About the course

The European Regulatory Affairs (ERA) course is organized by the SIR Institute for Pharmacy Practice and Policy and is approaching its 25th anniversary. During this time we have created a strong faculty of experts in industry, academia and regulatory bodies – and trained over 400 regulatory affairs professionals. Today, the SIR ERA course is seen as an established learning vehicle for professionals in regulatory affairs, both in industry and government.

Who is it for?
The ERA course is designed for professionals from industry, academia and regulatory agencies who want to boost their knowledge by getting acquainted with the full range of technical, scientific and administrative requirements in the EU regulatory system for medicines. New insights can be applied directly to the participant's own organization.

Participants will ideally have previous university training in biomedical or related disciplines, including medicine, pharmacy, biochemistry, pharmacology and toxicology. Experience in Regulatory Affairs is considered advantageous, but is not an absolute requirement for the course.

Why should you take this course?
The ERA course provides in-depth knowledge on European regulatory affairs through lectures by authorities In the field, but also gives hands-on experience through actual case studies. Further to this, the ERA course also addresses current developments in the field of Pharma R&D and healthcare that are relevant in the future of the regulatory field.

The participants come from regulatory agencies, industry and consultancy, which together with the interactive nature of the course provides for an opportunity to strengthen your network and gain insight in diverse perspectives on the field. Above all, the SIR ERA course will help you to become a more informed and effective professional.

We look forward welcoming you to this year's course!

Jens van Wijngaarden
Chairman

Thessa Bakker-Krol
Course manager

Module A: Foundations of the EU regulatory system

Module A: Introduction to EU regulatory affairs

The first module of the ERA course focuses on understanding the who, what and how of the structure of the regulatory system. We will discuss topics such as: the evolution of the regulation of medicines in the European Union (EU); the role of the regulatory authorities and their international context; the relevant legislative frameworks and future developments thereof as well as challenges in the compilation of a drug development dossier.

Learning objectives

After this module you will be able to:

- Outline the evolution of the regulatory system in Europe;
- Identify the responsibilities of the national competent authorities and the EMA and understand how it is organized;
- Outline the centralized procedure and other European registration procedures;
- Describe lifecycle management of the benefit-risk profile of a medicinal product as a key activity of drug regulators;
- Explain the necessity of collaboration between regulators, academia, HTA and clinicians to fuel policy & R&D decision-making;
- Describe the scientific basis of regulatory affairs, and the necessity of regulatory science for innovation within the regulatory system and healthcare policy;
- Understand and identify challenges in drug development from different perspectives;
- Understand the key challenges in the European legislative framework for medicines, for example around the following:
    - The pending new Pharmaceutical legislation's reform;
    - The importance of regulatory strategy thinking;
    - Clinical Trial Regulation;
    - Early access;
    - Medicines' shortages.

Module B: Quality & pre-clinical part of the dossier

Module B: The Quality & Pre-clinical part of the dossier

The second module discusses two important elements of the Common Technical Document (CTD): quality and non-clinical studies. Good manufacturing and distribution practices (GMP and GDP), pharmacology, toxicology and quality by design will be some of the topics discussed here.

Learning objectives

After this module you will be able to:

- Outline GMP and GDP requirements, with an understanding of the importance of the European Falsified Medicines Directive and how to avoid inspection failure.
- Outline the guidelines of the CMC/Quality part of the dossier.
- Explain the concept of 'quality by design' as it relates to quality target product profiles, critical quality attributes, critical process parameters and risk assessments.
- Discuss topics related to biologicals including biosimilars such as specific regulatory requirements for the dossier, the manufacturing process and the risks at each stage of the process.

- Discuss pharmacology and toxicology in the context of the preclinical development of a pharmaceutical product/biological product; relevant regulatory requirements; and also aspects of preclinical safety sciences, such as safety biomarkers.
- Explain the relationship between pharmacokinetics and pharmacodynamics and understand the fundamentals of (pre)clinical pharmacokinetics & metabolism studies and the legal framework/guidelines involved.
- Explain the relationship between pharmacology, clinical trial design, regulatory strategy and critical success factors for preclinical medicines development.
- Explain the role of preclinical safety studies in medicines development, and registration in Europe, and the scope, type and timing of studies needed.
- Discuss scientific and regulatory topics of interest, such as single and repeat dose toxicity; establishing first human dose; toxicity to the immune system; genotoxicity carcinogenicity testing; pharmaco-toxicokinetics; and impurities.
- Explain the importance of the preclinical dossier with regard to the pediatric development of a pharmaceutical product.
- Outline the regulatory requirements for bioavailability and bioequivalence in the development of a pharmaceutical product, including generics, and how specific issues such as food interaction should be addressed.
- Explain how the non-clinical dossier is translated in product information for a medicine, and used in a medicine's benefit-risk assessment.

Module C: Clinical part of the dossier

Module C: The Clinical part of the dossier

The third module is on clinical studies. We will discuss the clinical part of the Common Technical Document, e.g. how clinical development plans are made; how to interpret clinical data; and how to make a benefit-risk analysis.

Learning objectives

After this module you will be able to:

- Draft an outline of the full clinical development plan (CDP) of a new medicinal product, from first human studies up to phase III studies.
- Critique an existing CDP with solid arguments.
- Understand and work with clinical data reports, with a basic knowledge of data management techniques and statistical analysis methods.
- Understand what sort of benefit-risk assessment tools exist and apply such tools to clinical data.
- Outline the specific clinical needs for pediatric drug development and draft a global clinical outline for a pediatric drug development plan.
- Translate clinical study results into a regulatory submission.
- Understand how regulatory authorities assess clinical studies.

Module D: On the edge of pre- and post-marketing

Module D: On the edge of pre- and post-marketing

Finally, module D discusses trends and topics on the edge of the pre- and post-marketing environments. These include (current) developments in HTA; pricing and reimbursement; and use of medicines (e.g. adherence, off-label use and safety monitoring). These trends and topics include marketing, post-authorization studies and pricing.

Learning objectives

After this module you will be able to:

- Summarize major trends and developments in the pharmaceutical industry including main challenges, companies' development strategies and key drivers for developments in the future.
- Describe and illustrate (give examples) of the implications of utilization patterns after marketing authorization (e.g. adherence, off-label use and channeling, rational use of medicines).
- Describe the key pharmacovigilance processes (including reporting, good vigilance practice [GVP] and post-authorization requirements) and their rationale, from the perspectives of both the marketing authorization holder and the regulator.
- Discuss the pros and cons of different measures aimed at informing health care providers on emerging new risks of medicines.
- Have basic insight into patients' beliefs about drug treatment (health-beliefs model).
- Discuss the pathway from market authorization to market access.
- Describe different EU mechanisms for HTA, pricing and cost-containment (e.g. reference-pricing, price-volume agreements, pay-for-performance).