Level of Documentation in Enhanced (QbD) Regulatory Submissions

- **Risk Management Methodologies**
- **Design of Experiments**
- **Manufacturing Process Description**

User-friendly ICH Web page?

Pharmaceutical Development Q8

- Q8(R2) Pharmaceutical Development
- Q8/Q9/Q10 Q&As R4 Q8/Q9/Q10 ~~Questions & Answers~~ — **Implementation**

Quality Risk Management Q9

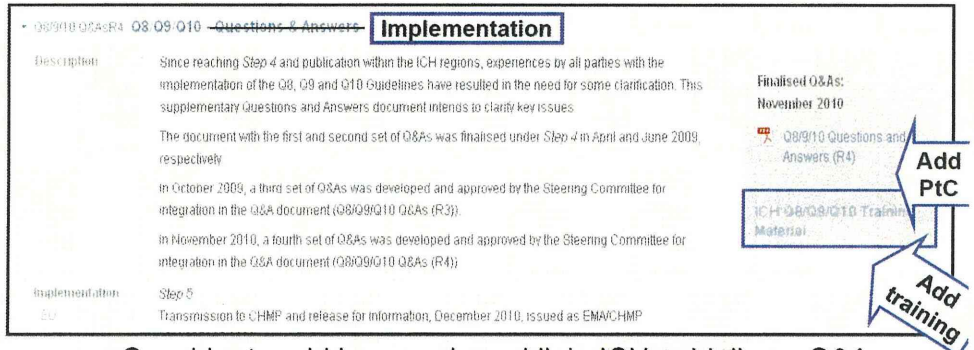
- Q9 Quality Risk Management
- Q8/Q9/Q10 Q&As R4 Q8/Q9/Q10 ~~Questions & Answers~~ — **Implementation**

Pharmaceutical Quality System Q10

- Q10 Pharmaceutical Quality System
- Q8/Q9/Q10 Q&As R4 Q8/Q9/Q10 ~~Questions & Answers~~ — **Implementation**

User-friendly ICH Web page?

- **Optimize ICH web page**



- Consider to add key words and link: ICH guidelines, Q&A, 'Points to Consider', training workshop (incl. key messages)

Steps forward / Work plan

- **Perform enhanced training workshop**
  - HC collaboration: Ottawa, Sept 26/27 2011
  - GCG collaboration: Seoul, Oct 04/05 2011
- **Prepare for Seville**
  - Telecons to work on the 3 PtC documents
  - Complete activities till end 2011

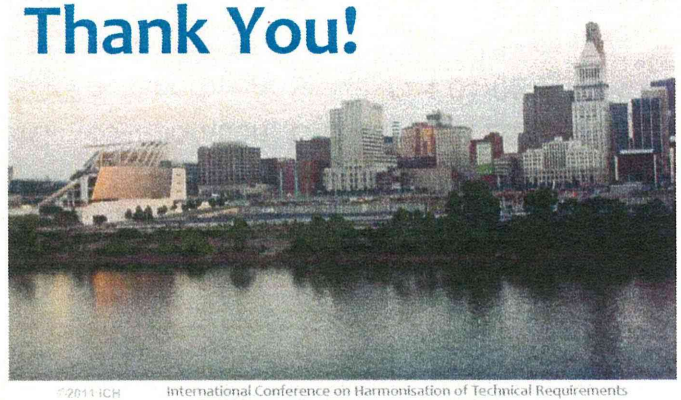
SC endorsement

Steps forward / Work plan

- **'Points to Consider' document to be endorsed**
  - Criticality of Quality Attributes and Process Parameters
  - Control Strategy
  - Level of Documentation in enhanced (QbD) Regulatory Submissions
- **'Points to Consider' document to be developed**
  - Process validation/process verification
  - Role of modeling in QbD
  - Design space
- **Q-IWG to meet in Seville**

ICH harmonisation for better health

Thank You!



Verification and Validation of Work Process (procedure/model): A note from YHiyama
November 9, 2011

1. Definitions

Validation: Performance confirmation/qualification which covers the entire scope of work process.
This can be achieved by accumulating results of Verification or by collecting performance confirmation of elements of work process.
Validation usually expects stability of work process.

Verification: Performance confirmation/qualification which covers a limited scope of work process (e.g. single run of work process).
This is possible only if/when direct and timely evaluation method of work process is available. Verification does not necessarily expect stability of work process.

2. Cases/Examples

Work processes where verification is practically impossible due to lack of evaluation method:
Analytical methods, Sterile manufacturing process

Work process where verification is possible:
Cleaning procedure, Design Space, Most of models

Work process where verification is becoming possible:
Manufacturing process

3. Operation aspects

There is general agreement that work process where verification is possible is allowed to use before validation is completed. (Cleaning verification, Design Space verification and Process Validation with CPV)

ICH Q-IWG
Quality Implementation Working Group

Jean-Louis Robert
ICH-SC report Seville November 2011

 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

Content

- Q-IWG scope
- Decisions in Cincinnati
- Achievements up to Seville
- ICH SC Endorsement
- Topics to be further addressed

Tasks of the Implementation Working Group on Q8, Q9, Q10

- ***"....due primarily to departure from the traditional approaches to quality guidance, proper implementation of these concepts is provided by bringing clarity, further explanation and removing ambiguities and uncertainties"*** (ICH Q-IWG Concept paper Nov 01. 2007)
- **Ensuring harmonised implementation**
- **Technical issues & related documentation:**
  - Communication – addressed June 2010
  - Need for training – addressed June 2011
  - Additional implementation issues: influence on existing ICH guidelines – addressed Nov 2011

Q-IWG: Implementation of Q8, Q9 and Q10

- **Identified areas needing further clarification:**
  - Design Space, Real Time Release Testing, Control Strategy
  - Pharmaceutical Quality System
  - Knowledge Management
- **Collaboration with external parties** – addrssed, June 2010
- **Publication of Q&As** – 46 Q&As(R4) addressed till Nov 2010
- **Comments and questions access from ICH website** – 2011
  www.ich.org, Quality-Guidelines-menu, under Q8, Q9 and Q10

Endorsement at Fukuoka Nov. 2010

- **Implementation documents ('Points to Consider') to address 6 remaining technical and regulatory gaps**
  - Completed by end of Q2 2011
    - Level of documentation in submission
    - Criticality
    - Control Strategy
  - Completed by end of 2011
    - Process validation
    - Design Space
    - Role of Modelling in QbD
  - Clearance procedure for the 'Points to consider' same as Q&A
- **Q-IWG to complete activities by End of 2011**

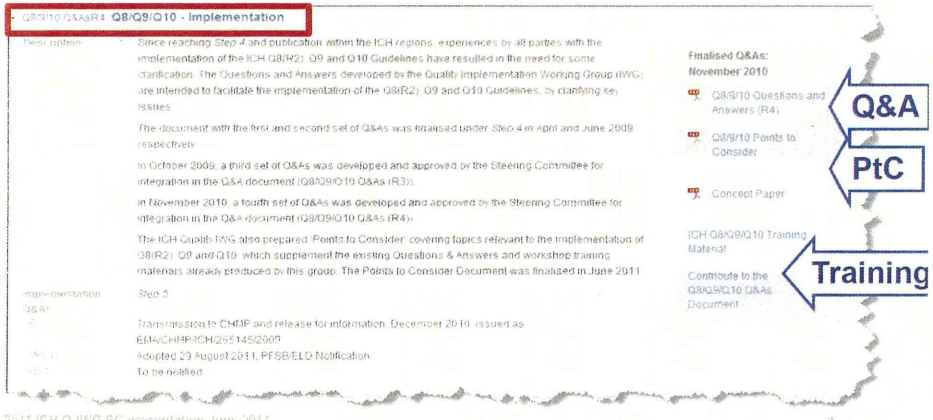
November 11, 2010 ICH Q-IWG, Fukuoka 23

Endorsement at Cincinnati June 2011

- **Points to Consider' documents**
  - Criticality of Quality Attributes and Process Parameters
  - Control Strategy
  - Level of Documentation in enhanced (QbD) Regulatory Submissions

Endorsement at Cincinnati June 2011

- **Update ICH homepage**



Q-IWG: Implementation of Q8, Q9 and Q10

- **Training has been a major achievement of Q-IWG**
  - ICH regions:
    - EU: Tallinn — June 2-4, 2010
    - US: Washington — October 6-8, 2010
    - Japan: Tokyo — October 25-27, 2010
  - ASEAN, Kuala Lumpur: July 2010
  - HC, Ottawa: September 2011
  - APEC/AHC, Seoul: October 2011
- **Material available**

http ://www.ich.org/products/guidelines/quality/training-programme-for-q8q9q10.html

Q-IWG Progress made since Cincinnati

- **2 Q-IWG teleconferences**
  - Several sub-teams telecons
- **Trainings performed**
  - HC, Ottawa: September 2011
  - APEC/AHC, Seoul: October 2011
- **'Points to Consider' document part II completed**
  - Process validation / continuous process verification
  - Role of models in QbD
  - Design space

PtC: Role of models in QbD

- **Categorisation of Models**
- **Developing and Implementing Models**
- **Model Validation and Model Verification**
- **Documentation of Model related Information**

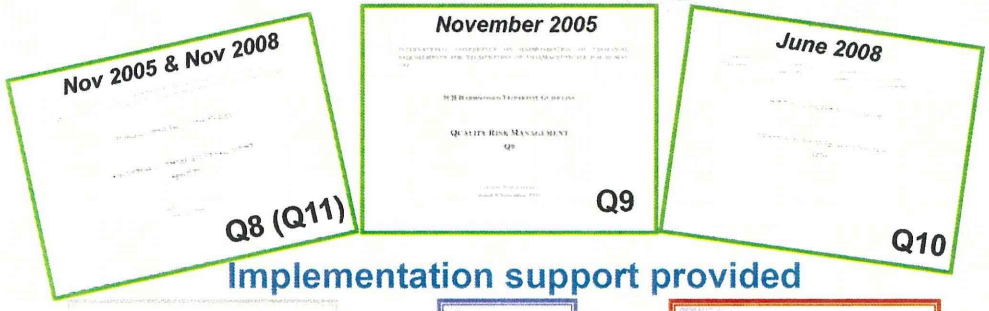
PtC: Design space

- **Development of Design Space**
- **Verification and Scale-up of Design Space**
- **Documentation of Design Space**
- **Life-cycle management of a Design Space**

PtC: Process validation / Continuous process verification

- **General considerations**
- **Continuous Process Verification (CPV)**
- **Pharmaceutical Quality System**

The 'New Quality Paradigm'



Implementation support provided

'Questions and Answers'

'Points to consider'

'Training & Workshop'

Acknowledgement

This presentation has been developed by members of the ICH Quality Implementation Working Group (Q-IWG)

- Jean-Louis Robert (rapporteur)
- Diana Amador-Toro
- Robert G. Baum
- Nicholas Cappuccino
- David Cockburn
- Georges France
- Richard L. Friedman
- Nigel Hamilton
- Hirotada Nagai
- Yukio Hiyama
- Fusashi Ishikawa
- Takao Kiyohara
- Urs Kopp
- Akira Kusai
- Yoshihiro Matsuda
- Motoaki Mitsuki
- Elaine Morefield
- Jacques Morénas
- Masatoshi Morisue
- Markus-Peter Müller
- Tamiji Nakanishi
- Moheb Nasr
- Kazuhiro Okochi
- Anthony Ridgway
- Rachael Roehrig
- Stephan Rönninger
- Swroop Sahota
- Hideki Sasaki
- Tetsuhito Takarada
- Shigeki Tamura
- Krishnan Tirunellai
- Mats Welin
- Jean M. Wyvratt
- Sabine Kopp

SC endorsement

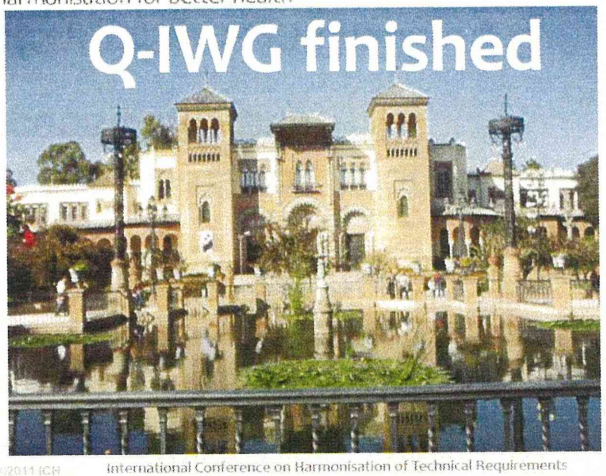
Points to Consider

- **Update the existing version to add**
  - Process validation / continuous process verification
  - Role of models in QbD
  - Design space

Topics to be further addressed

- Guidelines on specifications (Q6A / Q6B)
- Analytical method validation (Q2)
- Q-CTD (M4)
- GMP for APIs (ICH Q7)
- Training (GCG)
- Future challenges - pharmaceutical quality
- …

ICH
harmonisation for better health



International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

WORKSHOP AGENDA

APRIL 26-28, 2011
GRAND HILTON HOTEL, SEOUL, REPUBLIC OF KOREA

Day 1

APRIL 26, 2011 (TUESDAY)	
07:30 – 08:30	**CONFERENCE REGISTRATION**
09:00 – 09:40	*Opening Ceremony* *Chair* Dr. Sun Hee Lee (Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH Global Cooperation Group (GCG) Member)) *Chair* Dr. André W. Broekmans (Vice President, Most of World Regulatory Policy & Regulatory Affairs, MSD, The Netherlands (Program Committee Chair, ICH Steering Committee (SC) Member) **Opening Remarks** by *Dr. Seung Hee Kim* **Congratulatory Remarks** by *Dr. Yun Hong Noh* **Congratulatory Remarks** by *Dr. Bup Wan Kim* **Welcome from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)** by *Dr.Odette Morin* **Welcome from the Drug Information Association(DIA)** by *Dr. Yves Juillet*
09:40 – 10:00	**REFRESHMENT BREAK**
10:00 – 12:00	**Plenary Session :** Update on ICH Activities, Focus on New Activities *Chair* Dr. Sun Hee Lee (Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH GCG Member)) *Chair* Dr. André W. Broekmans (Vice President, Most of World Regulatory Policy & Regulatory Affairs, MSD, The Netherlands (Program Committee Chair, ICH Steering Committee (SC) and GCG Member)) **20 Years of ICH: Learning and Accomplishments** *Speaker* Dr. Justina A. Molzon (Associate Director, International Programs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH SC and GCG Member, Chair of the APEC RHSC Subcommittee on Training) **Japan's Experience with ICH and the Implementation of Guidelines** *Speaker* Mr. Shinobu Uzu (Director, International Planning, Ministry of Health, Labor and Welfare (MHLW), Japan (ICH SC Member and GCG Co-Chair) **Expanding Participation in ICH Technical Working Groups to Regional Harmonization Initiatives (RHIs) and Drug Regulatory Agencies (DRAs)** *Speaker* Mr. Mike Ward (Manager, International Program Division, Health Products and Food Branch, Health Canada, Canada, (ICH SC and GCG Member, Chair of the APEC RHSC) **KFDA's Perspectives on the Implementation of ICH Guidelines** *Speaker* Dr. Sun Hee Lee (Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH GCG Member))

12:00 – 01:00	**LUNCH BREAK (only provided for foreigners)**
01:00 – 03:30	**Plenary Session** : Regional Harmonization Initiatives *Chair* Dr. Justina A. Molzon (Associate Director, International Programs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH SC and GCG Member, Chair of the APEC RHSC Subcommittee on Training) *Chair* Ms. Weon Do (Head of Regulatory Affairs and Market Access. Sanofi-Aventis, Republic of Korea) **The Role of APEC in Advancing Harmonization Efforts in a More Strategic, Effective and Sustainable Fashion** *Speaker* Mr. Mike Ward (Manager, International Program Division, Health Products and Food Branch, Health Canada, Canada, (ICH SC and GCG Member, Chair of the APEC RHSC) **AHC Activities: Current Status and Future Prospects** *Speaker* Dr. Kui Lea Park (Director, Center for Drug Development Assistance, Korea Food & Drug Administration (KFDA), Republic of Korea) **ASEAN Regulatory Harmonization Activities and Future Perspectives** *Speaker* Dr. Yuppadee Javroongrit (Assistant Director & Head of International Affairs & IND Section Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ASEAN ICH GCG Observer, Co-Chair of ASEAN ACCSQ PPWG) **Triparitite Symposium on Rationalization of Clinical Trial Requirements** *Speakers* Ms. Hee Young Park (Korea Food & Drug Administration (KFDA), Republic of Korea) Mr. Shinobu Uzu (Director, International Planning, Ministry of Health, Labour and Welfare (MHLW), Japan (ICH SC Member and GCG Co-Chair) Dr. Li Jinju (Division Director, Division of Drug Research Supervision Department of Drug Registration, State Food and Drug Administration (SFDA), P.R. China)
03:30 – 04:00	**REFRESHMENT BREAK**

04:00 – 05:30	**PARALLEL TRACKS** **TRACK 1: Fighting Counterfeit Medicines in Emerging Countries: Addressing Infrastructure And Capacity Gaps** *Chair* Dato' Eishah A. Rahman (Senior Director, Pharmaceutical Services Division, Ministry of Health, Malaysia) *Chair* Mr. Arun Mishra (Director, Global Regulatory Affairs, GlaxoSmithKline, UK) **Counterfeit Medicines in Asia Today** *Speaker* Mr. Thomas Kubic (President and CEO of the Pharmaceutical Security Institute, USA) **The Malaysian Experience with Meditag** *Speaker* Dato' Eishah A. Rahman (Senior Director, Pharmaceutical Services Division, Ministry of Health, Malaysia) **Singapore's Experience in the Fight Against Counterfeits** *Speaker* Ms. Ruth Lee Choo Ai (Acting Director, Enforcement Branch, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore) **TRACK 2: Ensuring Quality - Enhance the Approach of Quality Driven by ICH Q8, Q9, Q10, and Q11: What about Practical Implementation?** *Chair* Dra. Kustantinah (Head, National Agency of Drug and Food Control (NA-DFC/BPOM), Indonesia) *Chair* Dr. Geroges France (Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer, UK (ICH Quality Implementation Working Group (ICH Q-IWG) Member) **ICH Q-IWG Updates and Challenges** *Speaker* Dr. Geroges France (Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer, UK (ICH Quality Implementation Working Group (ICH Q-IWG) Member) *Speaker* Dr. Jean-Louis Robert (Head of Division, National Health Laboratory, Department of Quality Control of Medicine, Luxembourg (Rapporteur of ICH Q-IWG) **CMC Requirements to Support New Technology in Development and Analytical Methods (e.g. NIR, UPLC)** *Speaker* Dr. Moheb Nasr (Director, Office of New Drug Quality, Center for Drug Evaluation and Research (CDER), Food and Drug Administration(FDA), USA (ICH Q-IWG Member) **Validation and Continuous Verification: Regulatory Challenges** *Speaker* Dr. Yukio Hiyama (Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Q-IWG Member) **TRACK 3: Practical Uses of Common Technical Documents (CTDs) in Asia** *Chair* Dr. Lembit Rägo (Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer) *Chair* Mr. Kum Cheun Wong (Director, Global Regulatory Policy & Intelligence, Asia Pacific, Johnson & Johnson, Singapore)

	Experience and Value of CTD *Speaker* Ms. Jalene Poh (Regulatory Consultant, Pharmaceuticals & Biologics Branch, Pre-Marketing Division, Health Products Regulatory Group, Health Sciences Authority (HSA), Singapore) **Practical Use of ICH CTD in Facilitating Approval of Prequalification of Pharmaceutical Products and the Benefits to the WHO Program** *Speaker* Dr. Lembit Rägo (Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer) **Practical Use and Value of CTD in Clinical Trials and New Drug Application (NDA), and Challenges Faced in the Asia Region** Speaker to be confirmed
05:30 – 07:00	**WELCOME RECEPTION — EMERALD HALL & FOYER** (***SEE APPENDIX***) **(Foreigners Only)**

Day 2

APRIL 27, 2011 (WEDNESDAY)	
08:30 – 10:00	**Plenary Session :** Early Clinical Development in Asia *Chair* Professor I. J. Jang (Seoul National University, Republic of Korea) Chair to be confirmed **Current Status of Early Clinical Development in Asia and Plan for the Future: Industry Perspective** *Speaker* Dr. Ken Kobayashi (Head of Clinical Science Oncology, Johnson & Johnson, Japan) **Regulatory Experience in Early Clinical Trial Approval** Speaker to be confirmed **How Asian Clinical Sites are Working for Early Clinical Trials** *Speaker* Professor I.J. Jang (Seoul National University, Republic of Korea)
10:00 – 10:30	**REFRESHMENT BREAK**
10:30 – 12:30	**Plenary Session :** Late Clinical Development in Asia *Chair* Dr. Herng-Der Chern (Distinguished Researcher, Center for Drug Evaluation (CDE), Chinese Taipei) *Chair* Mr. Adrian Waterson (Asia Regulatory Director, AstraZeneca, UK) **Simultaneous Multi-regional Clinical Trials** *Speaker* Dr. Moira Daniels (Vice President, Regulatory Affairs, AstraZeneca, UK) **Acceptance of Clinical Data – The Challenge of Generalizability** *Speaker* Dr. Yuki Ando (Principal Reviewer of Biostatistics, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA), Japan) **Towards Simultaneous Regulatory Approval** *Speaker* Dr. Herng-Der Chern (Distinguished Researcher, Center for Drug Evaluation (CDE), Chinese Taipei)
12:30 – 01:30	**LUNCH BREAK (only provided for foreigners)**
01:30 – 03:30	**PARALLEL TRACKS** **TRACK 1: Establishing the Asia Pacific Region as an Important Partner in Global Pediatric Development** *Chair* Dr. Min Soo Park (Director, Clinical Trials Center, Chair, Department of Clinical Pharmacology, Yonsei University, Republic of Korea) *Chair* Mrs. Angelika Joos (Head, Regulatory Policy, EU & Most of World, MSD (Europe), Belgium) **Participation in Asia in Global Pediatric Programs, Including Cultural Barriers to Conduct Pediatric Clinical Trials** *Speaker* Dr. Hidefumi Nakamura (Director, Division of Clinical Research, National Center For Child Health and Development, Japan) **How to Extrapolate Clinical Development Results to Asia Children: Usefulness of Bridging the Program with Adults** *Speaker* Dr. An Vermeulen (Head, Modeling & Simulation Department, Johnson & Johnson, Belgium) **FDA's Experience With Global Pediatric Development** *Speaker* Dr. Jean W. Temeck (Lead Medical Officer, Office of Pediatric Therapeutics (OPT), Office of

International and Special Programs (OISP), Office of the Commissioner (OC), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA)

Position of WHO ICDRA on Global Pediatric Development

Speaker Ms. Agnes Chan
(Regulatory Consultant, Pharmaceuticals & Biologics Branch, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore)

TRACK 2: Ensuring Quality: Harmonizing and Optimizing Inspection Approach in the Global Environment

Chair Dr. Yukio Hiyama
(Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Q-IWG Member)

Chair Dr. Georges France
(Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer UK (ICH Q-IWG Member)

Control Strategy and Batch Release: Challenges for a Global and an Harmonized Approach

Speaker Dr. Jacques Morénas
(Assistant Director, Inspectorate and Companies Department, The French Health Products Safety Agency (AFS-SAPS), France (ICH Q-IWG Member, PIC/S)

Quality Risk Management in the WHO Prequalification Process

Speaker Dr. Lembit Rägo
(Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

API: Role of EDQM in Globalization, Input on Inspections and Standards

Speaker Dr. Susanne Keitel
(Director, European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe, France)

Panel Discussion: CMC Harmonization and Regulatory Challenges

Chair Dr. Georges France
(Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer UK (ICH Q-IWG Member)

Panelists Dr. Moheb Nasr
(Director, Office of New Drug Quality, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH Q-IWG Member)

Dr. Yukio Hiyama
(Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labor and Welfare (MHLW), Japan (ICH Q-IWG Member)

Dr. Jacques Morénas
(Assistant Director, Inspectorate and Companies Department, The French Health Products Safety Agency (AFSSAPS), France (ICH Q-IWG Member, PIC/S)

Dr. Lembit Rägo
(Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

Dr. Susanne Keitel
(Director, European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe, France)

Dra. Kustantinah
(Head, National Agency of Drug and Food Control (NA-DFC/BPOM), Indonesia)

	TRACK 3: Ethical Business Practices: Towards Better Marketing Compliance *Chair* Dr. Megan Keaney (Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia) *Chair* Mr. In-Bum Kim (Sr. Director, Korean Research-based Pharmaceutical Industry Association (KRPIA), Republic of Korea) **Latest Developments on Ethical Business Practices (EBP) in Australia** *Speakers* Dr. Megan Keaney (Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia) Ms. Deborah Monk (Director, Innovation and Industry Policy, Medicines Australia, Australia) **Update on New RDPAC Code and Latest Developments in China** *Speaker* Ms. Jennifer Chen (Director, Legal Affairs, R&D-based Pharmaceutical Association Committee (RDPAC), P.R. China) **Code Compliance Governance in Japan** *Speaker* Mr. Yota Kikuchi (Manager, Promotion Code & Public Affairs, Sanofi-Aventis, Japan (Vice Chair of Japan Pharmaceutical Manufacturers Association (JPMA) Promotion Code Working Committee)
03:30 - 04:00	**REFRESHMENT BREAK**
04:00 – 05:30	**Plenary Session :** Similar Biotherapeutic Products (SBPs) in Asia: Opportunities and Challenges in Regulatory Evaluation *Chair* Dr. Sannie Chong Acting Director, Generics and Biosimilars Branch, Health Sciences Authority (HSA), Singapore) *Chair* Dr. Fermin Ruiz de Erenchum (Leader, Special Regulatory Task Force, Hoffmann-La Roche Ltd., Switzerland (Chair of IFPMA Biotherapeutic Group)) **Do We Have a Common Understanding? Definitions of SBPs and Key Principles in Evaluating SBPs** *Speaker* Dr. Peter Richardson (Responsible for Biological Quality of Medicines, Human Medicines Development and Evaluation, European Medicines Agency (EMA), UK) **Evolving Regulatory Landscape for SBPs in Asia** *Speaker* Dr. Fermin Ruiz de Erenchum (Leader, Special Regulatory Task Force, Hoffmann-La Roche Ltd., Switzerland (Chair of IFPMA Biotherapeutic Group) **Chinese Taipei's Perspectives of Regulation of Biosimilar Medicine** *Speaker* Ms. Joyce Wang (Division of Drugs & New Biotechnology Products, Food and Drug Administration, Department of Health, Chinese Taipei)

Day 3

APRIL 28, 2011 (THURSDAY)	
08:30 – 10:00	**Plenary Session :** Electronic Submissions and eCTD as Vehicle to Reconcile Differences in Technical Regulatory Requirements *Chair* Mr. Gary M. Gensinger (Deputy Director, Office of Business Informatics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration) *Chair* Mr. John W. Kiser (Senior Director, Global Pharmaceutical Regulatory Affairs, Submission Operations & Strategic Initiatives, Abbott Laboratories, USA) **The Advantages and Challenges of Electronic Regulatory Submissions in eCTD and Non-eCTD Electronic Submissions (NeeS) Formats – An Industry Perspective** *Speaker* Mr. John W. Kiser (Senior Director, Global Pharmaceutical Regulatory Affairs, Submission Operations & Strategic Initiatives, Abbott Laboratories, USA) **Benefits to Implementing eCTD – A Regulatory Perspective** *Speaker* Mr. Gary M. Gensinger (Deputy Director, Office of Business Informatics, Center For Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA) **Practical Use and Challenges Faced –An Asia Regular Perspective** *Speaker* Ms. Jalene Poh (Regulatory Consultant, Pharmaceuticals & Biologics Branch, Pre-Marketing Division, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore)
10:00 - 10:30	**REFRESHMENT BREAK**
10:30 - 12:30	**Plenary Session :** Pharmacovigilance: How Do Regulatory Agencies and Industry Work Together to Protect Patients? *Chair* Dr. Suzette Henares-Lazo (Acting Director IV, Food and Drug Administration (FDA), Philippines) *Chair* Dr. Paul Eisenberg (Senior Vice President, Global Regulatory Affairs and Safety, Amgen, USA) **Current Status and New Directions for Pharmacovigilance in Korea** *Speaker* Dr. Joungwon Oh (Deputy Director, Pharmaceutical Safety Bureau, Korea Food and Drug Administration (KFDA), Republic of Korea) **Integrating Risk Management into Global Drug Development – Opportunities and Challenges** *Speaker* Dr. Paul Eisenberg (Senior Vice President, Global Regulatory Affairs and Safety, Amgen, USA) **Post-Marketed Surveillance – A Shared Responsibility** *Speaker* Dr. Rebecca Wang (Head of Drug Safety Operation, Regional Center for Asia Pacific, Roche, P.R. China) **The Role of MedDRA in Pharmacovigilance Activities** *Speaker* Dr. Patricia Mozzicato (Chief Medical Officer, MedDRA Maintenance & Support Services Organization (MSSO), USA)
12:30 - 01:30	**LUNCH BREAK (only provided for foreigners)**

01:30 - 03:00	**Plenary Session :** Good Regulatory Practices, Including Assessment Report, Efficient Use of Certificate of Pharmaceutical Product (CPPs) and Transparency *Chair* Dr. Megan Keaney (Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia) *Chair* Dr. Yuppadee Javroongrit (Assistant Director & Head of International Affairs & IND Section Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ASEAN ICH GCG Observer, Co-Chair of ASEAN ACCSQ PPWG) **Good Regulatory Practices: Do We Have a Common Understanding?** *Speakers* Dr. Yoshiaki Uyama (Director, Division of Regulatory Research, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA),Japan) **Opportunities for Industry to Partner with Drug Regulatory Authorities (DRAs) to Further Good Regulatory Practices** Dr. Romi Singh (Executive Director, Global Regulatory Affairs & Safety, Amgen, USA) **Efficient Use of CPPs** Dr. Lembit Rägo (Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)
03:00 - 03:10	**CLOSING REMARKS BY PROGRAM COMMITTEE CHAIRS**
03:30 - 05:30	**GCP SITE TOUR** (OPTIONAL) **Korea National Enterprise for Clinical Trials** (Seoul National University Hospital) **For International Participants Only** ***See appendix for details.***

APPENDIX

Welcome Reception ** International Participants Only*	**TUESDAY, APRIL 26, 2011, 5:30 AM-7:00 PM** Emerald Hall & Foyer The Welcome Reception is an excellent opportunity to renew your existing contacts and to make new ones.
Network on the Exhibition Floor : **Emerald Hall & Foyer**	Meet with a wide range of companies to learn about new offerings and technologies—all at one event. Virtually every facet of the biopharmaceutical industry and related fields is represented by an exhibitor offering services or products in this extraordinary exhibit hall marketplace.
Exhibition Hours	April 26 9:00 AM-7:00 PM April 27 8:30 AM-5:30 PM April 28 8:30 AM-1:30 PM
PLEASE NOTE: *All refreshment breaks, lunches, and reception will be held in the Emerald Hall and Foyer.*	
GCP Site Tour ** International Participants Only*	**Korea National Enterprise for Clinical Trials** **Seoul National University Hospital** ***For International Participants Only*** The Korean government has been running a clinical trial research project called KONECT which stands for Korean National Enterprise for Clinical Trials over the last couple of years. Currently, the project is carried out by the Seoul National University Hospital. The Korea Food and Drug Administration (KFDA) would like to offer international attendees an opportunity to visit the GCP facilities at the University to better understand the current status of clinical trial research in Korea. If you are interested in participating, please indicate your interest on the online registration website.

Validation and Continuous Verification: Regulatory Challenges Ensuring Quality- Enhance the Approach of Quality Driven by ICH Q8, Q9, Q10, and Q11

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* This presentation reflects the author's personal view based on the ICH and other discussion and does NOT represent MHLW's view.

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Outline of Presentation

- Background
- Process Validation- what is it?
- Product Life Cycle Process Validation
- Basis for Process Validation
- Approach for "Existing Products"
- Q-IWG's plan on PV/CPV

Key Messages

- Process Validation is a Product Life Cycle event
  (relies on Development, Tech Transfer and Continuous Monitor)
- Process Validation Program should be managed under GMP and under PQS
- For innovative Process Validation approaches, technology development and senior management support are required
- Do not forget exiting products
- Further clarification is needed by ICH

Background – GMP requirement

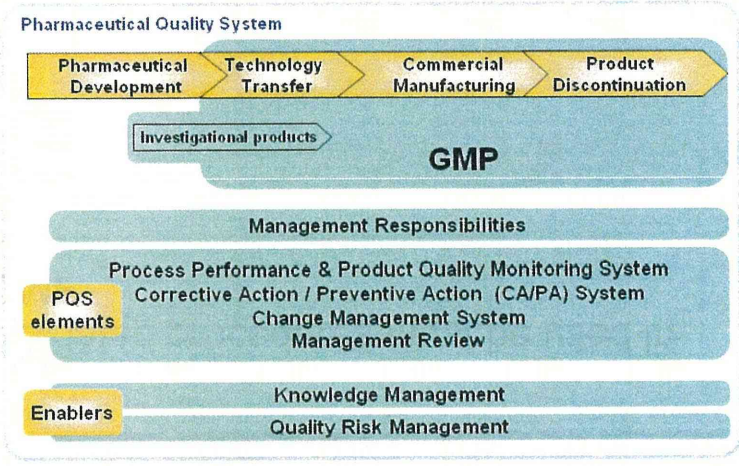
- Validated procedures must be used in GMP

Background – ICH Principle /Vision

- Three elements in total control strategy (from 1.2 ICH Q6A) : Thorough product characterization, Specifications and GMP
- 2003 ICH Quality Vision:

Develop a harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science

Back ground: Product Lifecycle from Pharmaceutical Quality System - Q10



Process Validation- what is it?

- Definition

Process Validation (PV) is the documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce an intermediate or API meeting its predetermined specifications and quality attributes (ICH Q7 12.40)

- What does it mean in practice?

Process Validation Approach in Q7

- Prospective validation, Concurrent validation
- Retrospective validation for well established processes-this may be used where CQA /CPP identified, appropriate in-process acceptance criteria/parameters established, etc