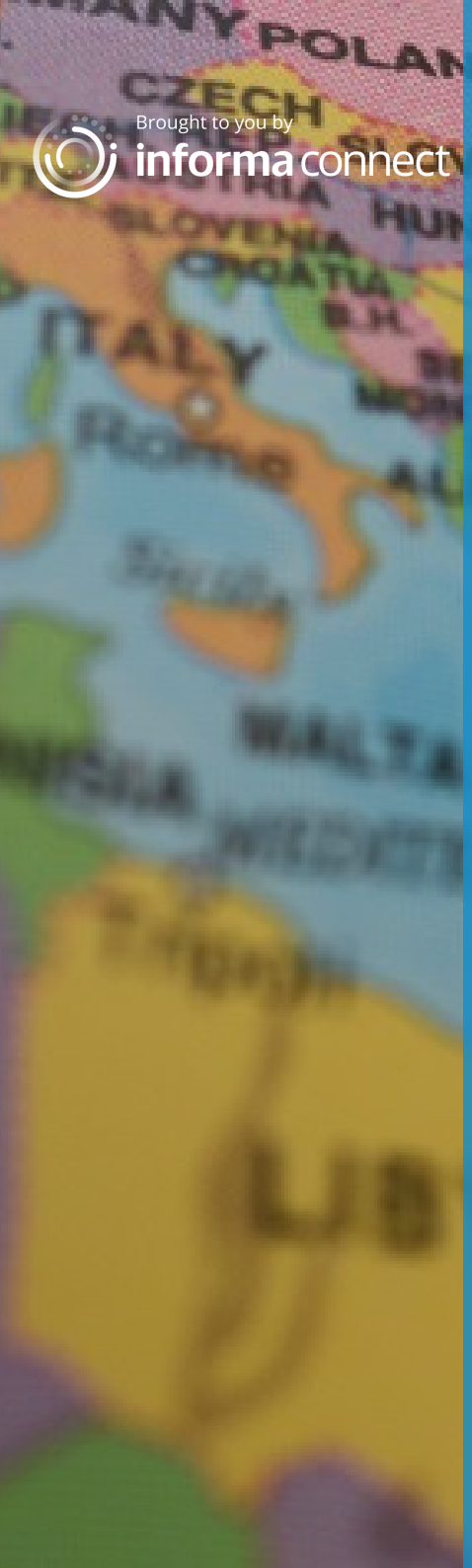

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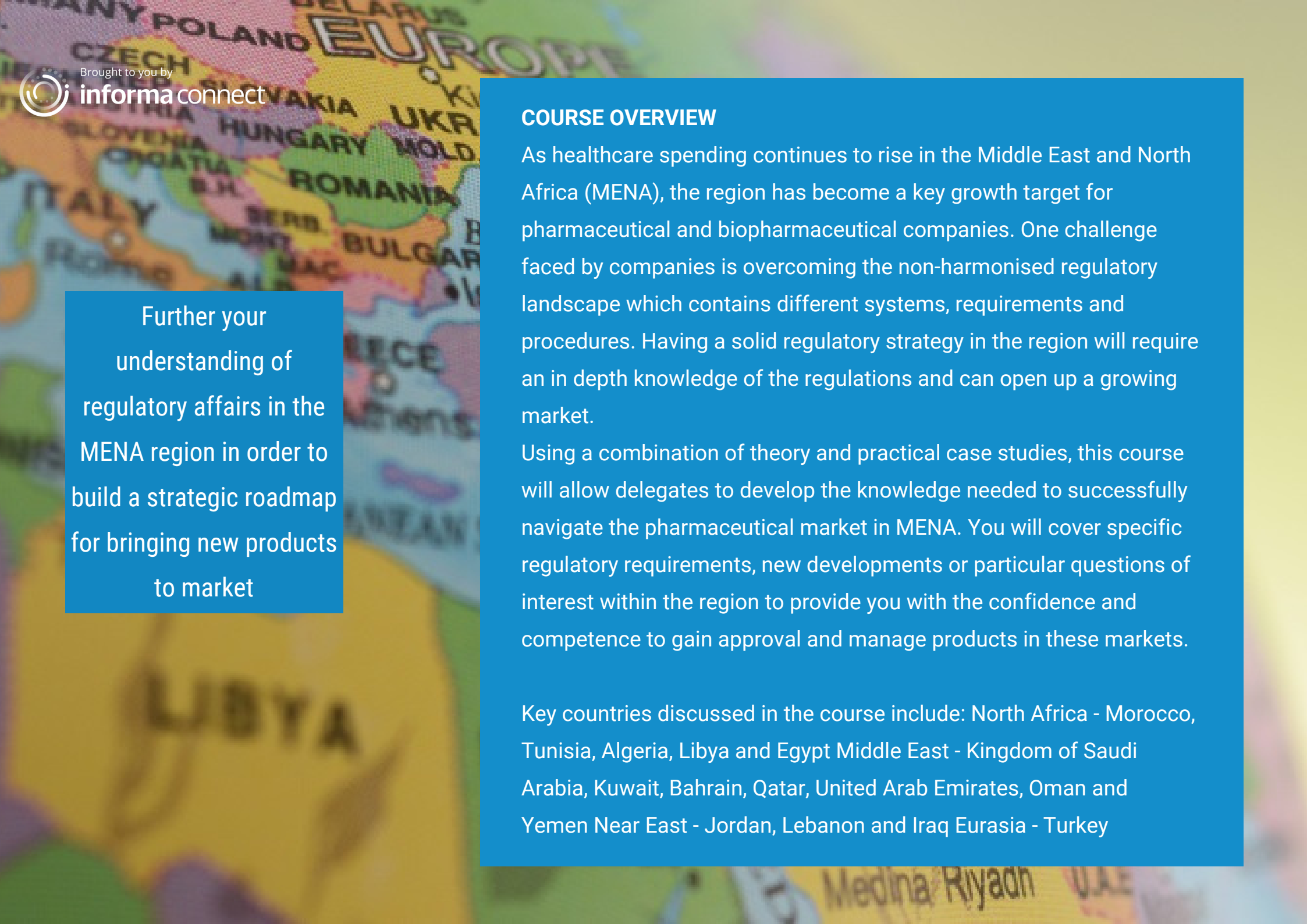
INTRODUCTION TO REGULATORY AFFAIRS IN THE MENA REGION

LIVE Online Academy



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Further your understanding of regulatory affairs in the MENA region in order to build a strategic roadmap for bringing new products to market

COURSE OVERVIEW

As healthcare spending continues to rise in the Middle East and North Africa (MENA), the region has become a key growth target for pharmaceutical and biopharmaceutical companies. One challenge faced by companies is overcoming the non-harmonised regulatory landscape which contains different systems, requirements and procedures. Having a solid regulatory strategy in the region will require an in depth knowledge of the regulations and can open up a growing market.

Using a combination of theory and practical case studies, this course will allow delegates to develop the knowledge needed to successfully navigate the pharmaceutical market in MENA. You will cover specific regulatory requirements, new developments or particular questions of interest within the region to provide you with the confidence and competence to gain approval and manage products in these markets.

Key countries discussed in the course include: North Africa - Morocco, Tunisia, Algeria, Libya and Egypt Middle East - Kingdom of Saudi Arabia, Kuwait, Bahrain, Qatar, United Arab Emirates, Oman and Yemen Near East - Jordan, Lebanon and Iraq Eurasia - Turkey

Heba Hashem

Heba Hashem has been working with Regulatory Affairs in the Middle East for more than 25 years. She has a Pharmaceutical and Business background being a graduate of the Faculty of Pharmacy (Cairo University), RAC certified in addition to an MBA at Maastricht School of Business.

For the past 20 years Heba held the position of Middle East & Africa Regulatory and Quality Head at different Pharmaceutical and Medical Device companies; Gambro, Bayer and Novo Nordisk. Heba now works for PPD as an Associate Director, Regulatory Affairs - Middle East and Africa, where she provides regulatory consulting services and training to HealthCare companies.

MODULE ONE

Introduction

- Introduction of speaker and attendees
- Collecting expectations of participants

General Information about MENA region

- An overview of the economic and political situation since the Arab Spring and the impact on the pharma industry
- Relation and communication with local affiliate/business partner/authorities
- Having a closer look at the geographical region

Workshop/Open discussion: Comparative analysis between EU MENA region

- Defining the similarities and differences
- How does your Headquarters handle these differences?

MODULE ONE

Regulatory Overview

- Exploring the organisation and structure of the authorities
- Health Care and Regulatory Environment
- General Requirements in MENA
- Regulatory procedures

Interactive sessions on regulatory intelligence

How to stay up to date with local regulations?

MODULE TWO

Country Focus/Main Markets: Saudi Arabia

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

MODULE TWO

Country Focus/Main Markets: GCC-DR

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

MODULE TWO

Country Focus/Main Markets : Kuwait, UAE, Bahrain, Qatar

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

Regulatory strategy within the Middle East

- Taking into account the different timelines, set up a regulatory strategy for the initial submission in MENA
- Defining the documentation required
- What are the possible pitfalls and how to avoid these

MODULE THREE

Country Focus/Main Markets: Jordan, Lebanon, Iraq

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

MODULE THREE

Country Focus/Main Markets: Egypt

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

MODULE THREE

Country Focus/Main Markets: Algeria, Tunisia, and Morocco

- Specific documentation requirements: CPPs, GMP, specific certificates, and Declarations…etc.
- Submission format and future development: CTD? NeeS? eCTD?
- Examine submission timelines and assess real-life examples
- New or imminent changes to regulations
- Extent of harmonisation

MODULE THREE

Life cycle management within the Middle East

- Taking into account the different timelines, set up a regulatory strategy for the life cycle management in theMiddle East
- What are the possible pitfalls and how to avoid these
- Necessary actions to undertake within Headquarters

WHO IS THIS COURSE FOR?

This course is suitable for professionals who are working in/working with affiliate offices in or are thinking of expanding into the MENA region.

In particular, the course will benefit Managers, Consultants, Project Leaders and Project Officers working in the areas of:

- Regulatory Affairs
- Regulatory Operations
- International Regulatory Affairs
- Emerging Markets
- Global Regulatory Operations
- Dossier Management
- Information Management

For information contact our training consultants

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