OVERVIEW

The process of new drug development has become increasingly global in the past two decades. Many companies are conducting multinational clinical studies and aiming for simultaneous submission of New Drug Applications (NDAs) to Japan, the US, the EU, China and other countries.

The globalization of the pharmaceutical industry means that it is no longer enough for regulatory and development staff and managers in Japanese pharmaceutical companies to understand only the Japanese regulations and process of drug development.

It is now essential for professionals in the field to understand the regulations, processes, and trends in other countries that participate in global drug development.

For several years DIA has offered a training course in the US focused on submission of IND/NDA to the FDA. The course is very popular with attendees from around the world, including Japanese participants. With this success, DIA has brought the course to Japan since 2012. The training features:

- Focus on regulations and processes (IND and NDA)
- How to work productively and efficiently with FDA
- Plus More

The trainers will be Dr. Alberto Grignolo and Dr. Carol H Danielson, who are two of the original FDA IND/NDA trainers in the US.

The course will be conducted in English except that Workshops will be conducted in Japanese for a deeper understanding.

WHO SHOULD ATTEND?

This training will benefit regulatory and clinical development professionals in Japan who are intending/planning US submissions and clinical trials or similar projects.
9:30–10:00 REGISTRATION

10:00–10:10 OPENING SESSION
- Overview of Training Course
- Introduction of Trainers and Facilitators

10:10–11:20
- Session 0 Introduction to Regulation of Drugs and Biologics in the United States
- Session 1 The IND – A General Introduction
- Session 2 The IND in Detail (Items 1 - 6) Modules 1, 2, and 5
- Session 3 Chemistry, Manufacturing, and Controls Item 7 Module 3 and Module 1

11:20–11:30 BREAK

11:30–12:30
- Session 4 The IND in Detail (Items 8 - 10) Modules 4, 5, 2 and 1
- Session 5 Additional Topics: Additional Requirements for Biologics and Biotechnology-Derived Products and Submission of the IND
- Session 6 FDA’s Actions on the Original IND

12:30–13:30 LUNCH BREAK

13:30–15:00
- Session 7 IND Amendments and Maintenance
- Session 8 Special Topics for Clinical Research

15:00–15:15 COFFEE BREAK

15:15–17:00
- Session 9 Special Regulatory Considerations for Development
- Session 10 Reporting Adverse Events (AEs) during Clinical Trials

17:00–17:10 BREAK

17:10–18:30 IND WORKSHOP
- IND Amendment (Discussion Language: Japanese)
- Wrap-up of Day 1

18:30–20:00 NETWORKING RECEPTION
8:45–10:15  
- Session 11 The NDA in CTD Format: Types of NDAs  
- Session 12 The NDA in CTD Format: Modules 1-5

10:15–10:30  COFFEE BREAK

10:30–12:00  
- Session 13 NDA Submission, FDA Review and Action on Applications  
- Session 14 The FDA and Risk Management  
- Session 15 Regulatory Requirements for Prescription Drug Labeling

12:00–13:00  LUNCH BREAK

13:00–15:35  
- Session 16 Post-NDA Approval Regulatory Requirements  
- Session 17 Interactions with the FDA Part 1 (Short Break 10min)  
- Session 18 Interactions with the FDA Part 2  
- Session 19 Regulatory Compliance & FDA Inspections: What to Expect After Submitting the NDA

15:35–15:50  BREAK

15:50–17:20  NDA WORKSHOP  
- Post-Approval Submissions (Discussion Language: Japanese)  
- Wrap-up

17:20–17:30  CLOSING SESSION
REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi-honcho, Chuo-ku, Tokyo 103-0023 Japan tel +81-3-6214-0574 • fax +81-3-3278-1313

8th DIA FDA IND/NDA Training Course Event #19351
• November 5–6 | Hulic Conference Room 0(zero) | Asakusabashi, Tokyo
Address: Hulic Asakusa Building 3F 1-22-16 Asakusabashi, Taito-ku, Tokyo, Japan 111-0053

DIA will send participants a confirmation mail within 10 business days after receipt of their registration.

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception (if applicable), and will be accepted by mail, fax, or online.

Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year: www.DIAGlobal.org/Membership

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<td>Academia Membership (Academia, Medicals)*</td>
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Early Bird Deadline: October 25, 2019

* To register for Academia Membership, please send this form to DIA Japan office by fax or e-mail.

Please check the applicable category:
☐ Academia  ☐ Government  ☐ Industry

Last Name
First Name  M.I.
Degrees  ☐ Dr.  ☐ Mr.  ☐ Ms.
Job Title
Company
Address (As required for postal delivery to your location)
City State Zip/Postal Country

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

TRAVEL AND HOTEL
Nearest airport: Haneda Airport
Attendees should make airline and hotel reservation as early as possible.

KEIKYU EX INN ASAKUSABASHI-EKIMAE
Address: 1-27-9 Asakusabashi, Taito-ku, Tokyo 111-0053
Telephone: +81 3 5820 3910
URL: http://www.keikyu-exinn.co.jp/hotel/asakusa-bashi/languages/en.html

CANCELLATION POLICY: On or before October 29, 2019
Administrative fee that will be withheld from refund amount:
Member or Nonmember = ¥20,000
Government/Academia/Nonprofit (Member or Nonmember) = ¥10,000

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Photography Policy
By attending the 8th DIA FDA IND/NDA Training Course, you give permission for images of you (captured during the conference through video, photo, and/or digital camera) to be used in DIA promotional materials, publications, and/or website and waive any and all rights including, but not limited to compensation or ownership.

PAYMENT OPTIONS
Register online at www.DIAGlobal.org or check payment method.

☐ BANK TRANSFER:
You will receive an invoice with bank information detail by email after registration completion.

All local and overseas charges incurred for the bank transfer must be borne by payer.

☐ CREDIT CARD (VISA, MASTERCARD AND JCB ONLY)
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CONTACT INFORMATION
Contact the DIA Japan office in Tokyo for further information.
tel: +81.3.6214.0574 | fax: +81.3.3278.1313
email: Japan@DIAGlobal.org
プログラム概要

国際共同治験が新薬開発において重要な戦略の一つと位置づけられるようになり、さらに日米欧規制当局への同時申請や同時承認を目指す企業も増えます。グローバル化が進んでいます。そのような戦略の変化に伴い、開発や審査の担当者が求められる知識の範囲も広がっており日本の薬事規制やプロセスのみを知っていればよいという時代は終わり、共同開発国の薬事規制やトレンドも把握しておくことが重要となっています。

DIAでは、米国FDAへのIND/NDA業務についてのトレーニングを米国で毎年開催しており、日本を含め世界各国から多数ご参加いただいております。この人気のあるトレーニングプログラムの資料をベースに、可能な限り最新情報を追加・更新し、日本の皆様にご興味を持っていただける内容にアレンジしております。

特徴として:
1. 米国での4日間のトレーニングプログラムから、日本の皆さんに役立つ情報を選び、参加しやすいよう2日間のプログラムとしました。
2. 詳細な実務の説明は省略し、制度やプロセスを中心に解説します。
3. FDAの考え方や留意すべき事項についても解説します。
4. 参加者同士での議論を通して理解を深めるための場を設けます。

DIA USのトレーニングコースで当該トレーニングに関するプログラムを企画し、さらに講師として活躍されているGrignolo氏とDanielson氏が講義を行います。使用言語は、理解を深めるためのディスカッションを除いて英語です。講師の英語は分かり易く、また、様々な質問にお答え頂けると評判です。

本トレーニングでは、現在米国での申請のための臨床試験、承認申請を実施・計画されている企業の方、これから計画されている企業の方、及び今後米国での申請のための臨床試験の実施をご検討されている方などにも大変役に立つ内容となっておりますので、ぜひご参加ください。

プログラム内容は変更の可能性があります。予めご了承の程、お願い申し上げます。

講師:

PAREXEL International
Alberto Grignolo

Regulatory Advantage International,LLC
Carol H. Danielson

ファシリテーター:

中外製薬株式会社
樋口 雅義

ヤンセンファーマ株式会社
池田 晶子

第一三共株式会社
犬飼 ゆみ

ファイザーR&D合同会社
金子 美由紀

第一三共株式会社
松岡 洋明

グラクソ・スマスクライン株式会社
玉田 美和

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第8回DIA FDA IND/NDAトレーニングコース

2019年11月5日〜6日 | ヒューリックカンファレンスルーム0(ゼロ) (浅草橋)

参加申込方法

111-0053 東京都台東区浅草橋1-22-16 ヒューリック浅草橋ビル3階
DIAウェブサイト(www.DIAglobal.org)よりお申し込み頂けますか、ご記入の上、FAXまたはメール添付Japan@DIAglobal.orgにてお申し込みください。

受付後、10営業日以内にメールにて申込受領書を送付いたします。

会員及び参加費

会員資格が失効している方および非会員の方は、会員登録（更新）することにより、会員価格にてご参加いただけます。会員資格はお支払いいただいてから翌年同月末まで1年間有効です。DIA各種機関紙の入手、DIAウェブサイトの会員専用ページへのアクセス等、種々の特典も得られます。不明な点がございましたら、ディー・アイ・エー・ジャパンまでお問い合わせください。

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電話（必須）  ファクス

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