붙임 2 2021년 ICH 가이드라인 교육 연자 및 강연 정보

복합/M

M3	**The overview of ICH Guideline M3(R2)** ICH M3(R2) **가이드라인의 개요**
Speaker	**Kang-Hyun Han** Head of Division, Division of Regulatory Toxicology Research, Korea Institute of Toxicology (KIT) 한강현 / 안전성평가연구소 규제독성연구부 부장
Summary	ICH M3(R2) is a guideline to recommend international standards and promote harmonisation of nonclinical safety studies required for drug product entry into clinical trials and marketing authorization. In this presentation, I will explain the basic concepts of non-clinical studies that must be performed in drug development.
	ICH M3(R2)는 의약품의 임상시험 진입 및 시판 허가를 위해 필요한 비임상 안전성 시험을 국제적으로 조화시키기 위한 가이드라인이다. 본 강의에서는 의약품 개발에 있어서 수행해야하는 비임상 시험의 기본적인 개념에 대해 설명하고자 한다.
Bio	assessment for hazardous substances, and general toxicity/carcinogenicity studies under the GLP condition in Korea Institute of Toxicology (KIT). The main research areas are the toxicity evaluation and development of toxicity evaluation method for biopharmaceuticals, and toxicity and carcinogenicity studies on electromagnetic waves and hazardous chemicals in the living environment.
	본 연자는 2007년도부터 안전성평가연구소에서 일반독성 및 발암성 GLP 독성평가, 유해물질에 대한 독성연구 및 신약개발과정에서의 비임상 평가에 대한 프로젝트 리더로서 활동하고 있다. 주요한 연구분야는 바이오의약품 등의 독성평가 및 독성평가기술 개발, 전자파 및 생활환경 유해 화학물질 등에 대한 독성 및 발암성 연구를 수행하고 있다.
M3+S6	**Applied cases of S6 and M3 in biologic new drug** **바이오 신약에서** S6 **및** M3**의 적용 사례**
Speaker	**Dohyun Lee** Principal Researcher, Laboratory Animal Center, Osong Medical Innovation Foundation 이도현 / 오송첨단의료산업진흥재단 실험동물센터 책임연구원
Summary	The general testing systems for pharmaceuticals (e.g., animal species and testing methods) are not suitable for most of biopharmaceuticals because it has special pharmacodynamics which are caused by biological activities. Therefore, ICH guidelines suggest flexible approaches, but it should have scientific and reasonable basis. In this lecture, scientific and suitable approach testing systems for biopharmaceutical will be reviewed based on documents for approvals, published paper and lecturer's data. Therefore, it will be helpful to prepare approvals for newly developing biopharmaceuticals.
	바이오의약품은 생물학적 작용을 통한 독특한 약력학으로 기존의 의약품 평가에서 사용되는 시스템(동물종, 평가항목 등)을 적용할 수 없는 경우가 대부분이다. 이러한 이유로 ICH 가이드라인은 이에 대한 평가를 위해 유연한 접근방식을 제시하고 있으나, 과학적이며, 합리적 근거를 가져야 한다. 본 강연에서는 기존의 바이오의약품에 대한 평가 시스템 적용에 대해, 기존의 허가자료, 문헌고찰 및 연자의 수행경

	험을 바탕으로 고찰하여, 과학적이며 명확한 근거의 바이오의약품 허가자료 준비에 도움이 되고자 한다.
Bio	Dohyun Lee received license for veterinary medicine from Ministry of Agriculture, Food and Rural Affairs, and received a master's and doctor's degree in veterinary internal medicine from Konkuk University. He worked for 7 years as research professor in Department of Clinical Pharmacology, Asan Medical Center, University of Ulsan College of Medicine, and had a post-doctoral fellowship in Barrow Neurological Institute St. Joseph Hospital and Medical Center, Phoenix, USA. He have engaged in preclinical pharmacokinetic-pharmacodynamic (PK-PD) research for new drug using various animals.
	대한민국 수의사면허를 취득한 후, 건국대학교에서 수의내과학의 석사와 박사를 취득하였습니다. 울산의대 서울아산병원 임상약리학과에서 7년간 연구교수로 재직하였으며, 미국 St. Joseph Hospital and Medical Center의 Barrow Neurological Institute에서 박사 후 연수과정을 수행하였습니다. 현재는 다양한 동물을 이용하여 신약에 대한 전임상 약동학-약력학(PK-PD)에 대한 연구를 지속적으로 수행해 오고 있습니다.
M7	**Assessment and Control of Mutagenic Impurities in Pharmaceuticals under ICH-M7**
Speaker	**Masamitsu Honma** Deputy Director General, National Institute of Health Sciences
Summary	ICH-M 7 Guideline " Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk " was established in June 2014. As safety aspect, it illustrates the use of structure activity relationship (SAR) to evaluate the mutagenicity of impurities. The M7 guideline also specifies the acceptable intake (AI) of mutagenic impurities in consideration of carcinogenic risk. Threshold of Toxicological Concern (TTC) concept was adopted, and 1.5 μg / day corresponding to a theoretical 10-5 excess lifetime risk of cancer can be justified. The TTC level can be mitigated depending on exposure duration. On the other hand, for mutagenic impurities available for rodent carcinogenicity test data, compound-specific AI can be calculated. We revised M7 (R1) guideline with addendum including 14 carcinogens' AIs in March 2017. Currently, the M7 Expert Working Group has expanded the addendum, prepared a Q & A document, and is aiming to reach the final M7 (R2) by June 2022.
Bio	Dr. Masamitsu Honma is Deputy Director-General of National Institute of Health Sciences (NIHS), Japan, since April 2020. He received the PhD degree in The University of Tokyo. After studying as a postdoctoral fellow at Harvard School of Public Health, he started research works in the field of genetic toxicology in NIHS. He has studied about DNA repair, mutagenesis, genotoxicity QSAR models, etc., and published more than 230 papers. Dr. Honma is also responsible for a lot of regulatory works in Japanese and international bodies. He has worked in International Council on Harmonisation (ICH) and Organisation for Economic Co-operation and Development (OECD) over 20 years, and currently takes a topic leader in ICH-M7. He works as a genotoxicity expert in the Drug Safety, Food Safety, Chemicals Safety, and Labor Safety Committees of Japan and reviews more than 500 genotoxicity studies annually.
M7	**ICH M7 step 2 Quality Q&A and Related Topics**
Speaker	**Kazusei Komatsu**

	Associate Principal Scientist, Analytical R&D Laboratory, CMC R&D Division, Shionogi & Co., Ltd.
Summary	After establishment of ICH M7 guideline in 2014, Q&A for the guideline is under preparation and currently in step 3 stage. In this presentation, Q&A for quality aspects and related topics, e.g. application of control strategy and purge factor, are explained.
Bio	Joined Shionogi & Co., Ltd. in 2006, and mainly working on analytical development and quality control of small molecule investigational medicinal products. ICH M7 EWG member (expert) from JPMA since 2010.
M8	**ICH M8: Shaping the Future of eCTD**
Speaker 1	**Arvind Arora** Sr. Dir. Regulatory Affairs, Regulatory Affairs Operations International, MSD International GmbH, Singapore
	Arvind Arora is currently working with MSD International GmbH, Singapore branch as a Sr. Director of Regulatory Affairs and is leading Regulatory Affairs Operations International, APAC team. His team is responsible for the regulatory operations activities related to submission planning, publishing, regulatory systems implementation & maintenance. He is also responsible for electronic submissions (including eCTD) implementation for subsidiaries in Asia Pacific. He is closely associated with eCTD format since the start of his career at Novartis where he served as a global submission publisher working on US, EU and MoW filings. Arvind is a big advocate of eCTD format and was a speaker at KRPIA 2019 Industry association meeting in Seoul, discussing about eCTD basics and its implementation. Arvind is also the Regulatory Affairs Cluster Lead for Asia North managing Hong Kong, Taiwan, Vietnam and Thailand regulatory teams. He is a master's in Pharmacy with specialization in Regulatory Affairs, Intellectual Property Rights and Pharmaceutical management.
Speaker 2	**Isabel Tan** Specialist, Regulatory Affairs, Regulatory Affairs Operations International, MSD International GmbH, Singapore
	Isabel Tan is currently working with MSD International GmbH, Singapore branch as a Regional Dossier Publisher in Regulatory Affairs Operations International, APAC team. Her responsibilities focus on publishing submissions in various formats, including eCTD, and providing technical consultation for Asia Pacific countries who have implemented eCTD or actively planning towards eCTD implementation. Isabel holds a bachelor's degree in Pharmacy from National University of Singapore.
Summary	1) As the pace of global adoption of electronic CTD (eCTD) submissions by health agencies becomes more rampant coupled with the release of the eCTD v4.0 implementation guide, the presentation will be elaborating more on the current state of eCTD technicalities, as well as how they are expected to evolve in the near future with more sophisticated functionalities. It will also cover concepts on how dossiers preparation, submission, delivery, and evaluation will be shaped with eCTD v4.0; an upcoming exciting milestone that is essential for the industry's progress. 2) The focus of presentation will be on ICH M2 which defines the current version of eCTD and ICH M8 which is shaping the future of eCTD, working on next major release, i.e., eCTD 4.0

유효성/E

E2(R3)	**Overviewof ICH E2BR3 and Japanese implementation**
Speaker	**Manabu Inoue** Manager, Drug Safety Information, MSD K.K
Summary	Overview of ICHE2BR3 finalized in 2021 and explanation of each elements will be given. In addition, I will introduce the outline and preparation of the E2BR3 report started in April 2016 in Japan, and the free tools prepared by PMDA. Finally, I will explain what should be suppressed in companies using global databases.
Bio	**Career** 1991 Joined Banyu Pharmaceutical co (Current MSD) 1991-95 MR (Sales reps) 1995-current PV dev **ICH activity** 2003-current E2BR3 EWG member(representative JPMA) **JPMA activity:** 2000-2010 Japan E2BR2 implementation project member 2011-Japan E2BR3 implementation project Leader
E3	**ICH E3 (CSR) guideline: EMA compared with FDA** ICH E3(CSR) **가이드라인** : EMA**와** FDA**의 임상 연구 보고서** (CSR) **차이점**
Speaker	**Nigel Goodman** CEO, GaeaOÜ / Gaea APAC Inc.
Summary	-
Bio	Nigel Goodman began a long working life in the pharmaceutical industry with 18 years' in Hoffmann- La Roche in the U.K and Switzerland and since then has had successful general management positions in a US biotechnology company, and a US CRO. He founded Gaea in the U.K. some 27 years ago, and in 2018 to avoid Brexit, founded GaeaOÜ a CRO working across Europe, Ukraine et al and in the USA, with headquarters in digital Estonia, one of the world's leading start-up countries. GaeaOÜ expanded CRO coverage area to Asia Pacific area, established Gaea APAC Inc. in Korea 2021. he is Respective Representative Director, and Co-founder at Gaea APAC Inc. in Seoul.
E8	**The scope and future vision of ICH E8(R1)**
Speaker	**OSAMU KOMIYAMA** Vice-chairman, Data Science Expert Committee, Japan Pharmaceutical Munufacturers Association (JPMA)
Summary	The goal of ICH GCP Renovation is to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources that are being employed to support regulatory and other health policy decisions. E8(R1), the first gudeline effort in GCP Renovation, is about to reach Step 4 agreement. E8(R1) is a high-level guideline, and the specific rules for clinical studies will be set by E6(R3). The GCP Renovation aims to re-create GCP in a new era with

	a view to diversifying study designs and data sources, as well as reflecting patients' voices in study design. The biggest impact on clinical trial practice will be a shift in clinical trial management techniques, from a backward-looking approach with ex-post quality checks at its core, to a forward-looking approach based on building quality into the trial processes. In this presentation, I will discuss what this means and how we can see the impact of this shift.
Bio	1989 Hoechst Japan (Now Sanofi) 1999 Pfizer Japan 2003 Senior Manager, Statistical Research & Consulting 2018 Senior Manager, Statistical Research & Data Science 2012-2020 Chairman, Data Science Expert Committee, JPMA 2020-now Vice-chairman, Data Science Expert Committee, JPMA ICH Expert Working Group/ Implementation Working Group; E3, E5, E17, E8(R1)
E17	**Further Consideration on the pooling strategies for MRCTs**
Speaker	**HIDEHARU YAMAMOTO** Chairman, Data Science Expert Committee, Japan Pharmaceutical Manufacturers Association (JPMA)
Summary	The pooling strategy is one of the concepts introduced by the ICH E17 guideline. When regional differences are observed in the multi-regional clinical trials (MRCTs), the pooling strategy may provide further insight into the exploration of the causes. The E17 guideline also states the value of pre-specification of pooling strategy in sections 1.4 and 2.2.5. By pre-specifying the pooling strategies, the allocation of a sample size to regions can be planned so that consistency among regions can be evaluated appropriately. We have sometimes experienced a strong dependence on the speed of enrollment, resulting in an exceptionally high or low number of subjects in some regions. In order to prevent this, it is important to define the pooling strategies in advance. The use case of the pooling strategy is not limited to the planning of the MRCT but includes unplanned exploratory analyses after the MRCT completes as well. Understanding effect modifiers and characterizing each population of interest by effect modifiers can be helpful in evaluating the consistency or inconsistency of treatment effects across populations. If effect modifiers that have a significant impact on treatment effect can be identified and agreed upon with regulatory authorities during the planning stage of an MRCT, we can construct pooled regions and allocate the overall sample size to these pooled regions.
Bio	1996 Nippon Roche 2002 Chugai Pharmaceutical Co.,Ltd 2011-2012 Genetech Inc, 2019-Now Head of Biostatistics in Biometric Department Chairman, Data Science Expert Committee, JPMA 2020-now Chairman, Data Science Expert Committee, JPMA ICH Expert Working Group/ Implementation Working Group; E17

안전성/S

S2(R1)	**Introduction of ICH S2(R1) Guideline** ICH S2(R1) **가이드라인 소개**
Speaker	**JenogJa Oh** Principal researcher, Alternative Test Center, Nonclinical Research Institute, Chemon Inc. 오정자 / ㈜켐온 비임상연구소 대체시험센터 수석연구원/센터장
Summary	I will share an overview of ICH S2(R1) guideline and genotoxicity trials.
	ICH S2(R1) 가이드라인 및 유전독성시험 간략하게 소개하고자 한다.
Bio	Since 2011, Chemon, a non-clinical CRO organization, has been in charge of genotoxicity and alternative toxicity testing.
	현재 비임상 CRO 기관인 ㈜켐온에서 2011 년부터 유전독성 및 대체독성시험 업무를 담당하고 있습니다.
S3B	**ICH S3B Pharmacokinetics: repeated dose tissue distribution studies** **약물의 분포 시험**
Speaker	**Jin-ah Hwang** Assistant professor, Department of medicinal bioscience, Konyang University 황진아 / 건양대학교 의약바이오학과 조교수
Summary	A comprehensive knowledge of the absorption, distribution, metabolism and elimination of a compound is important for the interpretation of pharmacology and toxicology studies. Tissue distribution studies are essential in providing information on distribution and accumulation of the compound and/or metabolites, this information may be useful for designing toxicology and pharmacology studies and for interpreting the results of these experiments. There has been a general agreement on the need to conduct single dose tissue distribution studies as part of the non-clinical study, however, repeated dose tissue distribution may need to be considered in cases where apparent half-life of the test compound (and/or metabolites) in organs or tissues significantly exceeds the apparent half life of the elimination phase in plasma, and steady-state levels of a compound/metabolite in the circulation are markedly higher than those predicted from single dose kinetic studies. This lecture provides you with basic concepts of drug distribution, repeated dose tissue distribution and case studies.
	약물의 흡수, 분포, 대사 및 배설에 대한 약동학적 정보는 약리 및 독성시험의 해석에 중요하다. 조직분포시험은 시험물질, 대사체 등의 분포 및 축적에 대한 유용한 정보를 제공함으로써 독성 및 약리시험을 해석하고 설계하는데 도움을 준다. 대부분의 경우 비임상 단회투여 조직분포시험만으로도 충분한 정보들을 제공하나, 생체내 반감기가 소실기의 혈장 반감기보다 확연히 길어진 경우 혹은 정상상태에서의 약물/대사체의 농도가 단회투여 동태시험을 통해 예측된 값보다 현저히 높은 경우 등에서는 반복투여 조직분포시험을 고려할 필요가 있다. 본 강의에서는 약물의 분포에 대한 이해를 돕기 위해 조직분포의 기본 개념과 약물분포시험의 일반적인 고려 사항 및 단회/반복투여 조직분포시험 등을 사례연구 자료와 함께 살펴보고자 한다.
Bio	Dr. Hwang is a professor of Medicinal Bioscience at Konyang University. She had worked for Drug metabolism & Pharmacokinetics(DMPK) team at LG Life Science 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.
	황진아교수는 건양대학교 의약바이오학과 교수로 재직 중이다. 2004 년 LG 생명과학에 입사하여 DMPK 팀에서 13 년간 연구원으로 근무하면서 약물대사 및 PK/TK 연구원, 비임상 총괄 책임자, 프로젝트 리더 등의 역할을 수행했다. 주요 연구분야는 다양한 타겟에 대한 합성의약품 및 바이오시밀러를 포함한 바이오의약품의 전임상/임상 약동학 분야이다. 충남대학교에서 생물학을 전공하고, 동대학교 약학대학에서 약물의 약동학적 특성 규명 및 최적의 임상 2 상 용량 선정을 위한 PK/PD 모델링&시뮬레이션을 주제로 학위 (석사, 박사)를 받았다.
S9	**ICH S9 Guideline (Nonclinical Evaluation for Anticancer Pharmaceuticals) Overview** ICH S9 **가이드라인 (항암제를 위한 비임상 평가) 개요**
Speaker	**Ju Mi Kim** Scientific Advisor, Non-Clinical Supervisor, Ginapath 김주미 / 지나패스 이사
Summary	The ICH S9 guideline provides information on overall recommendations for nonclinical studies necessary for the development of anticancer drugs. This lecture provides thorough understanding of the purpose and background, scope of application and general principles of this guideline and the aspects to be particularly considered in anticancer drugs are examined for each non-clinical test item in comparison to those considered in the general drug development.(Pharmacology, Safety Pharmacology, PK, General tox., Genotoxicity, Carcinogenicity, Immunotox., Photosafety)
	ICH S9 가이드라인은 항암제 개발시 필요한 비임상시험에 대한 전반적인 권고사항들에 대한 정보를 제공하고 있다. 이 가이드라인의 목적과 배경, 적용범위와 일반원칙 등을 잘 이해하고, 일반의약품 개발시 고려되는 비임상시험과의 비교를 통해 항암제에서 특히 고려되어야 하는 사항들에 대해 각각의 비임상시험 항목별로 살펴본다. (약리시험, 안전성 약리시험, 약물동태시험, 일반독성시험, 생식독성시험, 유전독성시험, 발암성시험, 면역독성시험, 광안전성 시험)
Bio	Director Jumi Kim received a bachelor's degree from Kyungpook National University's College of Veterinary Medicine and a master's degree from medical school, and has worked at Dong-A ST research center for 20 years to evaluate the effectiveness and safety of drug candidates. Currently, she provides advisory services on the overall process when performing non-clinical studies with overseas CROs in Ginapath. Specifically, she is working as an overall scientific advisor to the progress of contract toxicity tests with overseas CROs necessary when various domestic pharmaceutical industries and bio-ventures develop new drugs
	김주미 이사는 경북대학교 수의과대학에서 학사, 의과대학에서 석사학위를 받았으며, 동아 ST 연구소에서 20 년간 의약품 후보물질의 유효성 및 안전성 평가 업무를 수행하였다. 현재는 지나패스에서 해외 CRO 의 비임상시험 진행시 시험 전반에 대한 자문서비스를 제공하고 있으며, 구체적으로는 국내 여러 제약사 및 바이오벤처사의 신약개발시 필요한 해외 CRO 와의 위탁 독성시험 진행에 대한 전반적인 scientific advisor 로 활동하고 있다.

S8	**Successful Application of ICH S8 in IND and NDA Preparation** IND **및** NDA **작성시** ICH S8**의 적용**
Speaker	**Woo Suk Koh** Head of Quality, Quality Division, Prestige Biologics 고우석 / 프레스티지바이오로직스 품질본부 본부장
Summary	Immunotoxicity is one of the portions that is easily overlooked in nonclinical study program for new drug development. Immunotoxicity itself is not easy to evaluate in general toxicity studies performed in cleanly controlled environments without functional tests. This presentation will discuss how the nonclinical personnel in pharmaceutical companies understand immunotoxicity that might cause serious outcomes in clinical practice, and manage cases in association with the ICH S8 guidelines, especially considerations when preparing IND and NDA.
	신약개발에 있어 면역독성은 간과하기 쉬운 부분의 하나이다. 면역독성 자체는 기능시험 항목이 없고 청결하게 조절된 환경조건에서 수행되는 일반독성 시험에서 평가하는 것이 쉽지 않다. 본 발표에서는 임상에서 치명적인 결과를 유발할 수도 있는 면역독성을 제약사 실무자의 입장에서 어떻게 이해하고 경우에 따른 실제 대응방법 특히 IND 및 NDA 작성시 고려사항 등을 ICH S8 가이드라인을 통하여 다루어 보고자 한다.
Bio	Dr. Koh received his PhD in toxicology from KAIST, finished his post doc in Michigan State University and NIH, and joined Korea Institute of Toxicology as a study director in toxicology and immunogenicity studies. After then he had worked for Coretox, Hanwha Chemicals, and DGMIF in nonclinical studies. He currently works for Prestige Biologics as the Head of Quality Division.
	연자는 KAIST 에서 독성학으로 박사학위를 받았으며 미시간주립대와 NIH 에서 포스트닥을 마치고 2000 년 한국화학연구원 안전성평가연구소에서 주로 생물의약품의 독성시험 및 면역원성 분야에서 시험책임자로 근무하였다. 이후 코어톡스, 한화케미칼, 대구첨복 등에서 비임상시험 분야에서 주로 역할을 수행하였으며 현재 프레스티지바이오로직스에서 항체의약품분야의 품질본부장으로 근무 중이다.
S10	**Photosafety Evaluation of Pharmaceuticals since Implementation of ICH S10**
Speaker	**Daniel Bauer** Associate Director, Preclinical Safety, Novartis Pharma AG, Basel, Switzerland
Summary	Phototoxic properties of systemically applied pharmaceuticals may be the cause of serious adverse drug reactions. Despite being clinically manageable in principle, they can limit the use of a drug depending on the indication. Protective measures against sunlight can be applied very reasonably during a few days but may not be practicable for chronic treatments. Thus, both patients and health authorities are unlikely to accept a relevant phototoxicity risk in such situations. ICH S10 provides guidance how a potential phototoxicity risk should be addressed during drug development in a tiered approach. Importantly, safety margins can be used to support human risk assessment based on Cmax (NOAEL in animals vs. clinically efficacious exposure at steady state).
Bio	Daniel Bauer is a trained chemist and board-certified toxicologist. With 20 years of experience in the pharmaceutical industry as lab head and study director, he is currently leading in vitro screening for genetic toxicology and photosafety at Novartis in Basel, Switzerland. In addition, he acts as project toxicologist and global expert for photosafety. For EFPIA, he was a member of the ICH S10 Expert Working Group representing the European pharmaceutical industry. He is also a member of the OECD Expert Group for Skin & Eye Irritation supporting recently revision and adoption of Test Guidelines for Phototoxicity (revised TG 432, new 495 and 498).

품질/Q

Q3A (R2)	**Understanding of Guideline ICH Q3A (R2) Impurities in New Drug Substance** **신규원료불순물 가이드라인 이해**
Speaker	**SE KWEON KIM** Director, Head of CMC, BioPlant R&D, Hanmi Pharm. Co., Ltd. 김세권 / 한미약품 바이오플랜트 연구개발 이사
Summary	Through the explanation of the guideline 'ICH Q3A (R2) Impurities in New Drug Substance', classification, identification, lifetime management, establishment of analytical method, specification of impurities, and precautions for regulatory filing will be discussed.
	ICH Q3A (R2) Impurities in New Drug Substance 의 내용을 이용하여 원료의약품 제조 및 보관 중 발생할 수 있는 유연물질의 분류, 확인방법, 전주기적 관리방법, 분석법 설정 및 허가자료 작성을 위한 주의사항에 대한 설명
Bio	Kim Se Kweon received a master's degree in biotechnology from Inha University and joined Green Cross for 7 years in the quality control department. Since 2007, he had been responsible for the quality control of recombinant protein drugs (LAPSCOVERY Products), And currently, he is responsible for the process development, analytical development, and regulatory documentation department of Hanmi BioPlant. In addition, he is responsible for the CMC management of LAPSCOVERY products including products licensed out to global partners.
	인하대학교 생물공학과에서 생물공학 석사 학위를 받았으며, 2000 년부터 녹십자에서 품질관리 업무로 제약 관련 경력을 시작하였고, 2007 년부터는 한미약품에서 유전자재조합 단백질의약품(LAPSCOVERY products)의 품질관리 업무를 수행했습니다. 현재는 유전자재조합의약품의 공정개발, 분석개발, 및 허가문서의 작성 부서의 책임 업무와, Global 파트너사로 기술수출 된 Project 를 포함한 LAPSCOVERY 제품의 CMC management 업무를 담당하고 있습니다.
Q3B(R2)	**Overview of ICH Q3B and control strategies for impurities in Drug Product** ICH Q3B **개요 및 완제의약품의 유연물질 관리전략**
Speaker	**Hyesuk Hong**, Director, CMC development, Ubix Therapeutics 홍혜숙 / 유빅스테라퓨틱스 CMC 개발실 이사
Summary	This presentation will provide an overview of the impurities of the drug Product. It also broadly understands the structure of the drug substance and the characteristics of the excipients, predicts the origin of the impurities, and discusses how to control the amount of the impurities generated in the manufacturing and storage process of the Drug product. The formation of the impurities is not limited to drug related impurities and there is several possibilities of the drug-excipient adduct formations as well as excipient impurities reaction with Drug substances. This presentation will discusses basis drug-excipient interactions through case studies.
	프레젠테이션은 의약품의 불순물에 대한 개요를 제공합니다. 또한 주성분의 구조와 부형제의 특성을 폭넓게 이해하여 불순물의 발생원인을 예측하고 의약품 제조 및 보관과정에서 발생하는 불순물의 양을 조절하는 방법을 논의한다. 불순물의 형성은 약물 관련 불순물에만 국한되지 않으며 약물과 부형제의 반응을 통해 분해산물이 생성될 가능성이 있다.

	이 프레젠테이션에서는 사례 연구를 통한 기본적인 약물-부형제 상호작용에 대해 논의할 것이다.
Bio	Currently, Hyesuk Hong is the Director of Chemistry, Manufacturing, and Controls at Ubix Therapeutics. She has over 21 years of broadly diversified pharmaceutical development, having led analytical and drug development in the pharmaceutical industry. Prior to joining Ubix Therapeutics, HS Hong was Director of CMC at pH Pharma where she was responsible for API and DP development and manufacturing as well as Clinical Supply. She served as the Head of the research institute at Alvogen Korea and as the Head of the analysis team at Handok and CJ Healthcare, she was responsible for Product development, process analytical, method development, and testing for both API and DP.
	현재 유빅스테라퓨틱스에서 CMC 개발을 책임지고 있습니다. 그녀는 제약산업분야에서 제품개발, 분석업무 등 다양한 분야의 업무경험을 가지고 있고, 유빅스테라퓨틱스 이전에도 pH pharma 에서 CMC 책임자로서 원료, 완제 개발 및 임상의약품 공급에 대한 전반적인 업무를 총괄하였습니다. 이전에는 알보젠코리아에서 연구소장, 한독, CJ 헬스케어에서 분석팀장을 역임하면서 혁신신약, 바이오의약품 및 개량신약에 대한 제품개발 및 분석업무 등을 담당했습니다.
Q3D	**ICH Q3D: Elemental Impurities – Development, evolution and implementation**
Speaker	**Mark Schweitzer** Principal, Mark Schweitzer Consulting, LLC
Summary	This presentation will provide an overview of the history of the development of ICH Q3D: Elemental Impurities, approaches to the completion of Elemental Product Assessment and the in-process revision of the Guideline intended to address dermal routes of administration. The concepts introduced in the Guideline will be reviewed using example case studies to provide insight to ways in which companies have addressed the completion of the elemental impurity assessments. Finally, a summary of the current status of global pharmacopoeial harmonization efforts will be presented.
Bio	Over the past 37+ years, Dr. Schweitzer has held senior positions in analytical development, quality control and quality, the most recent of which was as the Global Head of Analytical Science & Technology and Scientific Initiatives in Novartis Quality. Prior to joining Novartis, he was the Global Head of Analytical Development (small molecules and biologicals) for AbbVie. Additional positions in Analytical and Formulation Development (Searle/Pharmacia/Pfizer) and specialty analytical (Battelle Memorial Institute and Rohm & Haas) provided increasing breadth and depth of experience in the analysis of impurities in a wide variety of matrixes. Most recently, Dr. Schweitzer directed the development of the strategic approach to the assessment of nitrosamine impurities and elemental impurities in pharmaceuticals. He has been active in ICH as the rapporteur for the ICH Q3D: Elemental Impurities Expert Working group through step 2 and was the PhRMA topic lead in the EWG until his retirement from industry. As the Vice-Chair of the USP General Chapters Chemical Analysis Expert Committee, he has been involved in sub-committees defining the standards for elemental impurities and chaired the USP Joint Subcommittee for Nitrosamine Impurities in Pharmaceuticals. Dr. Schweitzer earned his Ph.D. from The Ohio State University Department of Chemistry and has focused his career on analytical method development, validation and transfer of chromatographic analyses and complex

	methods (e.g. HPLC-MS/MS and GC-MS/MS). Additional areas of experience include: assurance of data integrity, development and validation of IT applications (e.g. LIMS), elemental impurity product assessments, and development of analytical strategies to improve compliance with new and evolving regulations, quality and efficiency improvement.
Q3D	**Guideline for the evaluation and control of elemental Impurities** **의약품 금속불순물 평가 및 관리**
Speaker	**Hyunkyung Kang,** Deputy Director, Pharmaceutical Standardization Division, Drug Evaluation Department, MFDS/NIFDS 강현경 연구관 / 식품의약품안전평가원 의약품규격과
Summary	This presentation explains the background of the development of the ICH Q3D guideline, its application in Korea, and the revision history of relevant regulations on drug review. In addition, it will discuss the main contents of the guideline, namely, risk assessment of elemental impurities and strategies to manage the established permitted daily exposures(PDEs). Real examples of assessing the risk of elemental impurities in the review are shared.
	ICH Q3D 가이드라인의 개발 배경 및 우리나라에서의 적용 및 관련 심사 규정 개정 연혁에 발표함, 이와 더불어 가이드라인의 주요내용, 즉 금속불순물 위해평가와 일일 최대투여량 관리전략에 대해 설명하며, 실제심사에서 금속불순물 위해 평가 예시에 대해 발표한다.
Bio	Hyun Kyung Kang is a pharmacist. She joined MFDS/NIFDS in 2004 and has been responsible for reviewing drugs and developing review criteria and guidelines.
	약사, 2004 년부터 식품의약품안전평가원에서 의약품 심사, 심사기준 연구 및 가이드라인 마련 업무 수행하고 있음
Q3C	**ICH Q3C: Overview and implementation of Guideline for residual solvents** ICH Q3C: **잔류용매 가이드라인 이해 및 의약품에서의 적용**
Speaker	**HeeJung Lim** Chief of analytical research, Analytical Research, Pharmaceutical Technology Research Center, JW Pharmaceutical 임희정 / JW 중외제약 제제연구센터 분석연구팀장
Summary	ICH Q3C guideline is to recommend acceptable amounts for residual solvents in pharmaceuticals for the safety of the patient. The presentation will provide overview of this guideline and introduce implementation of this guideline in the pharmaceutical industry.
	ICH Q3C 가이드라인은 환자의 안전을 위하여 의약품 중 잔류용매 허용량을 권고하는 것입니다. 이 가이드라인의 주요 내용을 정리하고, 의약품 산업에서 어떻게 적용하는지 살펴보고자 합니다.
Bio	HeeJung Lim received a master's degree in analytical chemistry from Yeungnam University and joined JW pharmaceutical for 20 years in the analytical research team. She is responsible for analytical method development, impurity profile, and CMC documentation of regulation approval for chemical API and Product. She is member of Korea Association of Research Pharmaceutical Analysis, KDRA
	영남대학교에서 분석화학을 전공하였으며, JW 중외제약에 입사하여 현재까지 약

	20 년간 원료 및 완제의약품의 분석법 개발, 불순물 프로파일, 국내외 허가용 CMC 문석 작성 등을 주관하고 있습니다. 한국신약조합개발 한국의약분석연구회 위원으로 활동하고 있습니다.
Q3C	**Considerations on ICH Q3C (R8) and USP General Chapters <467> Residual Solvents and <1467> Residual Solvents-Verification of Compendial Procedures and Validation of Alternative Procedures**
Speaker	**Edmond Biba** Principal Scientist, Science – General Chapters, United States Pharmacopeia
Summary	Several processes in drug substance and drug product manufacturing use solvents. With few exceptions, it has been proven almost impossible to completely remove the solvents used during manufacturing, and the remaining solvents are considered impurities. Therefore, the pharmaceutical industry has been always concerned regarding the kind of solvents they use and the levels of them remaining in the product. The today's presentation addresses the evolution of the residual solvents in pharmaceutical products topic, the status and updates in the ICH and US pharmacopeia and the road ahead. The Residual Solvents <467> was proposed in Pharmacopeia Forum (PF 29(4) in 2003 following the ICH Q3C Guideline of 1997. The ICH Q3C Guideline and USP <467> have been updated several times. The status of both documents will also be addressed today. More specifically, the new solvents added to Q3C in its eighth revision (ICH Q3C (R8) and ICH Stage 4 is covered. The USP is work on incorporating the ICH Q3C (R8) in Residual Solvents <467> chapter, as well as the different options that are available to the users from the latest revision to <467> and the new chapter Residual Solvents – Verification of Compendial Procedures and Validation of Alternative Procedures <1467> will also be discussed.
Bio	Dr. Edmond Biba is a Principal Scientist in the General Chapters Department-Science Division at United States Pharmacopeial Convention. He joined USP in 2001 and has served as a scientist in the Research and Development Laboratory and in the Reference Standards Evaluation Department prior to joining General Chapters in 2015. Before joining USP, Dr. Biba was a National Research Council-Walter Reed Army Institute of Research Postdoctoral Fellow in the Medicinal Chemistry Department of Experimental Therapeutic Division. Dr. Biba received his Ph.D. in Chemistry-Synthetic Organic Chemistry from the American University, Washington DC, and a B.Sc. in Chemical Engineering/Chemistry from University of Tirana, Tirana, Albania. Dr. Biba is member of Sigma Xi – The Scientific Research Honor Society, American Chemical Society, American Association of Pharmaceutical Scientists, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q3C (R9) Working Group, and a member of Product Quality Technical Committee of the Product Quality Research Institute (PQRI).