



Luthra *and* Luthra
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LIFESCIENCES AND HEALTHCARE NEWSLETTER

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PHARMACEUTICALS

LEGAL AND REGULATORY

ICMR Releases Guidance Document on Validation of Rapid Diagnostics for Pathogen Identification and Antimicrobial Susceptibility Testing

The Indian Council of Medical Research (ICMR) has released a guidance document on validation of rapid diagnostics for pathogen identification and antimicrobial susceptibility. Validation of a diagnostic test is a systematic evaluation of a test which has been developed, standardized and optimized, to determine its fitness for the specific intended use. The Guidance Document attempts to elaborate on the requisites, steps and process-flow for undertaking the validation of indigenous diagnostic tests for antimicrobial resistance (AMR). It supplements the existing guidelines by bridging information gaps and providing guidance on test validation for innovators and developers in the country.

ICMR has been active in recent times in combatting antimicrobial resistance and the present Guidance Document is a step in that direction.

https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1736941384_guidancedocument_amr_diagnostics_revised.pdf

India extends the timeline for small and medium pharmaceutical companies to comply with the revised good manufacturing practices

India's Ministry of Health and Family Welfare has extended the timeline for the small and medium pharmaceutical companies (having a turnover of INR 250 crores or less) to comply with the newly introduced good manufacturing practices (GMP). The revised GMP were introduced earlier in the previous year by way of amendment to Schedule M of the Drugs Rules, 1945.

The earlier deadline for complying with the revised GMP was 01 January 2025.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIzNDE=

INVESTMENTS

India's CRDMO, Aragen, Secures \$100 Million Investment from Quadria Capital

Aragen, a contract research, development and manufacturing organization (CRDMO), has secured a USD 100 million investment from Quadria Capital, an Asia-based healthcare private equity firm. The investment will result in Quadria Capital acquiring a minority stake in Aragen, at an approximate valuation of USD 1.4 billion, primarily through a fresh capital infusion, with a small portion from the sale of shares by existing investors.



This funding is expected to support Aragen's strategic expansion of its capabilities and infrastructure, enabling the company to meet the demand for outsourcing services from innovators in the United States and Europe.

<https://quadriacapital.com/publications/press-releases/aragen-secures-100-mn-investment-from-quadria-capital>

MEDICAL DEVICES AND MED-TECH

LEGAL AND REGULATORY

India's Medical Device Regulator Imposes Ban on Import of Pre-Owned and Refurbished Medical Devices in India

India's Central Drugs Standard Control Organization (**CDSCO**) has announced a ban on the import of pre-owned and refurbished medical devices into India until a proper regulatory framework is established. This clarification follows concerns about the safety and quality of refurbished devices and was highlighted in a letter from the CDSCO to the Principal Commissioner of Customs. The letter clarified that no license would be issued for import of pre-owned and refurbished medical devices under the existing Medical Devices Rules, 2017.

The Ministry of Health is forming an expert committee to develop a policy on this matter. The decision affects a market valued at Rs 1,500 crore, which plays a significant role in supplying medical equipment to underserved regions.

https://www.business-standard.com/health/cdsco-to-disallow-import-of-pre-owned-refurbished-med-devices-into-india-125011601409_1.html

INVESTMENTS

Innovaccer Secures \$275 Million to Boost Healthcare AI

Innovaccer, an artificial intelligence (**AI**) based healthcare company, has raised \$275 Million in Series F funding. The investment was a combination of primary and secondary sale, and includes participation from B Capital Group, Banner Health, Danaher Ventures LLC, Generation Investment Management, Kaiser Permanente, and M12.

This investment is expected to enhance Innovaccer's efforts to expand its collaboration with existing customers, introduce new AI and cloud capabilities, and scale a developer ecosystem on the platform.

[https://innovaccer.com/resources/news/innovaccer-secures-\\$275M-in-series-f-to-scale-its-healthcare-intelligence-cloud](https://innovaccer.com/resources/news/innovaccer-secures-$275M-in-series-f-to-scale-its-healthcare-intelligence-cloud)



HOSPITALS AND HEALTHCARE

LEGAL AND REGULATORY

ICMR and CDSCO Release Draft Protocol for HMPV Real-Time PCR Evaluation

The ICMR and the CDSCO have released a draft protocol for evaluating Human Metapneumovirus (**HMPV**) real-time PCR kits, aiming to set a clear standard for testing the quality and accuracy of In-Vitro Diagnostic (**IVD**) kits in India. The said protocol lays out detailed guidelines on how these kits should be tested, covering everything from sensitivity and specificity checks to ensuring no cross-reactivity with other respiratory viruses. As per the protocol, accredited labs with trained staff will handle the evaluations, with strict measures in place to keep the testing process unbiased.

The draft is open for consultation from stakeholders till 15 March 2025.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI0NTY=

CPCB Seeks Feedback on Draft Guidelines for Pharmaceutical Industry

The Central Pollution Control Board (**CPCB**) has rolled out draft 'Guidelines for the Pharmaceutical Industry in India'. This move follows a directive from the National Green Tribunal (**NGT**), prompted by pollution violations reported in Akkireddygudem Village, Andhra Pradesh. The guidelines will introduce stricter measures for managing pollution, hazardous waste, and mandate the use of Zero Liquid Discharge (**ZLD**) systems to curb water contamination. The guidelines also classify pharmaceutical units into 'Red' and 'Orange' categories based on their pollution potential. Covering a range of manufacturing processes, from chemical synthesis and fermentation to natural extraction and formulations, the guidelines also emphasize better air emission controls, solvent recovery, and the installation of online monitoring systems for real-time data.

<https://cpcb.nic.in/openpdffile.php?id=TmV3c0ZpbGVzLzExMV8xNzM3MDA1ODU1X21lZGlhcGhvdG8xMjUwMy5wZGY=>



This newsletter is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke.

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