EMA – Centralized vs. Decentralized Licensing Procedures

European Medicines Regulations

KONECT 한국임상시험산업본부 Korea National Enterprise for Clinical Trials

DIA DEVELOP INNOVATE ADVANCE

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※식약처 임상시험 등 교육실시기관 지정에 따라 상기 교육은 직능 공통의 보수 교육과정에 준합니다.

후원 보건복지부 Ministry of Health and Welfare

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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 • European Commission • European Medicines Agency (EMA) - Introduction to the new EMA organization - Scientific Committees • National Competent Authorities (NCAs) - Cooperation between the organizations - Pool of experts - Where ta 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 • Centralized procedure (incl. specific procedures like conditional approval) • Mutual Recognition Procedure/ Decentralized Procedure • National Procedure – 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 • 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 • Safety procedures/referrals • Pharmacovigilance Risk Assessment Committee (PRAC)
12:20~13:20	**LUNCH BREAK**
13:20~15:20	**SESSION 7** Variations / Post approval changes • 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: • 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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