식품의약품안전처
식품의약품안전평가원

NIFDS-USP 첨단바이오의약품 규제과학 공동 워크숍

첨단바이오의약품 특성을 고려한 품질평가 방안 및 국내·외 신기술 기반
규제과학 연구 정보 제공을 통한 제품화 촉진을 위해 식품의약품안전평가원(NIFDS)과
미국약전위원회(USP)와의 첨단바이오의약품 규제과학 공동 워크숍을 아래와 같이 개최합니다.
관심 있는 국내 연구·개발자 분들의 많은 참여를 바랍니다.

동시통역(한-영) 지원

2021. 10. 14(목) - 15(금) 09:00-12:00

장소 **온라인**

대상 **첨단바이오의약품 개발 업계 종사자 및 연구개발자**

사전등록

사전등록 기간 10월 11일(월요일)까지

- 사전등록 시 발표자에 대한 사전질의도 접수하고 있습니다.
- 사전등록하시고 행사 이후 만족도 설문에 참여하신 분들께 소정의 선물을 증정합니다.

문의사항(워크숍 준비사무국)
Tel. 031-967-0158 **Email.** nifdsusp@gmail.com

PROGRAM

DAY 1 10/14, Thursday

Opening Session

Moderator Misun Park (Director, NIFDS)

09:00-09:15
- Opening Remarks / Greeting
  Kyung Won Seo (Director General of NIFDS)
- Opening Remarks / Greeting
  Ronald T. Piervincenzi (CEO, USP)

Session 1

Regulatory Perspective of Raw Materials and Advanced Biopharmaceuticals

Moderator Minkyung Kim (Scientific Affairs Manager, USP)

09:15-10:25
- Regulatory perspective for advanced biopharmaceuticals
  Song Hee Park (Scientific Officer, NIFDS)
- Raw materials for cell and gene therapy products - Regulatory perspective
  Scott R. Burger (Founder and Principal, Advanced Cell & Gene Therapy)
- Qualification of raw materials - Compendial perspective
  Kevin Carrick (Director, USP)
- Q&A

Session 2

QC of Raw Materials and Manufacturing of Advanced Biopharmaceuticals

Moderator Minkyung Kim (Scientific Affairs Manager, USP)

10:25-11:15
- Standards to support quality of raw materials (case studies)
  Jerome Jacques (Principal Scientist, USP)
- Plasmid DNA – a critical raw material for gene therapy
  Lili Belcastro (Principal Scientist, BMS)
- Q&A

11:15-12:25
- New tools for QC assessment of raw materials (I)
  - Characterization of raw materials of advanced biopharmaceuticals
  Kyeung Min Joo (Professor, Sungkyunkwan Univ.)
- New tools for QC assessment of raw materials (II)
  - Genetic stability analysis of raw materials using microassay and NGS
  Myungshin Kim (Professor, Catholic Univ.)
- Recent mycoplasma test for cell therapy
  Ja-Lok Ku (Professor, Seoul National Univ.)
- Q&A

DAY 2 10/15, FRIDAY

Session 3

Comparability Plan

Moderator Ki Dae Park (Senior Scientific Officer, NIFDS)

09:30-10:20
- Transition from small lab scale to commercial production
  Kyungdong Bae (Executive Director, Helixmith)
- Comparability at different stages of development
  Mo Heidaran (Vice President, Parexel)
- Q&A

Session 4

QC Assessment for Advanced Biopharmaceuticals

Moderator Ki Dae Park (Senior Scientific Officer, NIFDS)

10:20-11:10
- Off-target analysis for genome-editing based gene therapy products
  Hyongbum Kim (Professor, Yonsei Univ.)
- Quality and safety evaluation test for 3D-bioprinting products
  Sung Won Kim (Professor, Catholic Univ.)
- Q&A

11:10-11:20
- Closing Remarks
  Soo Jung Sohn (Director General, NIFDS)