

# 2022 춘계 국제심포지움

2022 KSOT/KEMS Spring International Symposium

# Current Issues in Biotherapeutics

(바이오헬의약품 안전성 연구의 최신 동향)

May 13 (Friday), 2022

- In-Person & Virtual

- Venue : Samsung Convention Center, Seoul National University, Seoul, Korea

2022 춘계 독성학 워크샵

## 첨단바이오헬의약품과 살생물제의 안전성평가와 최신 이슈

May 12 (Thursday), 2022

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### 2022 춘계 독성학 워크샵

#### 첨단바이오헬의약품과 살생물제의 안전성평가와 최신 이슈

13:20-13:30 개회사 사회 : 이주영 교수 (가톨릭대학교)  
천영진 회장 (한국독성학회)

13:30-15:30  
**Part 1** **첨단바이오헬의약품의 안전성평가 및 개발동향**  
좌장 : 송미경 박사 (안전성평가연구소)

13:30-14:00 바이오의약품의 면역독성  
고우석 박사 (프레스티지바이오템즈㈜)

14:00-14:30 생체 분자영상을 이용한 바이오의약품의 비임상 분포 평가  
박현수 박사 (서울대학교)

14:30-15:00 항체-약물 중합체의 유효성/안전성 평가 관련 글로벌 연구 및 규제동향  
이병일 박사 (LG생명과학)

15:00-15:30 항체-약물 중합체의 특성 및 약물동태학적 특성 분석을 위한  
기반기술 개발  
진중화 박사 (오송첨단의료산업진흥재단)

15:30-16:00 Break

16:00-18:00  
**Part 2** **살생물제의 안전성평가 및 관리**  
좌장 : 박용주 교수 (경성대학교)

16:00-16:30 화학제품안전법 이행을 위한 살생물제 승인 규정의 이해  
김려욱 연구사 (국립환경과학원)

16:30-17:00 살생물제 구제제류의 효과 · 효능 시험방법 개발 및 평가  
탁준형 교수 (서울대학교)

17:00-17:30 화학제품안전법상 살생물제의 독성시험 개요  
엄현수 소장 (안전성평가솔루션(주))

17:30-18:00 중대재해처벌법 이해 및 대응  
김경윤 전문위원 (노무법인 더원)

18:00-18:10 총평 및 폐회사

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(바이오헬의약품 안전성 연구의 최신 동향)

09:30-9:50 **Welcome Remarks**  
Dr. Young-Jin Chun (President of KSOT, Chung-Ang University)  
Dr. Kyung Won Seo (Director General, National Institute of Food and Drug Safety Evaluation)  
Dr. Eun Ju Jeong (President of Korea Institute of Toxicology)

09:50-10:30 **Plenary Lecture I**  
Chairperson: Dr. Hyung Sik Kim (Sungkyunkwan University)  
Key Concepts in Nonclinical Safety Assessment of Antisense Oligonucleotides (ASOs)  
Dr. Tae-Won Kim (IONIS Pharmaceuticals, USA)

10:30-10:40 Break / Exhibition Visiting

10:40-12:10  
**Session 1 : The Development of mRNA Vaccine and Its Side Effects**  
Chairperson: Dr. Ki Taek Nam (Yonsei University)

10:40-11:10 mRNA Vaccine and Its Adverse Effect  
Dr. Jae-Hwan Nam (The Catholic University of Korea)  
11:10-11:40 Clinical Significance of mRNA COVID-19 Vaccine Adverse Reactions  
Dr. Jacob Lee (Hallym University Kangnam Sacred Heart Hospital)  
11:40-12:10 Myocarditis: A Serious Complication of mRNA Vaccine for COVID-19  
Dr. Eun Seok Jeon (Samsung Medical Center/Sungkyunkwan University)

12:10-13:30 Exhibition Visiting / Council Meeting

13:30-14:10 **Plenary Lecture II**  
Chairperson: Dr. Tae Cheon Jeong (Yeungnam University)  
Development of An Oral Delivery System for Immunomodulatory Oligodeoxynucleotides  
Dr. Suguru Shigemori (Shinshu University, Japan)

14:10-15:40  
**Session 2 : Advanced Biologics – Safety and Efficacy Issues in Preclinical and Clinical Study**  
Chairperson: Dr. Kyung-Min Lim (Ewha Womans University)

14:10-14:40 Forefront of In Vivo Genome Editing for Vision  
Dr. Jeong Hun Kim (Seoul National University Hospital)  
14:40-15:10 Current Status of CAR-T, Its Pros and Cons  
Dr. Hyoung Jin Kang (Seoul National University Hospital)  
15:10-15:40 Clinical Development of Olinvacimab and Other Novel Therapeutics  
Dr. Jin-San Yoo (PharmAbcine)

15:40-16:00 Break / Exhibition Visiting

16:00-17:30  
**Session 3 : Considerations on Non-clinical Assessment of Biologics**  
Chairperson: Dr. Ki-Suk Kim (Korea Institute of Toxicology)

16:00-16:30 PBMC-humanized Mouse Models for Efficacy Evaluation of Immuno-oncology Drugs  
Dr. Jong Soon Kang (Korea Research Institute of Bioscience and Biotechnology)  
16:30-17:00 Preclinical Safety Aspects of MSC-derived Extracellular Vesicles in Drug Development  
Dr. Kyoung-Sik Moon (Korea Institute of Toxicology)  
17:00-17:30 Considerations on Non-clinical Assessment of Biologics  
Dr. Kyoung Suk Choi (Ministry of Food and Drug Safety)

17:30-17:40 Closing Remarks