Quality Innovation for Better Health!
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The 6th International Webinar Conference on Pharmaceutical Quality Regulatory Sciences Organized Jointly by NIFDS and RFPQ

Development and Quality Assurance of Innovative Manufacturing Technology (IMT)-based Pharmaceuticals

Platform: Zoom
Presentation Room : Room K, 2F, KPBMA
Date: November 2 (Tuesday), 2021

Hosted by RFPQ and NIFDS
Supported by KPBMA, KPTA, KPA, KDRA, Yakup, Dailypharm

MFDS : Ministry of Food and Drug Safety
NIFDS : National Institute of Food and Drug Safety Evaluation
PMRJ : Pharmaceutical and Medical Device Regulatory Science Society of Japan
RFPQ : The Research Foundation for Pharmaceutical Quality
KPBMA : Korea Pharmaceutical and Bio-Pharma Manufacturers Association
KPTA : Korea Pharmaceutical Traders Association
KPA : The Korean Pharmaceutical Association
KDRA : Korea Drug Research Association

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Webinar's Agenda (Tentative)

This webinar is aimed to understand and promote development and quality assurance of innovative manufacturing technology (IMT)-based pharmaceuticals, by applying continuous manufacturing (CM, ICH Q13) technologies in pharmaceutical company. Webinar conference will be composed of three sessions and panel discussion with simultaneous translation.

1. Session I: Current regulatory considerations and challenges for IMT in Korea

- Policy-level support for application of IMT including CM to pharmaceuticals
- International regulatory status of IMT including CM
- Regulatory status of quality by design and PAT

2. Session II: Current status and challenges of CM in Japan

- Regulatory considerations (including approval review) and challenges
- Techniques for manufacturing and quality controls, and RTRT
- Industrial status in PAT, process system technologies and models

3. Session III: Promoting and realizing CM in pharma industry

- Governmental support and results for IMT in Korea
- Understanding and perspectives of CM in the viewpoint of ICH Q13
- Case study of PAT application in pharma industry
- Change control from batch production to CM
- Chemometrics and statistical tools

4. Panel discussion on CM

Six panelists (three speakers each from Japan and Korea) will discuss about challenges from regulatory, quality and technology aspects, each for five minutes, and related answers or comments among panelists will be given in real-time for 50 minutes.

Please understand that suggested agenda may be changed, depending on the request from speakers or moderator, and emerging topic

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혁신제조기술 기반 의약품 개발 및 품질보증

Program (Tentative)

Webinar Host : Prof. Jung Hwan Cho

08:30 – 09:00	**Registration**	
09:00 – 09:20	**Opening session**	
	Opening remark Words of encouragement Congratulatory message	RFPQ NIFDS KPBMA Shigeki Tsuda
09:20 – 10:50	Organizer : Sunmi Kim (Deputy Director, NIFDS) Moderator : Prof. Sung-Joo Hwang (Yonsei University) Session Ⅰ : Current Regulatory Considerations and Challenges for IMT in Korea 국내 혁신제조기술에 관한 규제 현황 및 과제	
09:20 – 09:40	- Current status of MFDS policy for quality by design (QbD) 설계기반 품질에 대한 식품의약품안전처 정책의 현황	Na-young Kim Deputy Director, Pharmaceutical Quality Division, MFDS
09:45 – 10:15	- Access to innovative medicine 혁신 의약품에 대한 접근	Oh, Sang-Yeon Deputy Director, Pre- Submission Consultation Division, NIFDS
10:20 – 10:50	- Regulatory perspective and cases on real time release testing (RTRT) 실시간 출하시험 적용 의약품의 심사 방안 및 사례	Kyungshin Lee Deputy Director, Advanced Drug Quality Division, NIFDS
11:00 – 13:45	Organizer : Shigeki Tsuda (Senior Managing Director, PMRJ, Japan) Moderator : Prof. Jong-Seong Kang (Chungnam National University) Session Ⅱ : Current Status and Challenges of Continuous Manufacturing in Japan 일본의 연속 생산 현황과 과제	
11:00 – 11:35	- PMDA perspective on continuous manufacturing 연속 생산에 대한 PMDA 관점	Yoshihiro Matsuda Senior Scientist for Quality, PMDA
11:40 – 12:15	- Monitoring and control techniques for continuous manufacturing 연속 생산을 위한 모니터링 및 제어 기술	Manabu Kano Professor, Department of Systems Science, Kyoto University
12:15 – 13:10	**Lunch**	
13:10 - 13:45	- Development of control strategy for continuous manufacturing 연속 생산을 위한 관리 전략 개발	Keiji Inoue Group Manager, CMC RA Department, GlaxoSmithKline K.K.

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13:50 – 16:55	Organizer : RFPQ Moderator : Prof. Kwan Hyung Cho (Inje University) Session Ⅲ: Promoting and Realizing Continuous Manufacturing in Pharma Industry 제약산업의 연속생산 활성화 및 실현	
13:50 – 14:20	- Pharmaceutical manufacturing process and quality advancement- current status and prospects of Korean pharmaceutical Industry 의약품 제조 및 품질 고도화 – 한국 제약산업의 현황과 전망	Kyung Hwa Huh CEO, Korea Innovative Medicines Consortium
14:25 – 14:55	- Regulatory considerations to adopt continuous manufacturing in Korea 국내 연속생산 도입을 위한 규제상의 고려사항	Hyang Won Min Sr Director / Regulatory & Medical Affairs, Janssen Korea
15:00 – 15: 30	- Case sharing: regulatory approval of drug product manufactured by continuous manufacturing 사례공유 : 연속생산으로 제조한 의약품의 규제적 허가	Yu Jin Jung PhV and RA Manager, MQRA, Lilly Korea Ltd.
15:30 – 15:50	**Break time**	
15:50 – 16:20	- PAT applications for continuous manufacturing 연속공정을 위한 공정분석기술의 이해와 적용	Woo, Young-Ah OSD Director, Chong Kun Dang Pharm
16:25 – 16:55	- Major chemometric tools for the process analytical technology 공정분석 기술을 위한 주요 계량화학적 도구	Jung Hwan Cho Professor, Sookmyung Women's University
17:00 – 17:50	Moderator : Prof. Hyo Jin Kim (Dongduk Women's University) Panel Discussion on Continuous Manufacturing	
17:00 – 17:50	- Panelists Na-young Kim (NFDS) Yoshihiro Matsuda (PMDA) Manabu Kano (Kyoto University) Keiji Inoue (GlaxoSmithKline K.K.) Hyang Won Min (Janssen Korea) Young-Ah Woo (Chong Kun Dang Pharm)	
17:50 – 18:00-	**Concluding remark**	NIFDS

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등록안내

가) 사전등록 : 2021년 8월 2일(월) ~ 10월 20일(수)까지

나) 등록비

구분	사전등록		사전등록 기간 이후 등록
	1인	1인 추가시 마다	
기업체	300,000원	200,000원	350,000원
대학 및 비영리기관	200,000원	150,000원	250,000원
학 생	70,000원		100,000원

* 등록비에는 교재비 및 참가수료증 비용 등이 포함됩니다.
* 교재는 사전등록자에게 행사일 이전에 받아보실 수 있도록 우편으로 발송되며, 사전등록 기간 이후 등록자에게는 행사일 이후에 우편으로 발송됩니다.
* 복수 등록 시 카드결제 및 계좌송금을 한 번의 결제로 진행하여야 하며, 부분취소 및 부분추가가 불가하오니 신중하게 신청해 주시기 바랍니다.

다) 웨비나 접속방법

- 등록자에게는 행사일 1주전에 ZOOM 접속안내(회의실ID, 암호 등)을 보내드리오니, 컨퍼런스 당일 ZOOM에 입실하여 주시기 바랍니다.

라) 사전등록방법

- 의약품품질연구재단 홈페이지(pharmq.or.kr) 학술대회 사전등록 참조
- 원만한 행사준비를 위해 사전등록 기한 내에 등록 신청하여 주시고 카드결제 또는 계좌송금을 요청드립니다.

마) 계좌송금

- 예금주 : 재)의약품품질연구재단
- 계 좌 : KEB하나은행 503-910015-31104

바) 계산서 요청 : 홈페이지에 사전등록 시 기재바랍니다..

- 사업자등록증 첨부
- 등록자 이름 및 등록비 금액
- 계산서 받으실 이메일 주소
- 계산서 발행일

사) 보내실 곳 및 연락처 : 연구재단 사무국

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