

FAQ

Strategic reserve

What the strategic reserve is

Q. What is the strategic reserve?

A. Our Reserve is first and foremost a security-of-supply commitment to Cytiva's customers that use our resins in approved and registered manufacturing processes for human therapeutics and vaccines, and other critical needs as Cytiva may determine including unusual peaks in demand (e.g. from COVID-19). The Reserve is part of our business continuity plan and is intended for use where there is an event outside of Cytiva's control that could have a significant business impact on Cytiva and which could affect Cytiva's ability to respond to demand for chromatography resins manufactured in Uppsala, Sweden (a "Business Impact Event").

The Reserve is primarily aimed at providing a reliable supply of resin during a Business Impact Event and the subsequent recovery phase. The Reserve is intended to cover approximately 6 to 12 months' customer demand, depending on resin type and our estimated business recovery time

Q. How is the business recovery time estimated?

A. Business recovery times are included in Cytiva's business continuity plans and are determined through modelling and estimation of the time to recover from an incident that affects our ability to produce resin. Business recovery times would include, for example, the time to move resin production from an impacted production line to an alternative suitable line.

Q. Where is the strategic reserve located?

A. The strategic reserve is held in both Sweden & the USA and is located independently from our manufacturing facilities.

What the strategic reserve contains

Q. Are all types of resins used in approved manufacturing processes represented in the strategic reserve?

A. The resin-types included in the strategic reserve are based on (to the best of our knowledge) the use of those resin-types in approved manufacturing processes for human therapeutics and vaccines. The strategic reserve does not generally include customized resins or resins with a remaining shelf-life of less than two years.

Q. How many products are covered by the strategic reserve?

A. Currently, approximately 90 various chromatography resin types are stored in the strategic reserve. Resin types, volumes and storage locations of the strategic reserve are regularly reviewed to ensure effective deployment of materials globally should an incident occur.

Q. Is the strategic reserve only covering BioProcess™ chromatography resin?

A. Currently the strategic reserve includes approximately 90 chromatography resins and 2 Microcarrier products.

Q. Are chromatography resins used in the manufacture of products for clinical trials covered?

A. No. Currently, the strategic reserve only covers resin used in approved manufacturing processes for human therapeutics.

Q. Are chromatography resins used in vaccine purification processes covered by the strategic reserve?

A. Yes

Q. How do we make sure that the products of the strategic reserve have not expired or are close to the expiry date?

A. Products in the strategic reserve are rotated on a regular basis.

How to use the strategic reserve

Q. How will the strategic reserve be used?

A. The strategic reserve is not allocated for any specific customer and will not be used as safety stock in the event of an incident within a customer's operations. In addition, the reserve is not intended for deliveries of regular orders or to compensate for temporary production variations. Where Cytiva determines a need to use the Reserve, a controlled order intake process will be implemented to minimize impact for customers during the resin production recovery period. Withdrawals from the reserve will be prioritized by Cytiva, on a case by case basis, considering factors including urgency and the immediate use of the resin in any approved manufacturing process for human therapeutics or vaccines.

Q. Can the strategic reserve be used to cover up for incidents at our customers' sites?

A. No. The reserve cannot be used to cover up for incidents within a customer's operations. For these types of incidents, our customers will need to follow their own risk management strategies.

Q. Is the strategic reserve earmarked for specific customers?

A. No. The chromatography resin in the strategic reserve is not earmarked for any specific customer.

Q. What are the prioritization criteria for deliveries from the strategic reserve?

A. Where Cytiva determines a need to use the Reserve, a controlled order intake process will be implemented to minimize impact for customers during the resin production recovery period. Withdrawals from the Reserve will be prioritized by Cytiva, on a case by case basis, considering factors including urgency and the immediate use of the resin in any approved manufacturing process for human therapeutics or vaccines.

Under the controlled order intake, customers will need to specify which registered manufacturing process the chromatography resin is intended for, volumes historically used, as well as estimate a nonbinding forecast.

Q. How can individual customers make sure that they get their share of the strategic reserve in case of an incident affecting our manufacturing?

A. The content of the strategic reserve is reviewed annually and adjusted based on customer information regarding resin used in their approved manufacturing processes.

Q. Can the strategic reserve be used in the case of a major incident at the site of any of Cytiva's suppliers?

A. Cytiva can use the strategic reserve where there is a serious incident at the site of any of our suppliers that threatens the manufacturing of a registered and approved pharmaceutical. Continuous measures, such as inventory of raw material and intermediates, are also ongoing to manage incidents impacting our supply chain, in line with Cytiva's business continuity plan.

Replenishment of the strategic reserve after deployment

Q. How is the Strategic Reserve replenished after deployment?

A. Should an incident occur, the volume in the Strategic reserve will reduce as it is deployed to support in the face of a Business Impact Event. The strategic reserve will then be replenished in time through the allocation of a proportion of our routine manufacturing being directed into the reserve.

Q. What is the expected timeframe to replenish the Strategic reserve back to target levels?

A. The specific timeframe for replenishment is dynamic and associated to the timeframe to recover from an incident, ongoing demand levels and annual delivery guidelines. Our aim is to replenish as quickly as possible with a view to meet target reserve levels without detrimentally impacting delivery timeframes.

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