

EMA - Centralized vs. Decentralized Licensing Procedures

European Medicines Regulations



- **교육일정:** 2016년 9월 26일(월), 27일(화)
- **교육장소:** 서울시 마포구 마포대로 137 KPX빌딩 6층 KAC(KoNECT ADVANCE CENTER)
- **교육대상:** 유럽 의약품 허가 절차 및 사례에 대해 관심이 있는 국내외 제약사, 바이오벤처, CRO등의 허가, 임상개발 임직원 등.
- **교육인원:** 60명 (선착순 등록)
- **접수기간:** 2016년 8월 18일(목) 오전 10시부터~ 마감 시까지
- **등록비:** 50만원
- **지원방법:** <http://www.konect.or.kr>에서 로그인 후 우측 하단의 교육신청(LMS)클릭
- **동시통역 제공**
- **문의사항:** 한국임상시험산업본부 전문인력교육실
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※ 식약처 임상시험 등 교육실시기관 지정에 따라 상기 교육은 직능 공동의 보수 교육과정에 준합니다.

후원



PROGRAM

DAY1 / MONDAY, SEPTEMBER 26

* Agenda는 일부 변경될 수 있습니다.

Time	Program
09:10~09:30	REGISTRATION
09:30~09:40	WELCOME AND INTRODUCTION
09:40~11:00	SESSION 1 The European Medicines Regulatory Network Key Organizations <ul style="list-style-type: none">• European Commission• European Medicines Agency (EMA)<ul style="list-style-type: none">- Introduction to the new EMA organization- Scientific Committees• National Competent Authorities (NCAs)<ul style="list-style-type: none">- Cooperation between the organizations- Pool of experts- Where to find information about the organizations in the Internet• Heads of Medicine Agencies (HMA)• European Directorate for the Quality of Medicines (EDQM) and the European Pharmacopeia
11:00~11:20	COFFEE BREAK
11:20~12:10	SESSION 2 Overview of the life cycle of a medical product and the relevant procedures: From Development to Postmarketing - an overall reference
12:10~12:50	SESSION 3 Scientific Advice Clinical Trials
12:50~14:00	LUNCH BREAK
14:00~16:00	SESSION 4 EU licensing procedures <ul style="list-style-type: none">• Centralized procedure (incl. specific procedures like conditional approval)• Mutual Recognition Procedure/ Decentralized Procedure• National Procedure<ul style="list-style-type: none">- Transparency (HMA/EMA agreement, Freedom of Information etc.)
16:00~16:15	COFFEE BREAK
16:15~17:15	SESSION 5 Overview of Pediatric Regulation, Orphan Medicinal Products, Herbals, homeopathic, advanced therapies, specific possibilities for Small & Medium size Enterprises (SME's)
17:15~18:00	GROUP WORK SESSION DAY 1

PROGRAM

DAY2 / TUESDAY, SEPTEMBER 27

* Agenda는 일부 변경될 수 있습니다.

Time	Program
09:30~11:00	SESSION 6 Pharmacovigilance <ul style="list-style-type: none">• Pharmacovigilance legislation• Post authorization safety study (PASS) & Post-authorization efficacy study (PAES)• Dossier requirements (Risk Management Plan (RMP), Pharmacovigilance System Master File (PSMF), Periodic Safety Update Report (PSUR))
11:00~11:20	COFFEE BREAK
11:20~12:20	SESSION 6 Pharmacovigilance <ul style="list-style-type: none">• Safety procedures/referrals• Pharmacovigilance Risk Assessment Committee (PRAC)
12:20~13:20	LUNCH BREAK
13:20~15:20	SESSION 7 Variations / Post approval changes <ul style="list-style-type: none">• Legal framework- Definition of Variations- Classification of a variation- Procedural Guidance Renewals
15:20~15:35	COFFEE BREAK
15:35~16:35	SESSION 8 EU Module 1: <ul style="list-style-type: none">• Specific requirements for a Common Technical Document (CTD) submission in the European Union• eSubmission including portals available
16:35~17:35	GROUP WORK SESSION DAY 2
17:35~18:00	CLOSING REMARKS

* 식약처 임상시험 등 교육실시기관 지정에 따라 상기교육은 직능공통의 보수교육과정에 준합니다.

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