OVERVIEW

This course will give you an overview of the European regulatory system to provide you with the tools you need to develop a successful regulatory strategy.

You will be given information about the different routes for obtaining a license for the European market, including centralized or decentralized procedures; mutual recognition procedures; national procedures; and the specific procedures for orphan drugs, pediatrics, advanced therapies. The course will cover the different steps and timelines for each procedure.

You’ll also receive a brief introduction to the unique setup of the European regulatory environment, including the different responsibilities of the European Commission, the member states, the European Medicines Agency (EMA), the National Competent Authorities (NCAs), and the Heads of Medicines Agencies (HMA).

Other key topics covered during the course include:

• Pharmacovigilance
• Scientific Advice
• Clinical Trials
• Variations
• Data Protection/Marketing Exclusivity
• Transparency
• Brexit

Please note: the language of this training course will be English.
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<td>registration</td>
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<td>9:30-9:40</td>
<td>welcome and opening remarks</td>
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| 9:40-11:20 | session 1 | EU regulatory affairs, drug legislation and regulation:  
- Development of drug legislation  
- Drug regulations in the EU  
- Regulatory bodies, structure, responsibilities  
- Communication with and between regulatory agencies  
- Regulatory guidelines: National and international  |
| 11:20-11:35 | short break |  |
| 11:35-13:05 | session 2 | The role of regulatory affairs during drug development:  
- Pediatric Regulation  
- Orphan Regulation  
- Scientific Advice  |
| 13:05-14:15 | lunch break |  |
| 14:15-14:30 | session 3 | Registration dossier:  
- Introduction to the CTD structure  
- Administrative Information in EU Module 1  
- Electronic submission; eCTD  |
| 14:30-15:45 | sessions 4 | Regulatory procedures of drug marketing authorizations in the EU:  
- Centralized Procedure (CP)  
- Decentralized Procedure (DCP)  
- Mutual Recognition Procedure (MRP)  
- National procedure  
- Potential serious risk to public health  |
| 15:45-16:00 | coffee break |  |
| 16:00-17:00 | questions and answers |  |
| 17:00-18:30 | networking reception | (end of day 1) |
9:00–10:00 SESSION 5

LEGAL TYPES OF MARKETING AUTHORIZATIONS IN THE EU

- Full dossier
- Generics, abbreviated drug application
- Biosimilars
- Bibliographic application, well-established use
- Combination products
- Regulatory data protection and exclusivity
- Data protection
- Market exclusivity
- Extension of supplementary protection certificate

10:00–10:15 SHORT BREAK

10:15–11:45 SESSION 6

VARIATIONS: THE ROLE OF REGULATORY AFFAIRS AFTER MARKETING AUTHORIZATION

- Variations
- Renewals
- Other activities

11:45–13:00 LUNCH BREAK

13:00–14:10 SESSION 7

THE NEW PHARMACOVIGILANCE REGULATIONS

- Pharmacovigilance Risk Assessment Committee (PRAC)
- Expedited Reporting
- Signal Management Systems
- Additional Monitoring
- New PSUR = PBRER (Periodic Benefit:Risk Evaluation Report)

14:10–14:25 COFFEE BREAK

14:25–15:15 SESSION 8

TRANSPARENCY IN DRUG REGULATORY AFFAIRS

- Freedom of information
- Public assessment report
- MRI – product index
- Co-operation between regulatory agencies
- Information exchange
- Confidentiality agreement
- Mutual recognition agreement
- Parallel / co-assessment during drug development, marketing authorization, and postmarketing

15:15–15:55 SESSION 9

REGULATORY STRATEGY

- International development plan
- International regulatory procedures
- Market access

15:55–16:10 SHORT BREAK

16:10–17:20 BREXIT / QUESTIONS AND ANSWERS

17:20–17:30 CLOSING REMARKS
REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
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5th DIA European Medicines Regulations Training Course
Event #18355 • August 24-25, 2018 | Hulic Conference | Asakusabashi, Tokyo
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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
http://www.DIAGlobal.org
http://www.DIAjapan.org
第5回DIA欧州医薬品規制トレーニングコース
ー欧州薬事規制体系の本質と概要ー

OVERVIEW

欧州における薬事規制、種々の医薬品承認プロセス及び市販後の対応に関するトレーニングです。本コースでは、現役のEU規制当局担当官及び元EMA担当官の一二人のトレーナーが最新のEUの規制について講義を行います。今回使用する資料は、米国で開催されたトレーニングプログラムの資料をベースにして、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。

トレーニングには以下の内容を含む予定です。

・ 欧州連合(EU)の薬事規制概要
  - 当局相談
  - 臨床試験申請
  - ファーマコピジランス
  - 医薬品承認申請制度（中央審査方式、非中央審査方式、相互認証審査方式、国別審査方式）
  - 承認後の変更

・ データ保護と独占販売期間
・ オーファン医薬品、小児用医薬品、Advanced therapies
・ 透明性の確保
・ Brexit

欧州の規制は、国ごとの法律と、EUの規制があり複雑になっています。本コースではこれからを整理して提供するとともに、医薬品開発及び市販後対応の留意点についても、可能な限り紹介する予定としています。

尚、本コースはこれまで4回開催され、参加された方々からは「体系的に理解できた」、「今後の業務に役立ちそう」、「英語を含め説明が分かりやすかった」等のコメントを頂き、毎回非常に高い評価を頂いております。

日米欧での同時開発に着手する企業が増えてきたこともあり、欧州における規制を学ぶ絶好の機会と考えられますので、多くの方の参加をお待ち申し上げます。

注：本コースは英語で行います。セッション内容は変更することがございます。予めご了承の程、お願い申し上げます。

講師：
Chair, CMDh, Federal Institute For Drugs and Medical Devices (BfArM)

Peter Bachmann

Former member of the CHMP, European Medicines Agency (EMA)

Steffen Thirstrup

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2018年8月23日(木)～24日(金)
浅草橋ヒューリックカンファレンス ルーム0

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.
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**EU REGULATORY AFFAIRS**

**DRUG LEGISLATION AND REGULATION**

- Development of drug legislation
- Drug regulations in the EU
- Regulatory bodies, structure, responsibilities
- Communication with and between regulatory agencies
- Regulatory guidelines: National and international

**THE ROLE OF REGULATORY AFFAIRS DURING DRUG DEVELOPMENT**

- Pediatric Regulation
- Orphan Regulation
- Scientific Advice

**REGISTRATION DOSSIER**

- Introduction to the CTD structure
- Administrative Information in EU Module 1
- Electronic submission; eCTD

**REGULATORY PROCEDURES OF DRUG MARKETING AUTHORIZATIONS IN THE EU**

- Centralized Procedure (CP)
- Decentralized Procedure (DCP)
- Mutual Recognition Procedure (MRP)
- National procedure
- Potential serious risk to public health

**15:45-16:00**

COFFEE BREAK

**16:00-17:00**

QUESTIONS AND ANSWERS

**17:00-18:30**

NETWORKING RECEPTION

*(END OF DAY 1)*
### SESSION 5

**LEGAL TYPES OF MARKETING AUTHORIZATIONS IN THE EU**
- Full dossier
- Generics, abbreviated drug application
- Biosimilars
- Bibliographic application, well-established use
- Combination products
- Regulatory data protection and exclusivity
- Data protection
- Market exclusivity
- Extension of supplementary protection certificate

### SHORT BREAK

### SESSION 6

**VARIATIONS: THE ROLE OF REGULATORY AFFAIRS AFTER MARKETING AUTHORIZATION**
- Variations
- Renewals
- Other activities

### LUNCH BREAK

### SESSION 7

**THE NEW PHARMACOVIGILANCE REGULATIONS**
- Pharmacovigilance Risk Assessment Committee (PRAC)
- Expedited Reporting
- Signal Management Systems
- Additional Monitoring
- New PSUR = PBRER (Periodic Benefit:Risk Evaluation Report)
- EU QPPV
- Pharmacovigilance System Master File (PSMF)
- Risk Management Plans (RMPs)
- Risk Minimisation
- Post-Approval Safety And Efficacy Studies (PASS/PAES)
- Referrals

### COFFEE BREAK

### SESSION 8

**TRANSPARENCY IN DRUG REGULATORY AFFAIRS**
- Freedom of information
- Public assessment report
- MRI – product index
- Co-operation between regulatory agencies
- Information exchange
- Confidentiality agreement
- Mutual recognition agreement
- Parallel / co-assessment during drug development, marketing authorization, and postmarketing

### SESSION 9

**REGULATORY STRATEGY**
- International development plan
- International regulatory procedures
- Market access

### SHORT BREAK

### BREXIT / QUESTIONS AND ANSWERS

### CLOSING REMARKS
第5回DIA 欧州医薬品規制トレーニングコース

2018年8月23日〜24日 浅草橋ヒューリックカンファレンスルーム0（ゼロ）

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<td>□クレジットカード (使用可能クレジットカード：VISA/マスターカード/JCB)</td>
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