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Challenges in providing adequate high-level education in regulatory affairs, especially in view of small countries

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The science advances whereby studies in targeted complex therapies for difficult and complex disease areas increase. Development of new therapies together with the pressure to keep the costs reasonable is challenging. Obtaining approvals within the shortest time possible without jeopardizing quality, safety and efficacy of the medicines, creates further challenges. Companies need skilled Regulatory Affairs (RA) professionals for ensuring compliance with strict criteria and timelines. Especially, small and mid-size enterprises (SMEs) face the problem in recruiting RA people who can tackle the continuously expanding demands. There are also differences between the countries regarding the education in RA. Continuous training for professionals in the field is necessary to keep the people up-to-date with the profession. For small countries, it is not always easy to give extensive training in the RA field as the Universities can only provide some courses on RA. A further obstacle in becoming knowledgeable in RA is the fact that currently there might only be a few pharmaceutical companies operating in small countries, whereby lack of on-job training prevails. Another problem is created by the fact that people are reluctant to change the position from bigger companies to an SME, e.g. due to financial uncertainty. For SMEs the way to acquire RA knowledge most often is to hire a consultant. All the above mentioned facts in mind, it is of utmost importance to safeguard the high level of professional education of RA people.

Biography

Elvi Metsaranta, after her graduation from the University of Turku, Finland, Elvi Metsäranta has held various positions within international pharmaceutical and biotechnological sector. Besides the industry experience, she has also worked with the Finnish National Agency for Medicines. Her current position is Director of Regulatory Affairs at Crown CRO Oy, a premier Finnish Contract Research Organisation. Her responsibilities are establishing and heading the Crown Regulatory Affairs department. Elvi Metsäranta is a Member of RAPS, TOPRA and the DIA.

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