(재)한국임상시험산업본부

혁신센터 개소기념
US FDA IND/NDA workshop

DIA World Tour Program

KONECT 한국임상시험산업본부 Korea National Enterprise for Clinical Trials

DIA DEVELOP INNOVATE ADVANCE

교육내용 소개

한국임상시험산업본부는 미국약물정보학회(Drug Information Association, DIA)와 공동으로 US FDA의 IND(임상시험계획승인) 및 NDA(신약승인신청) 교육을 실시합니다. 이번 교육은 FDA IND 및 NDA 전반 및 상세 절차 및 내용에 대한 소개뿐만 아니라, IND 신청 후 수정사항에 있어서의 사례, FDA와 효율적으로 미팅을 진행하고 커뮤니케이션 하는 원칙 등에 교육 내용도 포함될 예정입니다.

강사는 Regulatory Advantage International, LLC 캐롤 다니엘슨 대표, MORIAH Consultants 마이클 함렐 대표로 이들은 25년 이상 신약개발, 임상시험 규제 및 의약품 및 생물학적제제등의 인허가 등에 몸 담아온 IND 및 NDA 분야 전문가입니다.

- **장　　소**: 서울시 중구 바비엥2 스위트, B1 그랜드볼룸홀
- **교육일정**: 2015년 9월 7-8일 (월-화)
- **교육인원**: 80명 (선착순 마감)
- **교육대상**: 미국 FDA IND/NDA 절차 및 사례에 대해 관심이 있는 국내외 제약사, 바이오벤처, CRO 등의 등록, 허가, 임상개발 임직원 등
- **등 록 비**: 50만원
- **지원기간**: 2015년 7월 15일(수) 10:00 ~ 2015년 8월 19일(수)
- **지원방법**: http://www.konect.or.kr 에서 로그인 후, 수강신청(LMS)
- **동시통역 제공**
- **DIA 홈페이지**: http://www.diaglobal.org
- **문의사항**: 한국임상시험산업본부 전문인력교육실
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교육 오시는 길

후원 보건복지부

혁신센터 개소기념

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US FDA IND/NDA workshop

PROGRAM

DAY 1 | MONDAY, SEPTEMBER 7

* Agenda는 일부 변경될 수 있습니다.

Time	Program
09:30 - 10:00	**REGISTRATION**
10:00 - 10:15	**OPENING SESSION** • Overview of Training Course • Introduction of Trainers and Facilitators
10:15 - 11:00	**OVERVIEW OF US DRUG REGULATION** **Overview of US Drug Regulation** • Organization of FDA • Regulation of drugs, new drugs and biologics **Drug Development Overview** • Regulatory Strategy • Target Product Profile (TPP)
11:00 - 13:00	**IND SESSION(1)** **The IND: General Introduction** • When is an IND Required? • When is an IND Not Required? • Types of IND (Commercial, Investigator, Expanded Access, Exploratory) **Special Topics for Clinical Research** • Adaptive Study Designs • Patient Reported Outcomes • Trials Conducted Outside US
13:00 - 14:00	**LUNCH BREAK**
14:00 - 16:30	**IND SESSION(2)** **The IND in Detail** • IND Form 1571 • IND in CTD Format • Table of Contents • Introductory Statement • General Investigational Plan • Investigator's Brochure • Protocols • Chemistry, Manufacturing, and Controls • Nonclinical Pharmacology and Toxicology • Previous Human Experience • Additional Information **FDA's Action on the Original IND** • FDA's Review of an IND • Clinical Holds **IND Amendments** • Protocol Amendments - New Protocol - Change in Protocol - New Investigator • Information Amendments - Chemistry/ Microbiology - Pharmacology/ Toxicology - Clinical **IND Annual Reports** **Special Regulatory Considerations for Development** **Adverse Event Reporting** • Adverse Events • Serious Adverse Events • IND Safety Reports • Reporting Responsibilities • Termination of an IND for Safety
16:30 - 17:00	**COFFEE BREAK**
17:00 - 18:30	**IND WORKSHOP** • IND Amendments. • Wrap-up of Day 1

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PROGRAM

DAY 2 | TUESDAY, SEPTEMBER 8

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Time	Program
09:00 - 11:00	**NDA SESSION(1)** • Getting from the IND to the NDA • Considerations in NDA Planning • Study Data from Different Populations • Type of NDAs **The NDA in CTD Format: Module 1-5** **FDA Review and Actions** **FDA Review of Applications and Actions on Applications** • Amendments to an Unapproved Application • FDA Actions on an Application • Reasons Applications Are Not Approved
11:00 - 11:15	**COFFEE BREAK**
11:15 - 13:00	**The FDA and Risk Management** • Premarketing Risk Assessment • Post Marketing Risk Assessment • Risk Evaluation and Mitigation (REMS) **Post-NDA Approval Regulatory Requirements** • Post-NDA Approval Obligations • Supplements and other changes to an approved application 21 CFR 314.70 - Major Changes - Moderate Changes - Minor Changes • Postmarketing reporting of adverse drug experiences 21 CFR 314.80 - 15 Day Alert Reports - Periodic ADE Reports • Other postmarketing reports - NDA Annual Reports - NDA Field Alert Reports - Biologic Product Deviation Reports
13:00- 14:00	**LUNCH BREAK**
14:00- 15:30	**NDA SESSION(3)** **Interactions with FDA** • FDA Meetings (Type A, B and C) - FDA's Guidance on Meetings - FDA Meetings (Pre-IND, End of Phase 2, Pre-NDA, Labeling, Advisory Committees) - How to request and Prepare for a Meeting with FDA - Principles for Communicating with FDA • Resolving Issues or Disputes with FDA • Advisory Committee Meetings • GCP Inspections - Reasons for FDA Inspections (Routine, For Cause) - Targets of FDA Inspections - Inspection Outcomes: Additional Considerations in GCP Inspections - FDA Enforcement Actions
15:30- 15:50	**COFFEE BREAK**
15:50- 17:20	**NDA WORKSHOP** **Post-NDA Approval Requirements** **Wrap-up**
17:20- 17:30	**CLOSING SESSION**