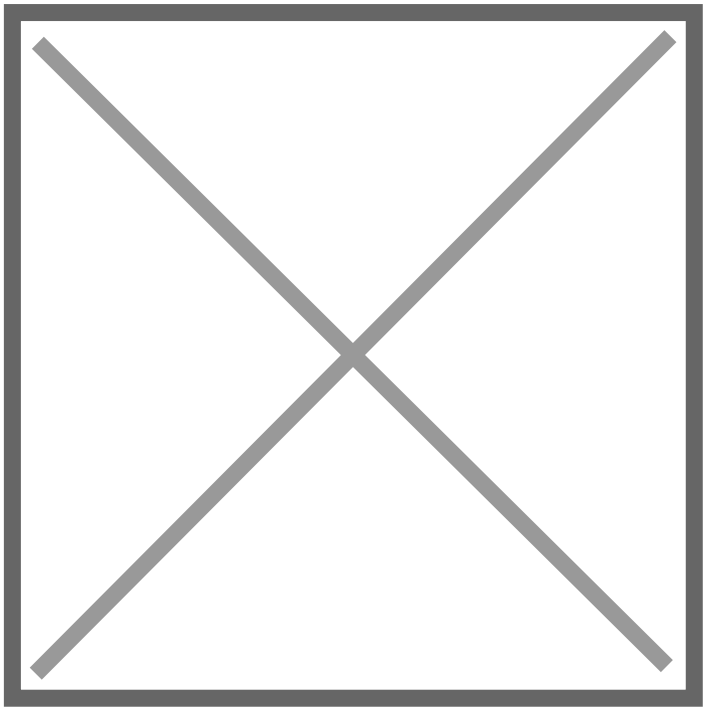
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Negative activism is a concern

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The Indian CRO industry has undergone incredible changes since its beginning in India. Here is a snapshot of the key trends and current issues concerning the industry.

Negative activism: The country has witnessed a significant increase in activism against the CRO industry recently. This activism is more detrimental than constructive. It doesn't have the judiciousness to separate 'right' from 'wrong' or issues like 'interests of human subjects' from a rational scientific drug development for fellow human beings. This one process can make or mar the future of Indian CRO industry. Indian CROs must come together and tackle this challenge in a two-pronged approach by ensuring ethics, quality and integrity and by improving public perception.

Regulatory process: Probably a fall-out of negative activism, Indian regulatory processes are still struggling to take an efficient, pro-research approach. Timelines are still unreliable and unrealistic, while additional complications related to compensation, study-related injury and insurance continue to haunt the industry.

With all appropriate intentions, our regulatory process seems to be stuck in reinventing the wheel. It is imperative that the industry come together and work with the regulatory authority to take some harmonized actions on these important matters. Developed countries have faced this issue and carved an approach to deal with them and India can take similar steps with necessary modifications.

The industry is globally witnessing unprecedented consolidation or maturation. In the last 18 months, 10 out of the top 20 CROs have changed the shape of their business existence. This has happened in the form of mergers, acquisitions and transfer of equity. As an estimate, these global changes have affected about a third of the workforce of the Indian industry.

Matters like mergers of SOPs/ WIs, business system integration and organogram integration are important and present themselves in complex forms. While they look great on a macroscopic view, project delivery-related issues affect at subtle yet significant level. The challenge here is to maximize the value built-up in such transactions and it requires a mature approach.

Changing organogram pattern: Strikingly different from how they started in India, CROs are now dissecting their processes on functional lines. This is a global process and is presenting itself in India in recent times. This phenomenon is also more specific to multinational CROs, as domestic CROs keep their workforce more versatile. In a segmented functional organization, this gives rise to multiple verticals performing different parts of a contiguous process, yet maintaining separate lines of commands. The challenges involved include identifying and managing areas of gap and overlap. At an individual CRA

level, this poses as a significant change when an individual migrates from one organization to another organization where the organogram set-up is different.

Lastly, the industry continues to struggle with people issues like lack of experienced resources and, sometimes, more serious issues like work integrity. After about 15-18 years of existence, this should not have been the case but it is. The answer to this lies within the organizations.

They must commit to invest in training and succession planning process. Because of the small size of the industry, it will never have enough number of associates. As an industry, we must make (or contribute to make) what we want. One can't depend solely on supply of candidates from outside without the risk of people issues.