Q Day 1 – September 4 (Wed)

Time		Program	Speaker
09:00 - 09:30	30′	Registration 등록	
Opening 개회식			
09:30 - 09:40	10′	Opening Speech 개회사	**Kyung-Won Seo** (NIFDS)
09:40 - 09:50	10′	Group Photo 사진촬영	
09:50 - 10:10	20′	ICH Guidelines and New Drug Development ICH 가이드라인과 신약개발	**Hoonjoo Kim** (President, DGMIF)
ICH Specifications Guidelines: Q6A/B **신규 원료의약품 및 신규 완제품, 바이오의약품의 시험절차 및 판정기준**			
10:10 - 11:20	70′	Compliance with the specifications for the global expansion of biologic medicines 바이오의약품의 글로벌진출을 위한 규격준수	**Jae-woong Hwang** (Director, Samsung Bioepis)
11:20 - 12:30	70′	Health Canada's experience with the application of ICH Guidelines on Specifications for Biotechnological/Biological Products ICH 시험절차 및 판정기준에 근거한 헬스캐나다의 바이오의약품 허가심사 사례	**Hugo Hamel** (Senior Reviewer, Health Canada)
12:30 - 14:00	90′	Lunch	
ICH Stability Testing Guidelines: Q1A(R2) & Q1D **새로운 원료의약품 및 완제의약품의 안정성 시험과 브래케팅 설계, 매트릭스 설계**			
14:00 - 15:10	70′	Experience in Implementing ICH Stability Guidelines Q1A(R2) and Q1D with Case Studies 사례로 보는 ICH 안정성 가이드라인(Q1A(R2), Q1D) 도입 경험	**Chi-wan Chen** (Executive Director, Pfizer Inc)
ICH Biopharmaceutical Guidelines: Q5A(R1) & Q5B/D **생명공학응용의약품 바이러스 안전성평가와 제조 시 사용되는 세포물질의 유도 및 확인**			
15:10 - 16:20	70′	Health Canada's experience with the application of ICH Guidelines on Viral Clearance for Biotechnological/Biological Products 바이오의약품 개발을 위한 바이러스 안전성 평가 가이드라인의 이해 및 적용사례	**Christopher Storbeck** (Senior Reviewer, Health Canada)
16:20 - 16:40	20′	Coffee Break	
16:40 - 17:50	70′	Quality of Biotechnological Product: Analysis of Expression Construct (Q5B) and Derivation/Characterization of Cell Substrates (Q5D) 생명공학 제품의 품질: 'Expression Construct' 분석 (Q5B) 와 'Cell Substrate'의 출처/특성 확인 (Q5D)	**Myongjin Kim** (Director, Celltrion)
17:50 - 18:00	10′	Closing	

Above programs is subject to change.

☐ Summary & Bio

Title	**ICH Guidelines and New Drug Development**
Speaker	**Hoonjoo Kim** (President, DGMIF)
Bio	Hoonjoo Kim has thirty years of industry experience in developing of new drug and quality control for drug substance and product. He was LG Life Science's team leader of pharmaceutical analysis, developing the analytical method of new drug compounds and biosimiiars. Now he is the president of the Drug Manufacturing Center.
Summary	It should be submitted to its approval with materials fulfilling Safety, Efficacy and Quality to approve a new drug. The ICH has announced guidelines and prepared new guidelines about what new drug developers should do to meet conditions of Safety, Efficacy, and Quality. This lecture will cover that how the ICH guidelines help develop new drugs, how the guidelines came into being, and what kinds of guidelines there are.

Scope	**Q6 A/B**
Title	**Compliance with the specifications for the global expansion of biologic medicines**
Speaker	**Jae-woong Hwang** (Director, Samsung Bioepis)
Bio	After receiving a bachelor's and doctorate degree from the College of Veterinary Medicine at Seoul National University, Hwang has been a postdoctoral research associate at the University of Rochester for four years since 2008. In 2012, he joined Samsung Advanced Institute of Technology in Biotherapeutic Lab and conducted research on the development of new antibody drugs for two years. In 2014, he managed overall physicochemical and structural method development / qualification/validation to establish specifications through evaluation of quality equivalence.
Summary	Biosimilars are biologic medicines (medicines manufactured by, or extracted from a biological source) that can improve patient access to high-quality treatment options. Samsung Bioepis has already gained approval of three key biosimilars for autoimmune conditions, and a key biosimilar in certain types of breast cancer and metastatic gastric cancer. Globally, regulatory expectations for the development and approval of biosimilars are not completely harmonized, which results in a variation in specifications of the same products. As specifications are considered critical part of the total product quality control strategy, Samsung Bioepis, as manufacturers, is considering potential lot-to-lot variability in quality attributes and tries to ensure the consistency of the manufacturing process to meet global specifications, which will be covered at this talk.

Scope	**Q6B**
Title	**Health Canada's experience with the application of ICH Guidelines on Specifications for Biotechnological/Biological Products**
Speaker	**Hugo Hamel** (Senior Reviewer, Health Canada)
Bio	Mr. Hamel spent the last 19 years working with the Biologics and Genetic Therapies Directorate (BGTD) at Health Canada as Senior Quality Evaluator with the Monoclonal Antibodies Division. He also acted for a year as Division Chief of the Radiopharmaceuticals and Gene Therapies Unit and as Division Chief of the Monoclonal Antibodies Division. During his career with BGTD, Mr. Hamel was involved with reviewing the Chemistry, Manufacturing and Controls information pertaining to Clinical Trial Applications (CTAs), New Drug Submissions (NDSs) and Post-Marketing changes associated with

	Biotherapeutics. He also acted from 2005-2019 as the BGTD lead of the working group in charge of developing and updating the Canadian Post-NOC changes quality guidance and represented Health Canada on the WHO drafting group in charge of developing the WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products. With almost 20 years of experience working for Health Canada, an official member to the International Council for Harmonisation (ICH), Mr. Hamel has significant experience applying the principles of the ICH quality guidelines. Adopted by Health Canada in 2001, he will be pleased to share the Health Canada's experience with the implementation of the Q6B quality topic entitled "Specifications: test procedures and acceptance criteria for biotechnological/ biological products". Hugo Hamel graduated from the University of Montreal with a B.Sc. in Biochemistry, a M.Sc. in Molecular Biology and a M.Sc. in Pharmaceutical Sciences. He also graduated with a MBA in 2015.
Summary	ICH Q6B document provides guidance on justifying and setting specifications for proteins and polypeptides which are derived from recombinant or non-recombinant cell cultures. In view of the nature of the products, the topic of specifications include in-process controls, bulk drug, final product and stability specifications and give guidance for a harmonised approach to determining appropriate specifications based on safety, process consistency, purity, analytical methodology, product administration and clinical data considerations. ICH Q6B was adopted by Health Canada in 2001 and Mr. Hamel started to work with Health Canada as quality reviewer at the same time. With close to 20 years of experience applying the principles of ICH Q6B in the review of drug applications for biotherapeutic products, Mr. Hamel will share his experience with the use of this guideline. A description of appropriate control strategy for products manufactured using a traditional approach versus an enhanced approach will be presented. The general principles on the setting and justification of specifications will be supported by the presentation of case studies.

Scope	**Q1A, Q1D**
Title	**Experience in Implementing ICH Stability Guidelines Q1A(R2) and Q1D with Case Studies**
Speaker	**Chi-wan Chen** (Executive Director, Pfizer Inc)
Bio	Chi-wan Chen is Executive Director in Global CMC, Pfizer, responsible for regulatory CMC policies and strategies with a focus on China and Asia Pacific. Prior to joining Pfizer in 2008, Dr. Chen had served in the U.S. FDA for more than 21 years. She started as a CMC reviewer and was promoted through the ranks and held several management positions in the Center for Drug Evaluation and Research (CDER), including Deputy Director in the Office of New Drug Quality Assessment (ONDQA). She represented CDER on the ICH Q1AR, Q3AR/Q3BR, and Q8R Expert Working Groups (EWGs) between 1998 and 2008. In 2005-2008, she provided technical leadership and management oversight for the FDA CMC Pilot Program, which emphasized the application of quality-by-design principles to pharmaceutical development. She chairs the Asia Pacific Focus Group under the International Society of Pharmaceutical Engineering (ISPE), and serves as a member on the China R&D-based Pharmaceutical Association Committee (RDPAC) CMC Council and an ad-hoc CMC advisor to the Association of South East Asia Nations (ASEAN) Pharmaceutical Research Industry Association (APRIA). Dr. Chen has made numerous presentations on regulatory and CMC topics in Asia Pacific. She is an active member of the Food and Drug Administration (FDA) Alumni Association International Network (FDAAAIN). She has a Ph.D. degree in organic chemistry from the

	University of Wisconsin, Madison, U.S.A.
Summary	A brief outline of ICH guidelines Q1A(R2), Stability Testing of New Drug Substances and Drug Products, and Q1D, Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products, including their history, objective, and basic principles, will be presented. The experience with implementing these guidelines in a global market will be shared from the perspective of a former FDAer and a current industry representative. Case studies will be discussed with the audience in a group exercise.

Scope	**Q5A**
Title	**Health Canada's experience with the application of ICH Guidelines on Viral Clearance for Biotechnological/Biological Products**
Speaker	**Christopher Storbeck** (Senior Reviewer, Health Canada)
Bio	Dr. Storbeck has been with Health Canada for the last four years as a CMC scientific reviewer in the Cytokines Division and a member of the Cell and Gene Therapy Evaluation group in the Centre for Evaluation of Radiotherapeutics and Biologics (CERB) in the Biologics and Genetic Therapies Directorate (BGTD). During this time, Dr. Storbeck was involved with reviewing the Chemistry, Manufacturing and Controls information pertaining to Clinical Trial Applications (CTAs), New Drug Submissions (NDSs) and Post-Marketing changes associated with Biotherapeutics. Prior to joining Health Canada, he spent several years as a Research and Development team leader in a Biotechnology company developing Oncolytic viral therapeutics for Cancer Treatment. Dr. Storbeck has a Ph.D. from the University of Ottawa in the field of molecular pathology of Myotonic Muscular Dystrophy and performed post-doctoral studies in the field of molecular control of protein kinases regulating cell migration, adhesion and metastasis. He has represented Health Canada at past Viral Clearance Symposia (2017 and 2019) and is the Health Canada representative on the ICH working group for the revision of the ICH Q5A guideline. Dr. Storbeck has experience with the application of ICH quality guidelines and will discuss Health Canada's experience with the implementation of ICH Q5A.
Summary	ICH Q5A provides guidance regarding testing and control of potential virus contamination in Biologic products. These products are often produced from mammalian cell lines that can potentially be infected with viruses that may present a risk to patients. ICH Q5A consists of three pillars of viral safety designed to control and minimize the risk of administering these types of products to patients with respect to potential pathogenic viruses. ICH Q5A was adopted by Health Canada in 2001. Dr Storbeck has significant experience in the field of virology, particularly with vaccinia virus and its application as an oncolytic therapeutic. He has also has significant experience in applying ICH Q5A in the review of drug applications for Biotherapeutic and Genetic therapies. Dr. Storbeck will discuss the principles of ICH Q5A and its application to Biotherapeutic and Cell and Gene therapy products and share experiences at Health Canada regarding the implementation of this guideline.

Scope	**Q5B, Q5D**
Title	**Quality of Biotechnological product: Analysis of Expression Construct (Q5B) and Derivation/Characterization of Cell substrates (Q5D)**
Speaker	**Myongjin Kim** (Director, Celltrion)
Bio	Myongjin Kim has 12 years of experience for microbial quality control at Celltrion and has worked in microbial analysis, in-process microbial monitoring, environmental and utility monitoring, cell-derived bioassay and genome stability analysis. Currently, he is the team leader of microbial quality control at Celltrion.
Summary	In order to ensure the quality of biotechnology products, it will be explained the analysis method and the precautions of “Expression Construct” mentioned in the ICH guideline (Q5B). And it will be also explained the information and test methods that need to be obtained to identify the derivation / characteristic of the Cell Substrate (Q5D).

S Day 2 – September 5 (Thu)

Time		Program	Speaker
09:30 - 10:00	30′	Registration 등록	
ICH Toxicokinetics & Pharmacokinetics Guidelines: S3A/B **독성동태시험에서의 전신노출평가와 반복투여 조직분포시험(약동학)**			
10:00 - 11:10	70′	Understanding and Applying Toxicokinetics in Drug Development 의약품 개발에서의 독성동태의 이해와 적용	**Jin Ah Hwang** (Assistant Professor, Konyang University)
11:10 - 11:30	20′	Coffee Break	
11:30 - 12:40	70′	An overview of ICH S3 guideline questions and answers ICH S3A QnA 해설 및 PMDA 허가심사 사례	**Jihei Nishimura** (Principal Assessor, PMDA)
12:40 - 14:00	80′	Lunch	
ICH Pharmacology Studies Guidelines: S7A/B **의약품의 안전성약리시험과 QT 간격연장에 대한 비임상 평가**			
14:00 - 15:10	70′	Introduction of safety pharmacology and basic mechanism of TdP and QT interval prolongation 안전성약리의 이해와 QT간격 연장에 의한 부정맥 발생 기초이론	**Jeong Wook Seo** (Executive Director, KIT)
15:10 - 15:30	20′	Coffee Break	
15:30 - 16:50	70′	A Regulatory Perspective on Implementation of the ICH S7B and E14 Guidelines on the Non-Clinical and Clinical Evaluation of QTc Prolongation Potential ICH S7B과 E14 가이드라인에 따른 QTc 간격 연장에 대한 비임상임상 평가사례 및 규제기관의 관점	**Colette Strnad** (Senior Scientific Advisor, Health Canada)
16:50 - 17:00	10′	Closing	

Above programs is subject to change.

☐ Summary & Bio

Scope	**S3A/B**
Title	**Understanding and Applying Toxicokinetics in Drug Development**
Speaker	**Jin Ah Hwang** (Assistant Professor, Konyang University)
Bio	Dr. Hwang is Assistant Professor of Medicinal Bioscience at Konyang University. She had worked for Drug metabolism & Pharmacokinetics(DMPK) team at LG Chem served as DMPK researcher, project coordinator for Joint Overseas Development, project leader for 13 years. The main areas of research are non-clinical/clinical pharmacokinetics of chemical drug and biologics including PK/PD modeling. She received her B.S. in Biology from Chungnam National University, M.S. and Ph.D. in Pharmacy from Chungnam National University under the theme of identifying pharmacokinetic characteristics of drugs and PK/PD modeling & simulation for optimal dose of phase II clinical trial.
Summary	Toxicokinetics (TK) is defined as the generation of PK data to assess systemic exposure in non-clinical toxicity studies. The purpose of TK is to describe the systemic exposure achieved in animals and its relationship to dose level and the time course of the toxicity study. It provides data such as species difference, gender difference and linearity of systemic exposures over the dose ranges, accumulation after repeat dosing. It would be used for interpretation of toxicological findings and assessment of the relevance of these findings to clinical safety. This lecture provides you with basic concepts of PK, differences of TK study design between drugs and biologics, general considerations for TK, and case studies.

Scope	**S3A Q&A**
Title	**An overview of ICH S3 guideline questions and answers**
Speaker	**Jihei Nishimura** (Principal Assessor, PMDA)
Bio	Biography: 10/2015-9/2018: Office of New Drug I, Pharmaceuticals and Medical Devices Agency 10/2018-Present: Office of New Drug V, Pharmaceuticals and Medical Devices Agency Activity of Academic: Ph.D degree (Pathogenetic Veterinary Science, United Graduate School of Veterinary Sciences, Gifu University, Japan) The Japanese Society of Toxicology Diplomate of the Japanese Society of Toxicology (JSOT) The Japanese Society of Toxicological Pathology Diplomate of Japanese Society of Toxicologic Pathology (JSTP)
Summary	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) S3A guideline on toxicokinetics (TK) was adopted by ICH in 1994 and the concept of TK was introduced in the drug development. Since then, besides that TK evaluation revealed systemic exposure of test compounds in test animals, TK evaluation enabled the understanding of the relationship between the toxicity data and drug exposure. As a result, TK evaluation is now becoming an important tool to estimate the risk and hazard in human. Recently, improvement of analytical sensitivity of measurement instrument made the amount of a specimen required for measurement smaller and made microsampling techniques available for TK evaluation. Based on such that background, ICH S3A Q&A was made to promote toxicological evaluations using microsampling techniques. In this presentation, ICH S3A Q&A document will be mainly discussed. In

	addition, usefulness and considerations in toxicological evaluations using microsampling techniques which is expected to be increasingly utilized from now in toxicological evaluations will be discussed.

Scope	**S7 A/B**
Title	**Introduction of safety pharmacology and basic mechanism of TdP and QT interval prolongation**
Speaker	**Jeong Wook Seo** (Executive Director, Korea Institute of Toxicology(KIT))
Bio	Joungwook Seo, Ph.D. has 25 years of experience in drug development at pharmaceutical company and KIT (Korea Institute of Toxicology). He carried out several research projects related to safety pharmacology and supervised the guidebook series of safety pharmacology (I to VI) issued by MFDS. His research activities include safety pharmacology and drug abuse. He serves as member of the committee in Korean Society of Toxicology and Korean Society of Regulatory Pharmacology.
Summary	I prepared the presentation slides to help pharmaceutical company employees understand the safety pharmacology. The main points to be covered are as follows 1) History and introduction of ICH S7A and S7B guideline 2) General considerations in study design of safety pharmacology studies 3) Differences between the concepts of general toxicology and safety pharmacology 4) Safety Pharmacology Core Battery 5) What is action potential and QT interval 6) QT interval prolongation and TdP (torsade de pointes)

Scope	S7B + E14
Title	**A Regulatory Perspective on Implementation of the ICH S7B and E14 Guidelines on the Non-Clinical and Clinical Evaluation of QTc Prolongation Potential**
Speaker	**Colette Strnad** (Senior Scientific Advisor, Health Canada)
Bio	Dr. Colette Strnadova is a Ph.D pharmacologist who serves as senior scientific advisor with the Therapeutic Products Directorate of Health Canada. Her professional responsibilities include cardio-renal safety consultations for drug submissions. Dr. Strnadova is the Health Canada representative on the working groups for two International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, ICH S7B and E14, as well as the Cardiac Safety Research Consortium (CSRC) Executive Committee, the Health and Environmental Sciences Institute (HESI) Comprehensive in Vitro Proarrhythmia Assay Steering Committee and Proarrhythmia Working Group, and the World Health Organization Committee on International Nonproprietary Names (INN).
Summary	The ICH S7B and E14 guidelines, competed in May 2005, are complementary documents that detail the recommended strategies for assessing the potential for QTc interval prolongation in non-clinical safety pharmacology studies and clinical trials, respectively. A Question and Answer document to support the ICH E14 guideline was issued in June 2008 and revised in April 2012, March 2014, and December 2015. A Question and Answer document to support the ICH S7A guideline is currently in progress. The fundamental components of the ICH S7B non-clinical testing strategy are the in vitro IKr assay and the in vivo QT assay. The in vitro IKr assay is typically a study of hERG currents in mammalian heterologous expression systems stably transfected with cDNA for

	the hERG gene that encodes the pore-forming alpha subunit of the Kv11.1 potassium channel responsible for the rapidly activating delayed rectifier potassium current, IKr. The ICH S7A core battery cardiovascular safety pharmacology study in non-rodent laboratory animals typically serves as the in vivo QT assay. This presentation will address best practice considerations for these assays. The ICH S7B guideline encourages follow-up studies when the results of the in vitro IKr assay or the in vivo QT assay are suggestive of effects on ventricular repolarisation. Follow-up studies can include assessment of other cardiac ion channels, such as Nav1.5 and Cav1.2; electrophysiological effects in ex vivo cardiac tissue preparations, cardiomyomytes from induced pluripotent stem cells, or anaesthetised laboratory animals; and proarrhythmia models. The ICH E14 guideline recommends strategies to assess QTc interval prolongation potential in clinical trials. Advice is provided regarding a 'thorough QT/QTc study' which is typically a randomised, double-blind, placebo- and positive-controlled study of parallel group or crossover design, assessing the electrophysiological effects of the investigational drug at therapeutic and supratherapeutic exposures in healthy subjects, with intensive ECG acquisition and pharmacokinetic sampling over the course of a dosing interval. An alternative strategy is incorporation of intensive ECG acquisition and pharmacokinetic sampling into single and/or multiple ascending dose first-in-human trials. The implications of the results of these studies for QTc evaluation in late state clinical development will be discussed. Recommendations are also offered for the assessment of the QTc interval in situations in which standard approaches might not be feasible, such as oncology drugs. Guidance will be provided on the analysis of drug effects on the QTc interval as a function of time and concentration, as well as categorical analyses of outliers.