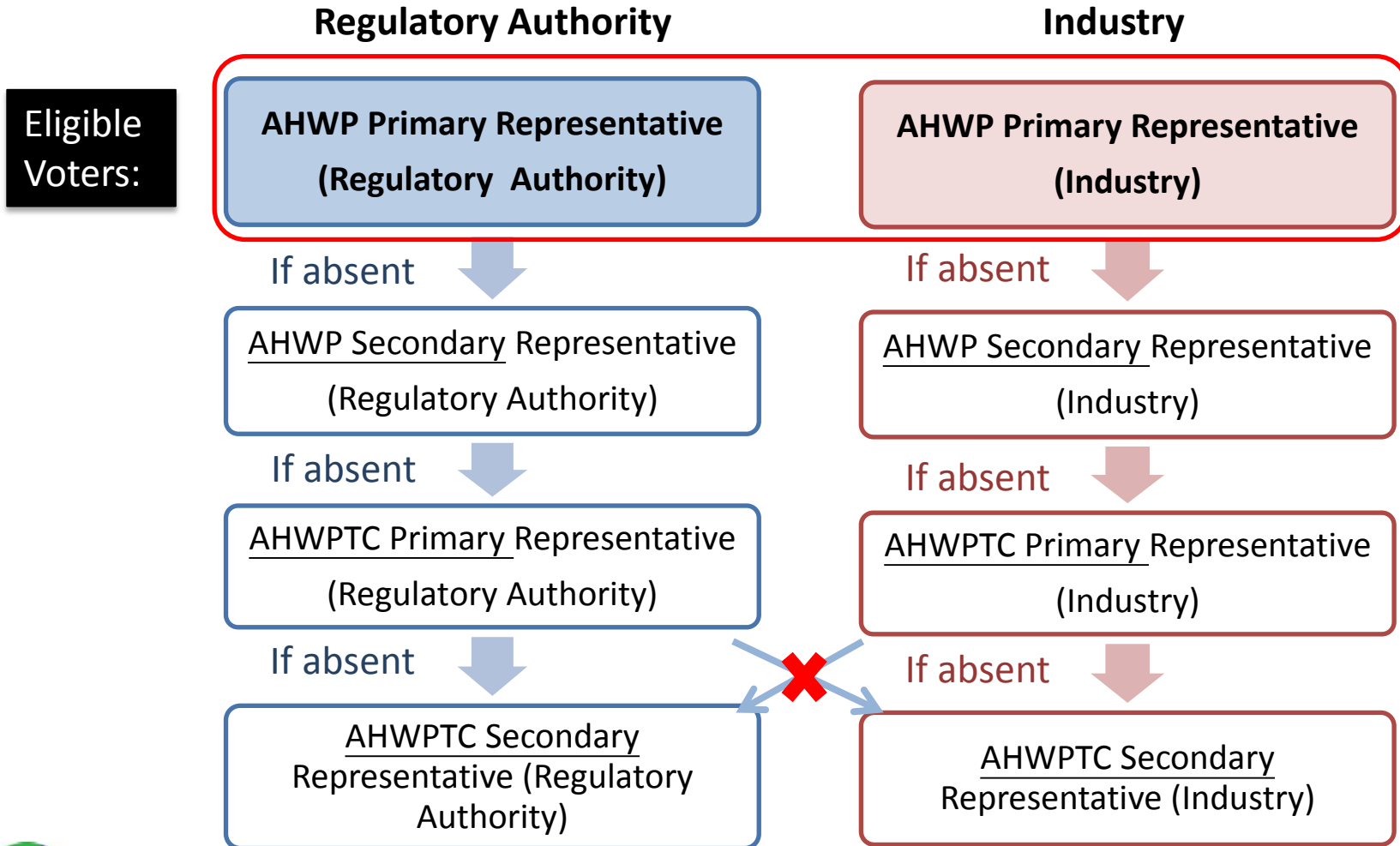
1.3 Leadership

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

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.

Voting Procedures

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 A is designed for the election of AHWP Vice-chair (Regulatory Authority)

AHWP Asian Harmonization Working Party
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Official Website: www.ahwp.info

Voting Slip A
- AHWP Vice-chair (Regulatory Authority)

Application of this Voting Slip
This Voting Slip A is designed for the election of AHWP Vice-chair (Regulatory Authority) at the 19th AHWP Seoul Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website www.ahwp.info for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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.

Nominated Candidates for AHWP Vice-chair (Regulatory Authority)		
Number	1	2
Name	Ms. Pei Weng TU	Mr. Zamane Abd Rahman
Member Economy	Chinese Taipei	Malaysia
Please put a tick (✓) in either one of the box on the right hand side.		

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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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 Vice-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)**

<u>Nominated Candidates for AHWP Vice-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.	1	

Voting Instruction (For Voters)

- **INCORRECT (Void)**

<u>Nominated Candidates for AHWP Vice-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.	X	

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)	2		✓
AHWP Vice-chair (Industry)	1	✓	

AHWP Office Bearers

Nomination Results

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

1	Dr. Hee-Kyo Jeong AHWP Primary Representative (Regulatory Authority)
	Director General
	Medical Device Evaluation Department
	Ministry of Food and Drug Safety (MDFS), Korea
	Republic of Korea



For Endorsement

Y / N ?

AHWP Office Bearers

Nomination Results

- **Post: AHWP Vice-chair (Regulatory Authority)**
- Number of nominees: **2**
- Information of nominees:

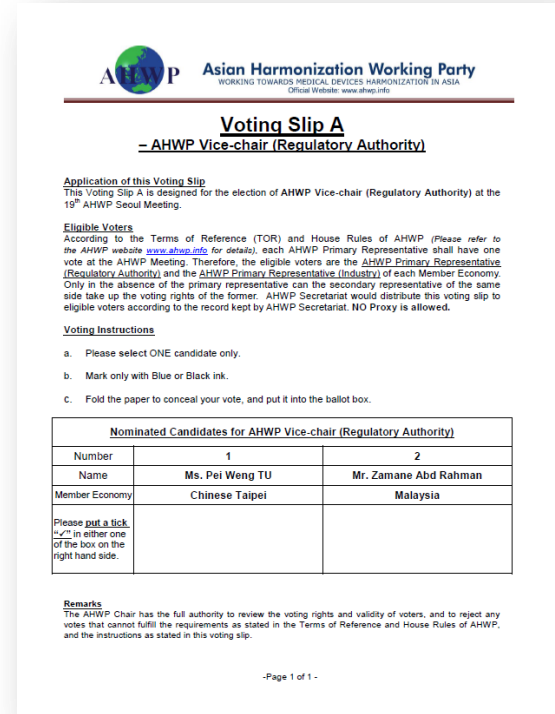
1	Ms. Pei-Weng TU AHWP Primary Representative (Regulatory Authority)	2	Mr. Zamane Abd Rahman AHWP Primary Representative (Regulatory Authority)
	Director		Chief Executive
	Ministry of Health and Welfare		Medical Device Authority
	Food and Drug Administration		Ministry of Health
	Chinese Taipei		Malaysia

 **For Election**

Self-introduction by Candidates

Please Vote

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 A
- AHWP Vice-chair (Regulatory Authority)

Application of this Voting Slip
This Voting Slip A is designed for the election of AHWP Vice-chair (Regulatory Authority) at the 19th AHWP Seoul Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website www.ahwp.info for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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.

Nominated Candidates for AHWP Vice-chair (Regulatory Authority)		
Number	1	2
Name	Ms. Pei Weng TU	Mr. Zamane Abd Rahman
Member Economy	Chinese Taipei	Malaysia
Please put a tick "✓" in either one of the box on the right hand side.		

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 A

Collection of Voting Slips

AHWP Office Bearers

Nomination Results

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

1	Ms. Quan TRAN AHWP Primary Representative (Industry)
	Vice President
	Regulatory Affairs and Quality Assurance, APAC and Greater China
	GE Healthcare Pte Ltd
	Singapore



For Endorsement

Y / N ?

Announcement of New AHWP Chair and Vice-chairs

New AHWP Chair and Vice-chairs

Position	Name	Affiliation	Member Economy
AHWP Chair	Dr. Hee-Kyo Jeong	MFDS Korea	Republic of Korea
AHWP Vice-chair (Regulatory Authority)	Mr. Zamane Abd Rahman	Medical Device Authority, MOH	Malaysia
AHWP Vice-chair (Industry)	Ms. Quan TRAN	GE Healthcare Pte Ltd	Singapore

Election of AHWP TC Office Bearers

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)	1	✓	
AHWPTC Co-chair (Industry)	1	✓	

Requirements in AHWP 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**.

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)	1	✓	
AHWP TC Co-chair (Industry)	1	✓	

AHWPTC Office Bearers

Nomination Results

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

1	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 nominee: 1
- Information of nominee:

1	Dr. Jeong-Rim Lee AHWPTC Primary Representative (Regulatory Authority)
	Director
	Cardiovascular Devices Division
	Ministry of Food and Drug Safety (MFDS), Korea
	Republic of Korea



For Endorsement **Y / N ?**

AHWPTC Office Bearers Nomination Results

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

1	Mr. Alfred Kwek
	AHWPTC Secondary Representatives (Industry)
	Regional Director
	Government Affairs/HME
	Samsung Electronics
	Singapore



For Endorsement Y / N ?

Announcement of New AHWP TC Chairs and TC Co-chairs

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 Korea	Republic of Korea
AHWPTC Co-chair (Industry)	Mr. Alfred Kwek	Samsung Electronics	Singapore

Election of AHWPTC
Working Groups/Special Task Groups
Office Bearers

Agenda

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

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	1		✓

Post		Number of Nominees	For Election	For Endorsement
WG4 (Post-Market)	Chair	1		✓
	Co-chair	2	✓	
WG5 (Clinical Performance)	Chair	1		✓
	Co-chair	1		✓
WG6 (QMS-Audit)	Chair	1		✓
	Co-chair	1		✓
WG7 (QMS-Implementation)	Chair	1		✓
	Co-chair	1		✓
WG8 (Standards)	Chair	1		✓
	Co-chair	1		✓
WG9 (Training)	Chair	0	-	-
	Co-chair	0	-	-
STG (U&N)	Chair	1		✓
	Co-chair	1		✓

Requirements in AHWP 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.

Voting Procedures

Voting Procedures (for voters)

- The Voting Slip C is designed for the election for the election of **AHWPTC WG4 Co-chair (Industry)**

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Voting Slip C
- AHWPTC Work Group 4 Co-chair

Application of this Voting Slip
This Voting Slip C is designed for the election of AHWP Technical Committee (TC) Work Group (WG) 4 - Post-market Co-chair at the 19th AHWP Seoul Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website www.ahwp.info for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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.

Nominated Candidates for AHWPTC WG4 Co-chair		
Number	1	2
Name	Ms. Kitty MAO	Ms. Christine LIM
Member Economy	Singapore	Malaysia
Please put a tick "x" in either one of the box on the right hand side.		

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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Eligible Voters:

AHWP Primary Representatives



(if absent):

AHWP Secondary Representatives



(If absent):

AHWPTC Primary Representatives





(If absent):

AHWPTC Secondary Representatives

Voting Instructions (For Voters)

- **Correct**

<u>Nominated Candidates for AHWPTC WG4 CO-chair (Industry)</u>		
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.		

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	1		✓
WG4 (Post-market)	Chair	1		✓
	Co-chair	2	✓	

Post		Number of Nominees	For Election	For Endorsement
WG5 (Clinical Performance & Safety)	Chair	1		✓
	Co-chair	1		✓
WG6 (Quality Management System : Audit & Assessment)	Chair	1		✓
	Co-chair	1		✓
WG7 (Quality Management System: Operation & Implementation)	Chair	1		✓
	Co-chair	1		✓
WG8 (Standards)	Chair	1		✓
	Co-chair	1		✓
WG9 (Training)	Chair	0	-	-
	Co-chair	0	-	-
STG (U&N) (UDI & Nomenclature)	Chair	1		✓
	Co-chair	1		✓

AHWPTC WG/STG Office Bearers Nomination Results

WG1 – Pre-market: General MD

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

1	Essam Mohammed Al Mohandis
	Executive Director
	Surveillance and Biometrics
	Saudi Food & Drug Authority
	Kingdom of Saudi Arabia

 For endorsement **Y / N**

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

1	Tan Minghao
	Manager
	Regulatory Associates LLP
	Singapore

 For endorsement **Y / N**

AHWPTC WG/STG Office Bearers

Nomination Results

WG2 – Pre-market: IVDD

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

1	Mr. Wen-Wei TSAI
	Technical Specialist
	Food and Drug Administration
	Ministry of Health and Welfare
	Chinese Taipei

 For endorsement **Y/N**

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

1	Mr. Albert POON
	Medical Device Consultant
	Freelance Hospital and Medical Device Consultancy
	Hong Kong

 For endorsement **Y/N**

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:

1	Dr. Rama SETHURAMAN
	Deputy Director
	Health Sciences Authority
	Singapore

 For endorsement **Y / N**

- **Post: WG3 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

1	Mr. Tony YIP
	Manager
	Quality Assurance/regulatory Affairs, Far East Region
	Elekta Limited
	Hong Kong SAR

 For endorsement **Y / N**

AHWPTC WG/STG Office Bearers Nomination Results

WG4 – Post-market

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

1	Ms. Jennifer MAK
	Senior Electronics Engineer
	Medical Device Control Office
	Department of Health
	Hong Kong SAR

- **Post: WG4 Co-chair (Industry)**
- Number of nominee: 2

1	Dr. Christine LIM
2	Ms. Kitty MAO

- Information of nominees will be shown in the **NEXT page**



For endorsement **Y / N**



For **Election**

AHWPTC WG/STG Office Bearers Nomination Results

WG4 – Post-market (Cont.)

- **Post: WG4 Co-chair (Industry)**
- Number of Nominees: **2**
- Information of nominees:

1	Ms. Kitty MAO
	RA Manger – ASEAN & APAC RA Operation
	GE Healthcare
	Singapore

2	Dr. Christine LIM
	Regional Senior safety Officer, Asia Pacific
	Johnsons & Johnsons
	Malaysia




For Election

Self-introduction by Candidates

Please Vote

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
– AHWPTC Work Group 4 Co-chair

Application of this Voting Slip
This Voting Slip C is designed for the election of AHWP Technical Committee (TC) Work Group (WG) 4 - Post-market Co-chair at the 19th AHWP Seoul Meeting.

Eligible Voters
According to the Terms of Reference (TOR) and House Rules of AHWP (Please refer to the AHWP website www.ahwp.info for details), each AHWP Primary Representative shall have one vote at the AHWP Meeting. Therefore, the eligible voters are the AHWP Primary Representative (Regulatory Authority) 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

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

Nominated Candidates for AHWPTC WG4 Co-chair		
Number	1	2
Name	Ms. Kitty MAO	Ms. Christine LIM
Member Economy	Singapore	Malaysia

Please put a tick "✓" in either one of the box on the right hand side.

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 C

Collection of Voting Slips

AHWPTC WG/STG Office Bearers

Nomination Results

WG5 – Clinical Performance & Safety

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

1	Ms. Yuwadee PATANAWONG
	Senior Expert in Medical Device Safety & Acting Director of Medical Device Control
	Medical Devices Control Division
	Food and Drug Administration
	Thailand

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

1	Ms. Sumati RANDEO
	Director Global Strategy Regulatory Affairs & Advocacy
	Abbott Quality and Regulatory
	Abbott Laboratories
	India

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:

1	Mr. Abdullah Al Rasheed
	Compliance and Enforcement Executive Director
	Saudi Food and Drug Authority
	Kingdom of Saudi Arabia

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

1	Ms. Shirley Sum
	Senior Director
	Johnsons and Johnsons Regulatory Compliance (Asia Pacific)
	Johnsons & Johnsons
	Singapore

 For endorsement **Y / N**

 For endorsement **Y / N**

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:

1	Mr. Aidahwaty M.Olaybal
	Principal Assistant Director
	Medical Device Authority
	Ministry of Health
	Malaysia

➔ For endorsement **Y / N**

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

1	Mr. Ee Bin LIEW
	Owner and Consultant
	Access-2-Healthcare
	Singapore

➔ For endorsement **Y / N**

AHWPTC WG/STG Office Bearers Nomination Results

WG8 – Standards

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

1	Ms. Maria Cecilia MATIENZO
	Division chief
	Medical Non-Radiation Device Regulation Division
	Bureau of Health Devices & Technology
	Philippines

➔ For endorsement **Y/N**

- **Post: WG8 Co-chair (Industry)**
- Number of nominee: 1
- Information of nominee:

1	Mr. Tony LOW
	Manager
	BS-P Medical South East Asia
	TUV Rheinland
	Malaysia

➔ For endorsement **Y/N**

AHWPTC WG/STG Office Bearers Nomination Results

WG9 – Training

- **Post:** WG9 Chair (Regulatory Authority)
- Number of nominee: 0

To be filled.

Acting by AHWPTC Chair
until this position being
filled up

- **Post:** WG9 Co-chair (Industry)
- Number of nominee: 0

To be filled.

Acting by AHWPTC Chair
until this position being
filled up

AHWPTC WG/STG Office Bearers

Nomination Results

STG (U&N): Special Task Group on UDI & Nomenclature

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

1	Mr. Lianchun YANG
	Division Director
	Medical Device Registration Department, Registration Division II
	China Food & Drug Administration
	China

➔ For endorsement **Y / N**

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

1	Ms. Carol YAN
	Vice President
	Regulatory Affairs
	Johnsons & Johnsons Medical
	China

➔ For endorsement **Y / N**

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

New WG/STG Chairs and Co-chairs

Position		Name	Affiliation	Economy
WG1 (Pre-market : General MD)	Chair	Mr. Essam Mohammed Al Mohandis	Saudi-FDA	Kingdom of Saudi Arabia
	Co-chair	Ms. Tan Minghao	Regulatory Associates LLP	Singapore
WG2 (Pre-market: IVDD)	Chair	Mr. Wen-Wei TSAI	TFDA	Chinese Taipei
	Co-chair	Mr. Albert POON	Freelance Hospital and Medical Device Consultancy	Hong Kong SAR
WG3 (Pre-market: Software as a Medical Device)	Chair	Dr. Rama SETHURAMAN	Health Sciences Authority	Singapore
	Co-chair	Mr. Tony Yip	Elekta Limited	Hong Kong SAR
WG4 (Post-market)	Chair	Ms. Jennifer MAK	MDCO, Department of Health	Hong Kong SAR
	Co-chair	Ms. Kitty MAO	GE Healthcare	Singapore

New WG/STG Chairs and Co-chairs

Position		Name	Affiliation	Economy
WG5 (Clinical Performance & Safety)	Chair	Ms. Yuwadee PATANAWONG	Thai-FDA	Thailand
	Co-chair	Ms. Sumati RANDEO	Abbott Laboratories	India
WG6 (Quality Management System : Audit & Assessment)	Chair	Mr. Abdullah Al Rasheed	Saudi-FDA	Kingdom of Saudi Arabia
	Co-chair	Ms. Shirley Sum	Johnsons & Johnsons	Singapore
WG7 (Quality Management System: Operation & Implementation)	Chair	Mr. Aidahwaty M.Olaybal	Medical Device Authority, MOH	Malaysia
	Co-chair	Mr. Ee Bin LIEW	Access-2-Healthcare	Singapore
WG8 (Standards)	Chair	Ms. Maria Cecilia MATIENZO	Bureau of Health Devices & Technology	Philippines
	Co-chair	Mr. Tony LOW	TUV Rheinland	Malaysia
WG9 (Training)	Chair	- (ag by TC Chair)	-	-
	Co-chair	-	-	-
STG (U&N) (UDI & Nomenclature)	Chair	Mr. YANG Lianchun	China-FDA	China
	Co-chair	Ms. Carol YAN	Johnsons & Johnsons Medical	China

Thank You