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Regulatory affairs as a strategy area - Case of study

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The development of new business into the pharmaceutical, cosmetic and medical device companies has been a frequent procedure that it has happened in emergent marketing since international and national companies have been working on the license of new finished products and on the acquisition, merger and split of companies in order to speed up the growth of their portfolio. With this new demand the area of new business development and project management have been recently created in so many companies and still now only sales, commercial, marketing, legal, logistic, etc., are involved on the process of these acquisitions. However with the recently experiences that industries had with the acquisition of new products or companies the new business area discovered the NEED of the involvement of Regulatory affairs area on these negotiations since the requirements ofproducts or companies acquired on another countries are not harmonizing with Brazilian requirements yet and the acquisition of new products or companies in the internal market also are not in compliance with the current law. So, through a study of case this presentation will show you as regulatory affairs area must be involved with the development of the new business given a great power of negotiation and good emplacements to decide to GO or not GO with a project, considering the needs of investments, real timeline to the submission of the products, registration granted and deadline to have the product placedon the market.

Biography

Roberta Rodrigues is a Regulatory Affairs Expert with over 12 years of professional experience in Regulatory Affairs of pharmaceutical companies as LaboratórioTeutoBrasileiro (A Pfizer Company), Stiefel (a GSK company), Bayer Group, GSK pharmaceutical and owner and writing of Regulatory Jigsaw Blog, current working as consultant and training in Regulatory Affairs. She is graduated on pharmaceutical science with bachelor degree in Pharmaceutical Industry since December of 2000. She is also speaker of issues related to the health surveillance at the largest virtual library available to Brazilian regulatory affairs professionals.

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