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The practice of Regulatory Intelligence: Case studies

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Regulatory Intelligence (RI) has always been an industry practice and is gradually being acknowledged in its own right. RI is an important task to execute when a company is making changes to it medicines and at the same time ensuring the continuation of supply.

Three following case studies all demonstrate the importance of gathering RI:

1. Company A updating their pack design and identified that the SPCs need to be updated to align to current guidelines
2. Company B are changing manufacturer of drug product, manufacturing method and also reformulating the excipients. The current manufacturer cannot meet Company B's current demand
3. Company C changing the legal entity name of manufacturing sites on a global scale

These case studies demonstrate that RI should be executed at an early stage to identify and mange risks prior to implementing a regulatory strategy.

Biography

Mariam Aslam has 10 years of Regulatory Affairs experience. Her current role is working as a Senior Consultant at PAREXEL International, United Kingdom. Her experience includes working with conventional medicines, herbal medicines, cosmetics and medical devices regulations. She studied a degree in Chemistry at the Manchester Metropolitan University in the UK. Mariam also attended and participated as a moderator and speaker at the OMICS Group Inc 4th 5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs (8-10 September 2014) in Raleigh, NC, USA. Her speech was Herbal Medicines: Product Licence to Traditional Herbal Registration in the UK.

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