



# NIFDS-USP 첨단바이오횰약품 규제과학 공동 워크숍

첨단바이오횰약품 특성을 고려한 품질평가 방안 및 국내·외 신기술 기반  
규제과학 연구 정보 제공을 통한 제품화 촉진을 위해 식품의약품안전평가원(NIFDS)과  
미국약전위원회(USP)와의 첨단바이오횰약품 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 **첨단바이오횰약품 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)

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|-------------|---|
| 09:00-09:15 | <p><b>Opening Remarks / Greeting</b><br/>Kyung Won Seo (Director General of NIFDS)</p> <p><b>Opening Remarks / Greeting</b><br/>Ronald T. Piervincenzi (CEO, USP)</p> |
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### Session 1

#### Regulatory Perspective of Raw Materials and Advanced Biopharmaceuticals

**Moderator** Minkyung Kim (Scientific Affairs Manager, USP)

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|-------------|---|
| 09:15-10:25 | <p><b>Regulatory perspective for advanced biopharmaceuticals</b><br/>Song Hee Park (Scientific Officer, NIFDS)</p> <p><b>Raw materials for cell and gene therapy products - Regulatory perspective</b><br/>Scott R. Burger (Founder and Principal, Advanced Cell &amp; Gene Therapy)</p> <p><b>Qualification of raw materials - Compendial perspective</b><br/>Kevin Carrick (Director, USP)</p> <p>Q&amp;A</p> |
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### Session 2

#### QC of Raw Materials and Manufacturing of Advanced Biopharmaceuticals

**Moderator** Minkyung Kim (Scientific Affairs Manager, USP)

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| 10:25-11:15 | <p><b>Standards to support quality of raw materials (case studies)</b><br/>Jerome Jacques (Principal Scientist, USP)</p> <p><b>Plasmid DNA - a critical raw material for gene therapy</b><br/>Lili Belcastro (Principal Scientist, BMS)</p> <p>Q&amp;A</p>   |
| 11:15-12:25 | <p><b>New tools for QC assessment of raw materials (I)</b><br/>- Characterization of raw materials of advanced biopharmaceuticals<br/>Kyeung Min Joo (Professor, Sungkyunkwan Univ.)</p> <p><b>New tools for QC assessment of raw materials (II)</b><br/>- Genetic stability analysis of raw materials using microassay and NGS<br/>Myungshin Kim (Professor, Catholic Univ.)</p> <p><b>Recent mycoplasma test for cell therapy</b><br/>Ja-Lok Ku (Professor, Seoul National Univ.)</p> <p>Q&amp;A</p> |

**DAY 2** 10/15, FRIDAY

### Session 3

#### Comparability Plan

**Moderator** Ki Dae Park (Senior Scientific Officer, NIFDS)

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| 09:30-10:20 | <p><b>Transition from small lab scale to commercial production</b><br/>Kyungdong Bae (Executive Director, Helixmith)</p> <p><b>Comparability at different stages of development</b><br/>Mo Heidarani (Vice President, Parexel)</p> <p>Q&amp;A</p> |
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### Session 4

#### QC Assessment for Advanced Biopharmaceuticals

**Moderator** Ki Dae Park (Senior Scientific Officer, NIFDS)

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| 10:20-11:10 | <p><b>Off-target analysis for genome-editing based gene therapy products</b><br/>Hyongbum Kim (Professor, Yonsei Univ.)</p> <p><b>Quality and safety evaluation test for 3D-bioprinting products</b><br/>Sung Won Kim (Professor, Catholic Univ.)</p> <p>Q&amp;A</p> |
| 11:10-11:20 | <p><b>Closing Remarks</b><br/>Soo Jung Sohn (Director General, NIFDS)</p>  |