“ Gate to Regulatory and Pharmacovigilance” Course

Are you looking for the most wanted and sustainable profession in the pharma Industry after your graduate?

Then join us in the coming course as we will surf with Dr. Rula Kawar throughout all the basic knowledge in the regulatory affairs and pharmacovigilance to prepare you and open the doors for you to be ready to join the pharma manufacturers, drug store, pharma companies’ regional offices as well as health Authority.

During this 20 hours course we will discuss the below topics:-

- Regulatory Affairs concept, role and importance.
- Why we register products and manufacturing site.

- Types of products that needs approval by health authority and the difference of requirements.
- Types of manufacturers and the requirement for each type and why inspection by the authority is needed.
- General regulations and reference authorities.
- Classification requirement and it`s need.
- Food supplement and their registration requirements.
- Natural products (Vitamins) and their registration requirements.
- Herbal products and their registration requirements.
- Cosmetic & cosmeceutical products and their registration requirements.
- Medical Devise products, classes and their registration requirements.
- Type of pharmaceutical products, the common technical documentation concept and the national /international requirement requirements, including: -
  -Stability concept
  -Clinical studies and BE concept-Pricing of Pharmaceutical products.
  -Packaging material requirements and importance.

- Re-registration and post approval changes along with their effect on the supply chain and goods availability.

- Pharmacovigilance concept and importance of post marketing including: -
  -Adverse events
  -PV system (PSSF/PSMF) and the need of legal agreements
  -Promotional material
  -Product Complaint.

Speaker `s Biography :-

Dr. Rula Ghazi Kawar

Holding a Bachelor degree in Pharmacy from the Jordan University, a Diploma Degree in “Regulatory Affairs of Pharmaceutical Products & Marketing Authorization” from the Jordan University.

Regulatory expert with more than 23 years of experience in the regulatory field .Key note Speaker in different conferences regarding Pharmaceutical product registration requirements in the Middle East such as the German Forum, Jordan University of Science and Technology , Jordan University ; Al Ahliyya Amman University; Apex Pharmaceutical Services Conferences.

Her experience in the regulatory field started since 2000 upon Joining Ferring Pharmaceutical Regional Office, as regulatory Officer handling the Middle East registration, then as regulatory Manager at several local drug stores representing Multinational companies such as Abbott, Altana, Hospira, Abbvie, Pharmaton , GSK, Pfizer and others .

Since 2014 , heading the registration departments of MSG ;as part timer , which allowed her in expanding the knowledge and experience in Jordan and in the export markets as well.

-Trainer about Middle East Product registration requirements for both private and governmental sector, and managed several merger projects for Multinational companies in the MENA region and project for local manufacturers as well.

-Member at the Jordanian Pharmaceutical Association ,The Drug Owners association, Jordanian Association Of Pharmaceutical Manufacturer (JAPM), Board member of Eagle Trading International Corporation Co and Filing Manufacturing Company , shareholder at Apex Pharmaceutical Services, member at the Friendship association between Jordan and San Marino .