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The Drug Regulatory Affairs Professional (With an insight into the Albanian context)

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Abstract

The Drug Regulatory Affairs profession was born as a need of governments to ensure public health, to enable the drugs that reach patients to be safe, of good quality and efficient. With a history starting at the second half of the past century, it can be considered a relatively new profession. However, due to developments in the manufacture of drugs, the rising number of pharmaceutical companies and their global reach, the increased potential of the sector to bring income, the enforcement of multiplied, complex, regulatory norms, this profession has developed rapidly, occupying a prominent place, not infrequently even a key one, in various professional teams. To better understand this professional, its educational background, core competencies as well as role and responsibilities are thoroughly analyzed. The development and the importance it has reached up to now in our country is also a point discussed.

In a globalized world, where there is a high public concern for safe and effective medicines, regulatory compliance is increasingly becoming a trend of the future. Due to the primary mission of drug regulatory affairs professionals to safeguard public health, it is in the general interest that every stakeholder involved supports the empowerment of this profession.

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