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"Chemical regulations are gaining increasing complexity globally & regionally"

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One of the major challenges today lies in creating a gradual shift towards animal-free test systems and approaches – collectively known as 'New Approach Methods' or NAMS. Navigating headwinds in regulatory toxicology and highlighting opportunities for the Indian contract research organisations (CROs) in this regard, Erica Kunz (Head-Global Product) and Fabian Grimm (Head of Toxicology & Ecotoxicology & Specialty Chemicals) at Switzerland-headquartered Clariant spoke to BioSpectrum at length.

What are the current challenges facing the regulatory toxicology space with respect to India?

By agreeing to the Organisation for Economic Co-operation and Development (OECD)'s "Mutual Acceptance of Data" (MAD) and implementation of quality and integrity standards of "Good Laboratory Practice", India has laid a foundation of internationally acceptable standards in toxicological testing. Indian Contract Research Organisations (CROs) are well-prepared to adhere to international standards, but challenges certainly lie – as for non-Indian CROs - within the timely adaptation of new testing standards to support increasing information requirements for new hazard classes and groups of chemicals, e.g. polymers.

What are the emerging trends driving regulatory evaluations in the toxicology industry?

Chemical regulations are gaining increasing complexity globally and regionally. Particularly in the European Union, the Chemical Strategy for Sustainability is expected to enhance regulatory scrutiny by expanding the scope of human and environmental hazard assessments, which is likely to result in an increase in testing requirements. At the same time, we do see tremendous technical advancements in the field of toxicology, particularly around alternatives to animal testing. There is a huge opportunity for stakeholders from all sectors to cooperate to advance and increase confidence in NAMs to allow implementation of these methods and improvement in regulatory safety evaluation of chemical products while meeting increased information demands with the most ethical testing strategies.

What will be the likely opportunities for the Indian CROs?

For Indian contract research organisations, this translates into business opportunities and will require them to adapt to their changing customer demands through timely implementation of new global testing standards, and by assuring that the testing infrastructure can provide sufficient capacity.

For the industry, the evolving complexity in global and regional chemical regulations offers incentive to reassess existing products and to identify critical areas where chemical substitution can offer advantages. Thus, there is an opportunity to adapt to regulatory challenges through safe and sustainable product innovation which is pillar of Clariant's corporate purpose and strategy. Nevertheless, substitution is challenging, not only to develop new technologies and enable investment plans, but simply as it takes time and it involves identifying alternatives, evaluating their health and safety hazards, potential trade-offs, and technical and economic feasibility.

Our industry is faced with significant challenges but can also benefit from great opportunities to enable the EU Green Deal ambitions and create value for society with low carbon, circular and bio-based solutions, that are truly safe and sustainable by design - Clariant is ready and committed to playing its part.

What role will Clariant play to bring in a transition from animal testing to animal-free test approaches?

Clariant consistently strives to implement testing strategies based on alternative methods to replace animal testing. Clariant is therefore proactively engaged – directly or through industry associations – in scientific and regulatory exchanges to promote the development of alternative test systems and support the validation process of these non-animal methods. In addition, Clariant is applying computational toxicology to minimise animal use in regulatory testing and to prioritise chemical substances in safe and sustainable product innovation projects. Clariant is also cooperating with academia advance the development of mechanistically based in vitro test systems.

The need to ensure proper product safety testing and maintain and respect animal and environmental welfare are both issues of great societal and ethical concern and subject to regulation and mandatory obligations.

Clariant places a strong emphasis on applying integrated testing techniques and new alternative non-animal methodologies when assessing our substances and products. These new alternative methodologies are diverse and include inter alia high throughput assays, toxicokinetic (PBK) modeling, toxicogenomics and transcriptomics, bioreactivity and biomarker assays, 3D cell systems and computational toxicology.

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