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Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy

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Path To Remove and Replace Safety Testing In India

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The evolution of vaccine manufacturing and regulatory science in India has created strong momentum toward modernizing safety testing and reducing dependence on traditional animal-based assays. Recent national and international reforms including the removal of the Abnormal Toxicity Test (ATT) and the shift from rabbit pyrogen testing to bacterial endotoxin testing highlight India's commitment to evidence-based, humane, and scientifically advanced quality control frameworks.

This abstract examines the regulatory, scientific, and ethical pathways for replacing legacy in-vivo safety tests with validated in-vitro, molecular, and process-based approaches. It outlines the roles of key authorities such as the Central Drugs Standard Control Organisation (CDSCO) and the Indian Pharmacopoeia Commission (IPC), as well as alignment with global frameworks including the WHO and EDQM, in enabling these transitions.

By mapping the requirements for method development, assay validation, inter-laboratory harmonization, and regulatory acceptance, this article provides a practical roadmap for vaccine manufacturers seeking to integrate Quality by Design (QbD), Process Analytical Technology (PAT), and next-generation analytical tools into routine quality control.
Advancing toward non-animal, rapid, and sensitive testing systems not only strengthens vaccine quality assurance and accelerates product release but also enhances international regulatory convergence and supports India's leadership in ethical, sustainable, and modern biopharmaceutical manufacturing. The time is right to move decisively toward science-driven, 3Rs-aligned strategies that reflect global best practices and the future of vaccine quality control.