

CENTER FOR VACCINE INNOVATION & ACCESS

Critical Reagents Shortages: Sustainable Access for Vaccine Manufacturers

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CVIA

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Critical Reagents – PATH Survey in 2025

Responses Received: 30

Detailed Responses:

- **China:** LIBP, SIBP, CCIBP, CanSino, Keygen, Innovax, Walvax, Sinocelltech, WestVac, Zhuoyi, Chengdu Olymvax, Curovax/Delonix, United Cell Biotech, ProKang, Alephbio, Wuxi
- **Vietnam:** Polyvac, IVAC, VABIOTECH
- **Thailand:** Government Pharmaceutical Organization
- **India:** GCBC Vaccines, Panacea, Zydus, Biological E
- **Africa:** IPD Senegal, BioVac, EVA Pharma
- **South Korea:** SK, EuBiologics
- **Russia:** Chumakovs

Critical Reagents suppliers and their locations

1. Frequently mentioned suppliers

NIBSC/WHO (top mention)

SSI, CBER/FDA, Sigma Aldrich, TakaRa, Cytiva,

In house production.

2. Others

Asahi Kasei, ECACC/WHO, DKI, NIFDV, Lanzhou Institute, Thermo, Sangon Biotech, Berna Biotech Korea, Denka Japan, Janssen Korea, Afrigen, Jena Bioscience, Malvern Pananalytical, Agilent, ATCC, Curia, NBE, Reagecon, Cygnus Technology, LLC US, VWR France, Merck Millipore, BioFarma, NIHE

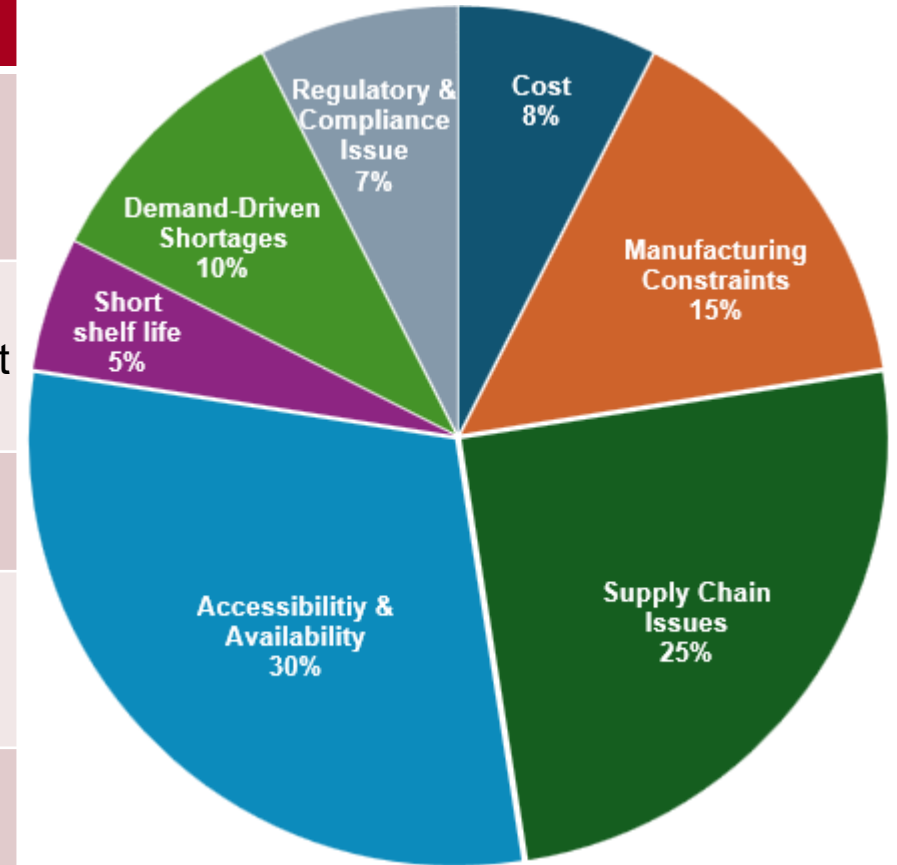
Supplier's location

(by decreasing volume of mentions)

USA, UK, Japan, Denmark, China, Germany, Korea, South Africa, France, Ireland.

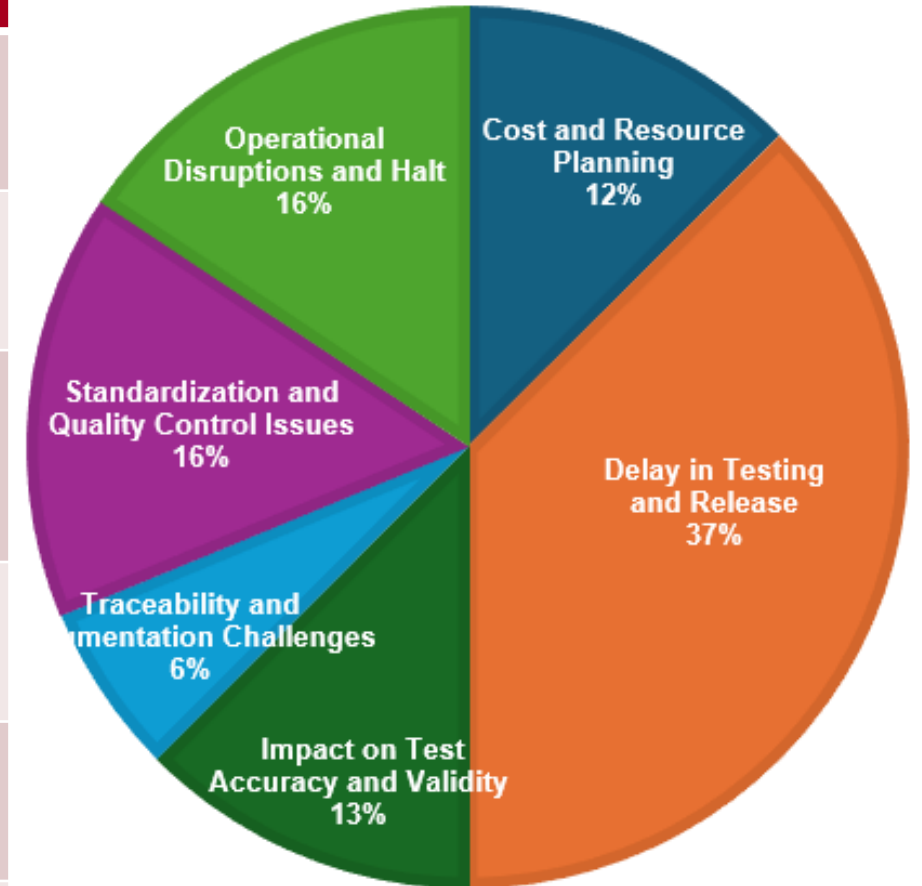
Shortage Root cause

Causes	Description
Supply Chain Issues	Erratic supply chain, delays, and long lead times; issues with vendor shipping or internal processing delays; raw material shortages, backlog, regulatory disruptions.
Availability and Accessibility	No suppliers or limited availability in certain regions; restrictions on imports, lack of commercial suppliers, import permit delays.
Cost	High expense of reagents due to production, long lead time, or sourcing challenges.
Manufacturing Constraints	Discontinued production by suppliers; short product shelf life; batch size limitations mABs production delays, method establishment issues.
Demand-Driven Shortages	Increased demand due to specific projects or accelerated production needs.
Regulatory and Compliance Issues	Regulatory restrictions, safety compliance issues for high-risk reagents, importation permits, supplier restrictions by region



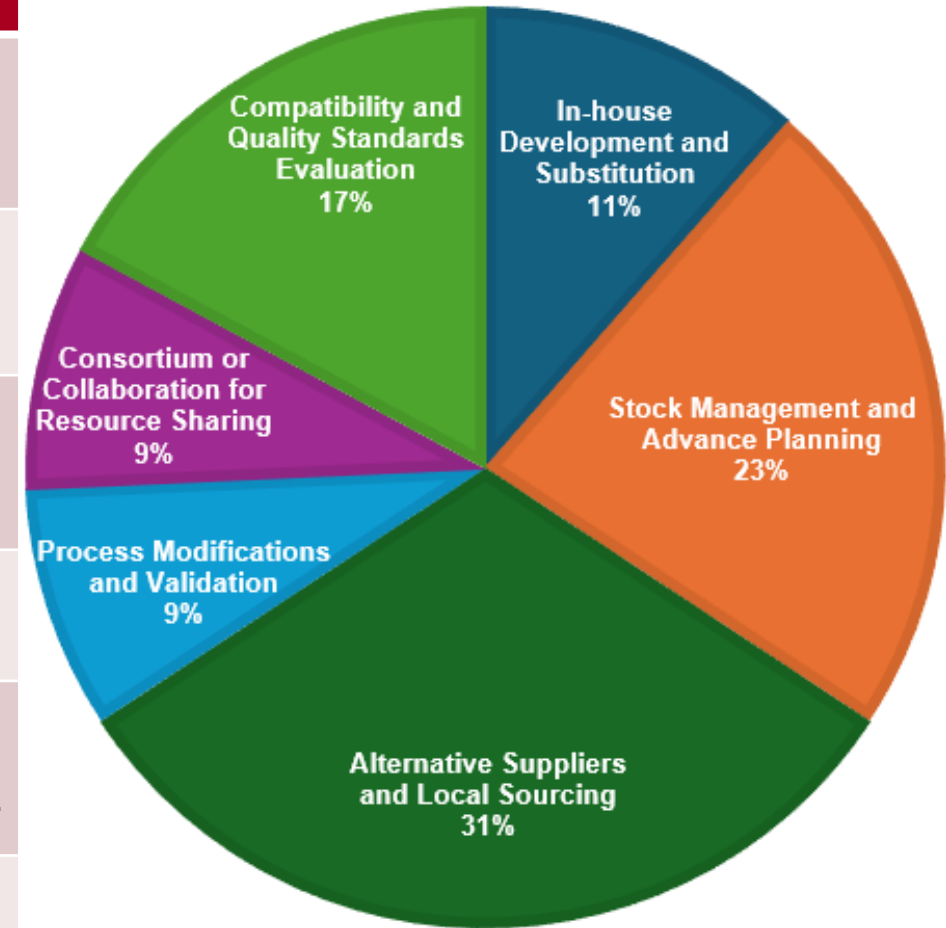
Impact of reagent shortage on QC testing

Impact	Definition
Delay in Testing and Release	Delays in conducting QC tests, obtaining critical reagents, or releasing products due to shortages, impacting timelines and regulatory compliance.
Cost and Resource Planning	Increased costs and challenges in planning resources due to reagent scarcity, variability in availability, or the need to secure alternative reagents.
Standardization and Quality Control Issues	Issues with maintaining consistent standards in QC processes across different tests, batches, and laboratories, including variability in reagents and the need for universal standards.
Impact on Test Accuracy and Validity	Impact on the accuracy, validity, or reproducibility of tests due to reagent shortages, unavailability of critical functional reagents, or difficulties in potency test verification.
Operational Disruptions and Halt	Potential or actual halting of QC testing, ELISA testing, or product release processes due to reagent shortages, testing limitations, or lack of critical components.
Traceability and Documentation Challenges	Difficulties in ensuring traceability, estimation, and comprehensive documentation for quality control purposes, impacting regulatory compliance and batch release.



Shortage mitigation measures

Mitigations	Definition
In-house Development and Substitution	Developing reagents within the organization, utilizing polyclonal or monoclonal antibodies, or finding substitutes to replace unavailable items.
Stock Management and Advance Planning	Managing stock levels proactively, including placing purchase orders well in advance to prevent shortages.
Alternative Suppliers and Local Sourcing	Identifying and utilizing alternative suppliers, local agents, or commercial products to ensure supply continuity, even if some options are unproven.
Process Modifications and Validation	Adapting or modifying existing processes, including validation, to accommodate different or new reagents.
Consortium or Collaboration for Resource Sharing	Collaborating with other organizations or forming consortiums to share resources and mitigate shortages.
Compatibility and Quality Standards Evaluation	Ensuring compatibility and compliance of substitute reagents and commercial alternatives with quality standards and existing protocols.



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