붙임 1 2020년 ICH Guideline 교육 세부 프로그램

M Day 1 - 11월 3일(화)

Time		Program		Speaker
Introductory Session				
10:00 - 10:30	30′	-	ICH Cooperation Activity and Implementation Status of ICH Guidelines in Korea 한국의 ICH 활동 및 ICH 가이드라인 이행 현황	최영주 과장 (MFDS/NIFDS)
M1: MedDRA 국제의약용어				강연영상 참고: M1
10:30 - 12:00	90′	M1	MedDRA Applications: Coding and Data Analysis MedDRA 활용: 코딩 및 데이터 분석	도윤희 (Clinical Associate, MedDRA MSSO)
12:00 - 14:00	120′	Break		
M4(R4): Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use 인체대상 의약품 등록을 위한 공통기술문서(CTD)의 구성				강연영상 참고: M4(CTD,eCTD)
14:00 - 15:00	60′	M4	The Common Technical Document 국제공통기술문서	이정욱 전무 (아이큐어)
15:00 - 16:00	60′	Break		
M9, Q&As: Biopharmaceutics Classification System-based Biowaivers 생물약제학적 분류체계 근거 생동면제				
16:00 - 16:30	30‘	M9	Biopharmaceutics Classification System-Based Biowaivers ICH M9 ICH M9 생물약제학적 분류체계 근거 생동면제	**James Mann** **Xavier Pepin** (AstraZeneca)
16:30 - 16:50	20′	M9	Revision on BCS-Based Biowaivers as establishment of M9 M9 제정에 따른 BCS 기반 생동성시험 면제기준 주요 개정사항	이경신 연구관 (MFDS/NIFDS)
		Closing		

E | Day 2 – 11월 4일(수)

Time		Program		Speaker
E2B(R3), Q&As: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Report 임상적 안전성 정보관리: 개별사례 안전성 보고(ICSR)의 데이터 요소				강연영상 참고: E2A, E2B(R3) 이행
10:00 - 11:00	60′	E2B (R3)	E2B(R3) to improve the quality of Individual Case Safety Reports (ICSRs) E2B(R3) 품질향상을 위한 개별사례 안전성 보고	**Jean Christophe Delumeau** (Bayer Pharma AG and Bayer (South East Asia))
E2C(R2), Q&As: Periodic Benefit-Risk Evaluation Report 유익성-위해성 평가 정기보고				
11:00 - 12:00	60′	E2C (R2)	How to prepare PBRER and DSUR - ICH E2C and ICH E2F PPBRER과 DSUR 준비 방법 - ICH E2C와 ICH E2F	**Dawn Ren** (Bayer AG)
12:00 - 14:00	120’	Break		
E6(R2): Good Clinical Practice 임상시험 관리기준: 통합된 지침서				강연영상 참고: E6(RBM, QMS)
14:00 - 15:00	60′	E6 (R2)	E6 (R2): More systematic prioritized risk-based approach: successful implementation in Clinical Development E6 (R2): 성공적인 임상시험 이행	김택로 박사 (F. Hoffmann-La Roche)
15:00 - 15:15	15′	Break		
E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure and Format of Qualification Submissions 의약품 또는 생물의약품의 생체 지표개발: 적격성 확인을 위한 자료의 기재요령, 구조 및 양식				
15:15 - 16:15	60′	E16	E16 Biomarkers Related to Drug or Biotechnology Product Development	**Gideon Blumenthal** (MSD)
		Closing		

S | Day 3 – 11월 5일(목)

Time		Program		Speaker
S6(R1): Biotechnological Products 비임상 안전성 평가 + **M3(R2): Nonclinical Safety Studies** 비임상적 안전성 연구				강연영상 참고: S6, S6 Q&A, M3
10:00 - 11:00	60′	S6+ M3	A Comparison of ICH S6 and ICH M3 S6과 M3 비교	**Jian Wang** (Health Canada)
11:00 - 12:00	60′	S6	Considerations for Nonclinical Studies of Biopharmaceuticals (in terms of assessment for Coronavirus Vaccines Nonclinical studies) 생물의약품 비임상시험 시 고려사항 (코로나19 백신 비임상 자료 심사 관련)	**오상연 주무관** (MFDS/NIFDS)
12:00 - 13:30	90′	Break		
S5(R3): Reproductive Toxicology 생식독성				
13:30 - 15:10	100′	S5 (R3)	Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals 의약품의 생식발생독성 독성 평가 [ICH S5(R3)]	**유욱준 책임연구원** (안전성평가연구소)
15:10 - 15:20	10′	Break		
S11: Nonclinical Paediatric Safety 소아용 비임상				
15:20 - 16:30	70′	S11	Preclinical safety study of paediatric pharmaceuticals 소아용의약품 개발지원을 위한 비임상 안전성 시험	**차주영 책임연구원II** (JW홀딩스)
		Closing		

Q | Day 4 – 11월 6일(금)

Time		Program		Speaker
Q12: Lifecycle Management 의약품 전주기 관리				
10:00 - 11:15	75′	Q12	ICH Q12: Pharmaceutical Product Lifecycle Management ICH Q12: 의약품 전주기 관리	**Jean-Louis ROBERT** (ICH Q12 EU topic leader)
11:15 - 12:15	60′	Q12	Practical Implementation of ICH Q12 ICH Q12 이행 사례	**Frank Montgomery** (AstraZeneca)
12:15 - 14:00	105′	Break		
[ICH Guidance on Q Trio]				
Q8(R2): Pharmaceutical Development(제제개발경위) **Q9: Quality Risk Management**(품질위해관리) **Q10: Pharmaceutical Quality System**(의약품품질시스템)				강연영상 참고: Q trio(AHC)
14:00 - 15:00	60′	Q8/9/10	Strategic interpretation of ICH Q8, 9, and 10 approaches ICH Q8, 9, 10 접근방법에 대한 전략적 해석	김태규 대표 (비앤피케어)
15:00 - 16:00	60′	Q8/9/10	Interpretation and implementation of ICH Q-trio from the industry perspective 산업계 측면에서의 ICH Q-trio 해석 및 이행	김현철 이사 (한미약품)
16:00 - 16:15	15′	Break		
16:15 - 17:15	60′	Q&As	Q8/9/10 Q&As (R4) - The road to drug development and license by QbD QbD 에 의한 의약품 허가개발의 해설과 이행방안 – Q8/9/10 Q&As (R4)	김국희 책임 (오송첨단의료산업진흥재단)
		Closing		

☐ Bio & Summary

ICH Guidelines

Title	**ICH Cooperation Activity and Implementation Status of ICH Guidelines in Korea** 한국의 ICH 활동 및 ICH 가이드라인 이행 현황
Speaker	**Youngju Choi** (Director, Pre-Submission Consultation Division, NIFDS, MFDS) 최영주 과장 (식품의약품안전처/식품의약품안전평가원 사전상담과)
Summary	The Presentation will provide MFDS Activities including ICH Guideline Implementation, ICH Cooperation Activity and Future Plans.
	한국의 ICH 활동현황, ICH 가이드라인 이행 활동, 향후 계획에 대해 소개한다.

Multidisciplinary

Title	**MedDRA Applications: Coding and Data Analysis** MedDRA 활용: 코딩 및 데이터 분석
Speaker	Yunhui DO (Clinical Associate, MedDRA MSSO)
Bio	Yun Hui Do works as a Clinical Associate with responsibility for conducting MedDRA training and providing Help Desk services and other support in the Republic of Korea. She was a researcher/assistant manager at Korea Institute of Drug Safety & Risk Management (National PV agency) from 2015 to 2018. She was mainly involved in methodological research in Pharmacovigilance and signal detection and assessment in the Office of Drug Safety Information. In 2018, She was dispatched to affiliate organisation, the Korean Ministry of Food and Drug Safety to engage in a project to develop a new integrated drug information management system. She earned her Bachelor's degree in Pharmacy from Sookmyung Women's University in 2012 and the Master of Public Health (MPH) from Imperial College London in 2015. Prior to MPH, she worked as a clinical pharmacist in Changwon Fatima Hospital as well.
	2019년 1월부터 MedDRA MSSO 한국 지원 및 교육 담당으로 근무하고 있습니다. 2015년부터 약 3년간 한국의약품안전관리원에서 국외 안전성 정보 수집 및 실마리 분석 업무를 담당하였으며, 2018년 식품의약품안전처 차세대 의약품통합정보시스템 구축 TF팀으로 파견되어 프로젝트에 참여하였습니다. 2012년 숙명여자대학교 약학 학사 학위를 받았고 2015년에는 임페리얼 칼리지 런던에서 보건학 석사 학위를 마쳤습니다.
Summary	The main topics include coding and data analysis, which are the application aspects of ICH M1 MedDRA terminology. First, this presentation will provide the recent updates and projects from the MedDRA MSSO. A basic

	understanding of the scope, structure, and characteristics of MedDRA will be discussed so that Points to Consider documents, ICH-endorsed Guide documents for MedDRA users, can be explained in more details. The MedDRA browser will be used to demonstrate a few examples of clinical data coding. The session will then conclude with a brief introduction of SMQs(Standardised MedDRA Queries) to explain how MedDRA resources can be used in data analysis.
	ICH 가이드라인 M1 MedDRA의 활용 적인 측면인 코딩 및 데이터 분석을 주제로 한다. 먼저, MedDRA MSSO의 최신 정보와 소식을 소개하고 MedDRA 배경과 기초적인 지식을 간단히 설명한 뒤, ICH 보증한 MedDRA 가이드라인 문서인 고려 사항(Points to Consider) 문서의 내용과 활용 방안에 대해 자세하게 다룬다. 특히, MedDRA 브라우저 사용법을 시연하고 이를 활용한 코딩 예시 문제를 풀어보며 최적의 용어를 찾기 위한 접근법을 익힌다. 마지막으로, 표준 검색어 목록(SMQ)이 무엇인지 어떻게 활용되는지 설명하며 MedDRA를 활용한 데이터 분석의 기초적인 사항을 다룬다.

Title	**The Common Technical Document** 국제공통기술문서
Speaker	**Jeong Uk LEE** (Senior managing director, ICURE Inc) 이정욱 전무 (아이큐어㈜)
Bio	Jeong Uk LEE has over 20 years of experience for Regulatory Affairs at pharmaceutical industry and cosmetic industry. She has worked for Ferring Korea, Bukwang Pharmaceuticals etc. Jeong Uk LEE currently works for Icure Inc. as a senior managing director of Global R&D/Clinical Development.
	박사룡특허사무소, 국립보건안전연구원 (현, 식약처), 한국페링제약, 부광약품, 코스맥스 등 다양한 분야에서 제약산업을 경험하였으며, 신세계인터코스 등 화장품 분야와 IMGT 등 의약품 개발 벤처사의 자문역을 수행하였으며, 현재 경피투여용 제제 전문개발 제약사 아이큐어㈜에서 임상개발본부장을 맡고 있음.
Summary	To prepare M8 implementation in Korea, briefly introduce M8 eCTD implementing status of ICH member countries with the summarized presentation for M4 CTD.
	ICH 가이드라인의 M4 국제공통기술문서 (CTD) 및 M8 eCTD의 개요와 각국 도입현황 등에 대해 설명하여 향후 국내 M8 시행에 대비할 수 있는 정보를 제공하고자 한다.

Title	**Biopharmaceutics Classification System-Based Biowaivers ICH M9** **ICH M9:** 생물약제학적 분류체계 근거 생동면제
Speaker 1	**James Mann** (Associate Principal Scientist In Vitro Product Performance, AstraZeneca)
Bio 1	James Mann is an associate principal scientist of in vitro product performance at AstraZeneca in the UK. An experienced analytical scientist

	with more than 14 years' experience in pharmaceutical industry specializing in all aspects of dissolution testing. At AstraZeneca, James is the global lead for the in vitro product performance scientific community with oversight of all dissolution related activities in product development. Prior to joining AZ, James was with Merck in the UK where he jointly led the global in vitro predictive technologies team as well as supervising a small team of product development analysts and more recently was the analytical manager at Molecular Profiles. James received his first degree from University of Strathclyde, followed by a PhD from the University of East Anglia.
Speaker 2	**Pepin Xavier** (Principal Scientist Biopharmaceutics, AstraZeneca)
Bio 2	Xavier is a pharmacist (University Paris XI). He has a Ph.D. in granulation technology where he studied powder surface energy and liquid bridges during wet high-shear granulation. He has more than 20 years' experience in the pharmaceutical industry and has occupied several positions from preformulation, clinical and commercial formulation development, industrial transfer, regulatory CMC and biopharmaceutics. He's worked in biopharmaceutical tools development for 10 years in transversal collaboration with scientists from CMC, Clin Pharm & MPK departments, using in vitro, in silico, and in vivo tools to support biopharmaceutical evaluation of drugs along the development value chain and post marketing. He was the co-leader of WP4 in silico tools for the OrBiTo IMI project 2012-2018. He has 35 publications in the field of powder surface energy, granulation technology and biopharmaceutics.
Summary	A walkthrough of the recent ICH M9 BCS-Based Biowaiver guideline from an industry perspective covering the topics of solubility, permeability, excipients and in vitro dissolution.

Title	**Revision on BCS-Based Biowaivers as establishment of M9** M9 제정에 따른 BCS 기반 생동성시험 면제기준 주요 개정사항
Speaker	**Kyungshin Lee** (Senior Reviewer, Bioequivalence Evaluation Division, Drug Evaluation Department, NIFDS, MFDS) 이경신 연구관 (식품의약품안전처/식품의약품안전평가원 의약품심사부 약효동등성과)
Summary	ICH has issued M9 guideline. The main difference of ICH M9 and MFDS regulation is extension to BCS Class III drug products. The presentation includes summary of additional changes such as drug amount for solubility test, excipient criteria and in vitro permeability methods using Caco-2 cells.
	ICH M9 (생물약제학적 분류체계에 의한 생물학적동등성시험 면제기준) 가이드라인 제정에 따른 현재 규정 중 변경 사항에 대한 교육을 진행한다. 계열 3 약물로 생동성시험 면제가 확대되는 것을 포함하여 용해도 시험 시 약물의 양, 첨가제 기준, Caco-2 세포를 이용한 생체 외 투과도 시험방법 등 현재 규정과의 차이점을 설명한다.

Efficacy

Title	**E2B(R3) to improve the quality of Individual Case Safety Reports (ICSRs)** E2B(R3) 품질향상을 위한 개별사례 안전성 보고
Speaker	**JEAN-CHRISTOPHE DELUMEAU** (Head of Pharmacovigilance Policy Strategy, Bayer Pharma AG and Bayer (South East Asia) Pte. Ltd., Singapore)
Bio	Based in Asia since 2001, Jean-Christophe Delumeau graduated in medicine, toxicology, pharmacology, applied statistics and methodology of clinical trials, from universities of Rennes and Paris (France). After completing residency, he joined a research program on intracellular signalling at the French National Institute of Medical Research. He obtained his PhD from the University Pierre and Marie Curie in Paris. From 1991, he moved to clinical research, working in Basel (Roche, Novartis), Paris and Tokyo (Rhone-Poulenc) where he conducted multinational trials in neurodegenerative diseases and cerebrovascular disorders. From 2002, he took over the responsibility of the pharmacovigilance department of Bayer Yakuhin (Japan) until his appointment in 2009 as head of Pharmacovigilance for Asia-Pacific and China, based in Beijing until 2014, then in Singapore until 2017. In July 2017, he was appointed head of Pharmacovigilance Policy Strategy, still based in Singapore but extending his scope beyond Asia to Africa and Middle-East, Eastern Europe, Central Asia and Latin America. Since October 2016, he is serving as Board and Executive Committee Member of the International Society of Pharmacovigilance (ISoP) and coordinating ISoPs Special Interest Group on Risk Minimisation methods for Asian Countries. Jean-Christophe Delumeau is also serving the European Federation of Pharmaceutical Industries and Associations (EFPIA) as vice-chair of the International PV group, coordinator of the Asia-Pacific Pharmacovigilance Work-Stream, and leader of EFPIA's initiative aiming at Simplifying and Improving Global ICSR Submission (SiGiR) collaborating with the Uppsala Monitoring Centre. Jean-Christophe Delumeau is regularly involved in academic teaching activities at Duke-NUS University (Singapore) Peking University and APEC as well as ISoP.
Summary	The purpose of this lecture is to explain the rationale for undertaking to upgrade E2B to the E2B(R3) standard, which took more than a decade to complete. Compared to the earlier R2 standard, E2B(R3) allows a much greater degree of granularity to capture the information of Individual Case Safety Reports (ICSRs) and, as consequence, improve the quality of the case evaluation. Additional featured that are essential to reach this goal include: a) repeatable sections or data elements which architecture allows to evaluate each event of the case separately and to support evaluation by multiple stakeholders, b) the addition of specific core data elements designed to capture contents in native languages, c) the concept of null flavor to specify the reason why a data is missing, d) the possibility to include regional of country customization within the framework of the

	E2B(R3) standard, e) the possibility to embed source documents of diverse formats including, PDF, tables, and various image formats including DICOM. The MedDRA is part of the E2B(R3) as well as the future IDMP for Drug names and related information. The last section of this lecture will focus on the E2B(R3) Implementation Guide for Korea which includes Korea-specific Data Elements, Korea-specific customization of the verification rules and the use MFDS's Drug Dictionary codes.

Title	**How to prepare PBRER and DSUR - ICH E2C and ICH E2F** PPBRER과 DSUR 준비 방법 - ICH E2C와 ICH E2F
Speaker	**Shuguang (Dawn) REN** (Senior Director. Benefit Risk Management, Pharmacovigilance, Bayer AG)
Bio	Dawn obtained her Clinical Medical Degree from Harbin Medical University. Dawn practiced as an Obstetrician and Gynecologist in Beijing for eight years. She joined the pharmaceutical industry in 2005 and has 13 years' experience on PV. Dawn had worked in MSD and Roche. Dawn joined Bayer Pharmacovigilance Benefit-Risk Management in 2011 as a Global Safety Leader. Now Dawn is the Head of therapeutic area in Pharmacovigilance Benefit Risk Management department of Bayer.
Summary	To assist the industry to prepare PBRER and DSUR according to ICH E2C and ICH E2F, this presentation covers: 1) general steps of the preparation process. 2) Section by section explanation on what to be included in each section and what aspects the MAH should pay attention.

Title	**E6(R2): More systematic prioritized risk-based approach: successful implementation in Clinical Development** **E6 (R2):** 성공적인 임상시험 이행
Speaker	**Taekrho Kim** (Global Medical Collaboration Lead, gPDMA, F. Hoffmann-La Roche) 김택로 박사 (Global Medical Collaboration Lead, gPDMA, F. Hoffmann-La Roche)
Bio	Taek has over 19 years industrial experiences in the various field of drug research and development Her experiences with clinical trials from Phase 1-Phase 4 covered CNS, antibiotics and oncology, etc. at the local and the global pharmaceuticals and the global CROs. Currently she is with F. Hoffmann-La Roche Ltd, Basel, Swiss, working a personalized health-care (PHC)-oncology in Korea, Taiwan and Hong Kong.
	국내외 제약사 및 CROs에서 약 19년간 의약품 연구 및 개발업무를 담당해왔습니다. CNS, 항생제, CV 그리고 oncology 등의 관련 업무를 해왔고 그 중에서도 Oncology가 주력 업무였습니다. 임상1-4상 다양한 경험을 하였으며 현재는 global 부서 소속으로 한국 대만 홍콩에서의 Personalized healthcare (PHC)-oncology 관련 전략 및 임상을 담당하고 있습니다.

Summary	In conducting clinical trial, ICH E6 (R1) had been an industrial guidance to ensure data quality and protection. And ICH E6(R2) addendum had been rolled out as the need for modernization are increased that was led by the universal shift toward electronic data capture system and risk-management to ensure not only the process but also the responsibilities of responsible individuals in clinical trial. ICH E6 (R2) described the responsibilities and expectation of investigators, monitors, sponsors and IRRs. This session will discuss risk-based new approach to improve efficiency in the rapid growing trial landscape, which based on the GCP main principles, refinement, reduction and replacement. .
	임상시험에서 ICH E6(R1)은 양질의 데이터와 보호를 위한 관련산업계의 가이드라인 이였다. 그리고 전자데이터수집 및 위해성관리등의 사회적 변화로 안하여 근대화가 필요로 하였고 임상시험 각 단계 과정 뿐 아니라 임상 시험의 관련자들의 열할 부분들이 추가 되었다.; ICh E6(R2)에서는 연구자, 모니터, 스폰서 그리고 IRBs의 역할 및 책임이 서술되었다 이 세션에서는 급변하는 임상업계에서 효율성을 높이기 위해 GCP기본 원리에 입각한 위해성 관리를 함께 논할 것입니다.

Title	**E16 Biomarkers Related to Drug or Biotechnology Product Development**
Speaker	**Gideon Blumenthal, MD** (Vice President, Global Regulatory Affairs in Oncology, Merck)
Bio	Dr Gideon Blumenthal is a hematologist oncologist who is currently Vice President, Global Regulatory Affairs in Oncology, Merck. Prior to joining Merck, Dr Blumenthal spent over a decade at the US Food and Drug Administration Oncology office, taking on increasing leadership responsibilities during his time at the Agency. He initially served as a medical reviewer, then clinical team leader, followed by Acting Deputy Director in the Office of Hematology Oncology Products and Associate Director for Precision Oncology, and most recently served as the Deputy Center Director of the Oncology Center for Excellence. Dr Blumenthal did his internal medicine training at the University of Maryland School of Medicine, followed by a hematology oncology fellowship at the National Cancer Institute. He was an attending physician in the NCI thoracic oncology clinic. He received numerous awards, including the 2018 American Society for Clinical Oncology Public Service Award. He has co-authored over 100 articles in the Oncology and Drug Development peer reviewed literature and has authored 3 book chapters.
Summary	TBD

Safety

Title	**A Comparison of ICH S6 and ICH M3** S6과 M3 비교
Speaker	**Jian Wang** (Division Manager, Health Canada)
Bio	Dr. Jian Wang is the Division Manager for Clinical Evaluation Division - Radiopharmaceuticals and Haematology in Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics (CERB), Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Health Canada The division has regulatory responsibility for assessing non-clinical, pharmacology and clinical data for biological drugs, including advanced therapies, gene therapies and biosimilars, for the treatment of malignant and non-malignant haematologic diseases, and COVID 19. The Division also regulates diagnostic and therapeutic radiopharmaceuticals for all clinical indications. Dr. Wang has broad regulatory experience in pre-market drug regulations for generics, biologics, biosimilars and radiopharmaceuticals. He joined the Health Canada Pesticide Management Regulatory Agency in 1996. He started working for the Therapeutic Products Directorate (TPD) in early 1999. Then in 2001, Dr. Wang moved to BRDD. He actively participates in various Health Canada, ICH, WHO and DIA working groups and expert committees. Dr. Jian Wang received his MD from Harbin Medical University, Harbin, China in 1982, and his PhD from the University of British Columbia, Vancouver, Canada.
Summary	The presentation will provide an overview of types and timing of Non-clinical studies required at different stages for drug development and a comparison of regulatory requirements for non-clinical studies between small molecules and large molecules.

Title	**Considerations for Nonclinical Studies of Biopharmaceuticals (in terms of assessment for Coronavirus Vaccines Nonclinical studies)** 생물의약품 비임상시험 시 고려사항(코로나19 백신 비임상 자료 심사 관련)
Speaker	**Sang Yeon Oh** (Scientific Officer & Reviewer, Pre-Submission Consultation Division, NIFDS, MFDS) 오상연 보건연구사 (식품의약품안전처/식품의약품안전평가원 사전상담과)
Summary	General contents of ICH guideline S6(R1) will be explained, and the assessment of nonclinical studies for Coronavirus vaccines will be explained.
	ICH S6(R1)에 대한 전반적인 내용에 대한 교육을 진행하고, 코로나19 백신 비임상 자료 평가에 대해서 설명한다

Title	**S5(R3): Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals** 의약품의 생식발생독성 독성 평가 ICH S5(R3)
Speaker	**Wook-Joon Yu** (Principal Researcher, Korea Institute of Toxocology) 유욱준 책임연구원 (안전성평가연구소)
Bio	Wook-Joon Yu has 17 years of experience for developmental and reproductive toxicology research area at Korea Institute of Toxicology. He has worked as a study director of various reproductive and developmental toxicity studies based on test guidelines including OECD and ICH and as a project leader conducted various research projects related to reproductive toxicology. Currently, I am the team leader of developmental and reproductive toxicology research group.
	안전성평가연구소에서 2004년도에 입소한 후 생식발생독성관련 분야의 연구그룹에 속하여 현재까지 17년간 생식발생독성 관련 시험책임자 업무와 관련된 생식발생독성 관련 연구 과제를 책임자로 수행하고 있습니다. 현재는 생식발생독성연구 그룹에서 그룹장을 맡고 있습니다.
Summary	Recently, ICH guideline S5(R3) related to reproductive and developmental toxicity studies for pharmaceuticals was issued and general contents of this guideline will be explained, and the differences between S5(R2) and S5(R3) will be also explained.
	최근 개정되어 공포된 ICH 의약품의 생식발생독성가이드 라인[S5(R3)]의 전반적인 내용에 대한 교육을 진행하고 이전 버전인 S5(R2)와의 차이점에 대해서 설명한다.

Title	**S11: Nonclinical Paediatric Safety** 소아용의약품 개발지원을 위한 비임상 안전성 시험
Speaker	**Joo Young Cha** (Principal Research Scientist, JW Holdings) 차주영 책임연구원II (JW홀딩스)
Bio	About 17 years of experience for new drug discovery and development of small molecule new chemical entities with expertise for pharmacology, toxicology (GLP tox) and R&D strategy in JW Pharmaceutical. Currently, I'm in charge of open innovation and research funding as a leader of research innovation group in JW Holdings.
	17년간 JW중외제약에서 저분자 화합물 기반 신약 연구 개발 업무를 담당하고 있으며, 비임상 효능 평가, 비임상 독성 평가 (GLP tox) 및 연구 기획 등의 업무를 수행했습니다. 현재는 Research Innovation실 리더로 오픈 이노베이션 연구 및 연구 투자 관련 업무를 맡고 있습니다.
Summary	In order to support preclinical safety study of paediatric pharmaceuticals, it will be explained the information and examples of ICH S11 guideline (adopted on 14 April 2020).
	소아용 의약품 개발 비임상 안전성 시험을 위해 새롭게 개정된 ICH 가이드라인 (S11)의 주요 내용과 사례를 설명한다.

Quality

Title	**ICH Q12: Pharmaceutical Product Lifecycle Management** ICH Q12: 의약품 전주기 관리
Speaker	**Jean-Louis ROBERT** (EC_EU ICH Q12 topic lead)
Bio	Dr Jean-Louis Robert studied chemistry at the University of Basle (CH) and obtained his Ph.D. from there in 1976. He was head of the Unit "Pharmaceutical Chemistry", an Official Medicines Control Laboratory (OMCL) at the National Health Laboratory (LNS) in Luxembourg. He retired from LNS in March 2015. He was a member of the Committee for Human Medicinal Products (CHMP) since 1995 (co-opted member since 2004) till December 2017 at the European Medicines Agency (EMA). He was chairman of the CHMP/CVMP Quality Working Party from 1995 to June 2017. Within the International Council on Harmonization (ICH), he was involved in different topics as expert of the European Commission (EC): ICH Q2, Q8, Q10, chair of Q8, 9 and 10 implementation and CTD-Q. Currently he is EC topic leader for ICH Q12 (Pharmaceutical Product Lifecycle Management). At the European Pharmacopoeia (Strasbourg, Council of Europe), he was chair of the European Pharmacopoeia Commission (2013-2016) and he was a member of the group of experts 10 B (chemical). Currently he is chair of the CEP (Certification of Suitability) Steering Committee.
Summary	The lifecycle of a pharmaceutical product and its corresponding manufacturing process is a dynamic process, meaning that the evolution of product and process does not stop after first approval. Therefore post-approval changes are an important part in the lifecycle of a medicinal product. They can be influenced for instance by additional experience gained during commercial phase, scientific progress, new safety information and/or change in Regulation. The concepts and principles of lifecycle management as described in ICH Q12 will be presented including tools like post-approval change management protocols (PACMP) helping to facilitate post-approval changes. Emphasis will be made on the importance of a risk based approach for changes supported by a sound pharmaceutical development, on the need for a categorization change policy and on the necessity of the demonstration of an effective pharmaceutical quality system. Implementation challenges will be discussed.

Title	**Practical Implementation of ICH Q12** ICH Q12 이행 사례
Speaker	**Frank Montgomery** (Global Head Regulatory CMC, AstraZeneca)
Bio	Frank obtained his degree and PhD from Imperial College London and Post-Doc at Ohio State University USA in synthetic chemistry. He joined AstraZeneca in 1996 and spent 14 years in API and drug product development and manufacture before moving to Regulatory CMC in 2009. Frank is now Global Head Regulatory CMC at AstraZeneca and a member of Implementation Working Group (IWG) as EFPIA Expert for ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management since its initiation in 1994 and has been responsible for leading teams drafting several sections of the guideline. He has presented and organised several international conferences on implementation of QbD & ICH Q12 for DIA, ISPE, PDA, CASSS, facilitated training activities and workshops for regulatory agencies including EMA, FDA, NMPA, MFDS on topics such as implementation of ICH Q8-11 and training and implementation of ICH Q12.
Summary	The presentation will highlight the need for ICH Q12 to enable the vision for Q10 of continual improvement in Pharmaceutical drug quality. This will also illustrate some of the learning and experience from AstraZeneca as well as future challenges.

Title	**Strategic interpretation of ICH Q8, 9, and 10 approaches** ICH Q8, 9, 10 접근방법에 대한 전략적 해석
Speaker	**Tae Kyu Kim** (CEO, BnP Care.) 김태규 대표 (비앤피케어)
Bio	I have been conducting QA and QC work in biopharmaceutical R&D and manufacturing companies for about 15 years. I was primarily responsible for QA of vaccines and antibody drugs. I have been serving as the CEO of a QbD and GMP advisory company at BnP Care Co., Ltd. for 6 years from 2014.
	약 15년간 바이오의약품 연구개발 및 제조회사에서 QA, QC업무를 진행했었습니다. 현재 2014년부터 6년간 ㈜비앤피케어에서 QbD 및 GMP 자문회사의 대표이사로 재직중에 있습니다.
Summary	Design-based quality based on ICH's Q8(R2) “Pharmaceutical Development”, Q9 “Quality Risk Management”, and Q10 “Pharmaceutical Quality System” Based on (Quality by Design, hereinafter QbD), it will be described including the concept of the Product Life Cycle to establish an understanding of product quality and process in a systematic approach.
	의약품국제조화기구(ICH)의 Q8(R2) “의약품 개발 (Pharmaceutical

	Development)”, Q9 “품질 리스크 관리 (Quality Risk Management)”, Q10 “제약 품질 시스템 (Pharmaceutical Quality System)”에 의거한 설계기반품질 (Quality by Design, 이하 QbD)을 기반으로 체계적인 접근 방식으로 제품의 품질과 공정 이해를 확립하도록 제품 수명 주기 (Product Life Cycle) 개념을 포함하여 설명한다.

Title	**Interpretation and implementation of ICH Q-trio from the industry perspective** 산업계 측면에서의 ICH Q-trio 해석 및 실행
Speaker	**Hyun Cheol Kim** (Director, Hanmi Pharm.) 김현철 이사 (한미약품)
Bio	**2017.10.~ Hanmi Pharm.Co.,Ltd., Bioplant QA director** Operation of QMS for clinical trial medicines, medical devices, and biopharmaceuticals, Validation of new bio plant construction, Conduct inspection by many of regulatory agencies including US FDA **2016.01.~2017.09 LG Life Sciences (now, LG Chem.), Head of CQA** Corporate level quality management system planning and coordination **2010.01.~2015.12. LG Life Sciences (now, LG Chem.) Head of Osong Plant QA** GMP control of construction and operation of new bioplant, development of bio-similars and vaccine products, and quality management for commercial production **2008.01.~2009.12. LG Life Sciences (now, LG Chem.) Planning of Corporate QMS** **2000.01.~2007.12. LG Life Sciences (now, LG Chem.) Head of Iksan Plant QA** Supervised QA of US FDA approval process for Korea's first self-developed new drug **1997.01.~1999.12. LG Life Sciences (now, LG Chem.) Iksan Plant QC** Set up of test method and initial laboratory management system for 1st generation biopharmaceuticals
	2017.10.~ 한미약품. 바이오플랜트 QA임원(이사) 임상약, 의료기기, 바이오의약품의 제품 품질 관리, 바이오 신공장 건설 밸리데이션, US FDA 포함 선진 규제기관의 실사 수검 2016.01.~2017.09 LG화학. 생명과학본부 CQA팀장 Corporate level 품질관리 시스템 기획 및 운영 2010.01.~2015.12. LG생명과학 오송공장 QA팀장 신규공장의 건설 및 운영주관, 바이오시밀러 및 백신제품 개발 및 상업생산 지원 2008.01.~2009.12. LG생명과학 품질경영 기획 2000.01.~2007.12. LG생명과학 익산공장 QA팀 국내 최초 자체 개발 신약의 FDA 승인 과정의 QA 주관 1997.01.~1999.12. LG생명과학 익산공장 QC팀 1세대 바이오의약품의 시험법 및 초기 시험실관리 시스템 set-up
Summary	ICH Q-trio (Q8, 9, 10), which presents the latest guide for the quality management system in all stages of drug development and manufacturing, is to be interpreted in terms of industry implementation. Also, based on the interpretation of the regulations, we would like to share our experiences of robust and efficient operation for PQS.
	의약품 개발 및 제조 전 단계의 최신 품질 운영 시스템에 대한 최신 규정을

	제시한 ICH Q-trio (Q8, 9, 10)를 산업계 적용 측면에서 해석하고자 한다. 또한 규정의 해석에 기반하여 견고하면서 효율적인 적용에 대한 경험을 공유하고자 한다.

Title	**The road to drug development and license by QbD** QbD 에 의한 의약품 허가개발의 해설과 이행방안 - Q8/9/10 Q&As (R4)
Speaker	**Cook Hee Kim** (Principal Researcher, K-Bio NDDC) 김국희 책임연구원 (오송첨단의료산업진흥재단)
Bio	Cook Hee Kim has 15 years of experience for process development and project manager of Biological drug and 3 years of experience for QA team leader in GMP & GLP. He had developed the “GreenGene” (recombinant Human Coagulation Factor VIII) in-GC pharma. and the “NES-bell” (NESP biosimilar) in CKD pharm.
	GC녹십자에서 재조합단백질 혈우병치료제인 “그린진”의 연구개발을 수행하였고, 종근당에서 바이오시밀러인 “네스벨”의 연구개발 및 제조시설 구축과 QA팀장을 수행하였습니다. 현재 오송첨단의료산업진흥재단의 신약센터의 QA및 GLP 실험실인 “임상시험검체분석실”의 신뢰성보증책임자를 맡고 있습니다.
Summary	QbD is not mandatory for licensing. However, parts recognized as important by QbD's experience in implementation have already been revised and strengthened in legislative and GMP regulations. The requirements of ICH Q/8/9/10, which may be of interest to practitioners in the field of drug development and production, are intended to be more specific. Most of the activities required for QbD are under the recently strengthened GMP regulations including guidelines. It is only integrated and not connected. Drug development by QbD is like sewing jewelry from each individual activity to complete a jewelry necklace.
	QbD에 의한 의약품 개발은 허가 시 필수사항이 아니다. 그러나 QbD의 실행 경험에 의해서 중요하다고 인식된 부분들은, 이미 법규 및 GMP 규정에서 수정되고 강화되었다. 의약품의 개발과 생산의 현업의 실행자들이 궁금해할 수 있는, ICH Q/8/9/10에서 요구하는 것들은 보다 구체적으로 설명하고자 한다. 가이드라인을 포함한 최근 강화된 GMP규정에서 QbD에 필요한 활동은 대부분 하고 있다. 단지 통합되고 연결되어 있지 않을 뿐이다. QbD에 의한 의약품 개발은 각 개별활동의 보석들을 꿰어서 보석목걸이를 완성하는 것과 같다.