

# FAQ

Strategic reserve



# What the strategic reserve is

**Q. What is the strategic reserve?**

**A.** The strategic reserve is a back-up inventory of chromatography media (resins), should anything happen at our manufacturing site in Uppsala, Sweden or at the site of any of our suppliers of critical raw materials that severely impacts our manufacture ability. The strategic reserve is a security-of-supply commitment to the industry using GE Healthcare Life Sciences' media in approved manufacturing processes for human therapeutics. The aim of the strategic reserve is to cover for potential supply interruptions during the recovery time following a major incident at our manufacturing site. The back-up inventory covers an approximate 6 to 12 months' supply, depending on the recovery plan for each product, until manufacturing is up and running according to our business continuity plan.

**Q. How is the business recovery time estimated?**

**A.** The aim of GE Healthcare's business continuity plan is to prevent and mitigate major incidents at the site. The greatest risk identified is fire or explosion caused by the large amount of organic solvents that are stored and used at the site. The general, estimated recovery time at a major incident of our media production is up to six months. For certain products, the recovery time can be as much as 12 months. The strategic reserve enables deliveries of GE Healthcare chromatography media during business recovery until the production is up and running according to our business continuity plan.

**Q. Where is the strategic reserve located?**

**A.** The strategic reserve is located in Örebro, Sweden and in Cranbury, USA.

# What the strategic reserve contains

**Q. Are all chromatography media used in approved manufacturing processes represented in the strategic reserve?**

**A.** The content of the strategic reserve is based on the best of our knowledge of media used in approved manufacturing processes. Customized media and media with shelf life less than two years are excluded.

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

**A.** Currently, approximately 70 000 L of more than 60 various chromatography media are stored in the strategic reserve.

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

**A.** Yes. Currently only chromatography media are covered.

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

**A.** No. Currently, the strategic reserve only covers media used in approved manufacturing processes for human therapeutics. With the strategic reserve, GE Healthcare shares the risk with pharmaceutical companies in the public's supply of life-preserving drugs. For clinical trials, customers need to hold their own safety stocks or protect their supply of media by using our safety-stock offering.

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

**A.** Chromatography media used in vaccine purification processes will be implemented in the strategic reserve during 2014.

**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 regular basis.

# How to use the strategic reserve

## **Q. How will the strategic reserve be used?**

**A.** The content of the reserve will only be used in the case of a major incident, at our manufacturing site in Uppsala or at the site of any of our suppliers of critical raw materials, which severely affects the production of our media. The strategic reserve will not be used by GE Healthcare for deliveries of regular orders or to compensate for temporary manufacturing variations.

## **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 at our customers' manufacturing sites. For these types of incidents, our customers will need to follow their own risk management strategies. However, it is possible for our customers to protect their media supply by using our safety-stock offering.

## **Q. Is the strategic reserve earmarked for specific customers?**

**A.** No. The chromatography media in the strategic reserve is not earmarked for any specific customer. The reserve content is an aggregated volume of chromatography media known, to the best of our knowledge, to be used in registered and approved pharmaceutical manufacturing processes. For specific requests, our customer safety-stock services can be set up for individual customers.

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

**A.** In case of utilization of the strategic reserve, a controlled order-intake process will be implemented to minimize impact on pharmaceutical manufacturing processes during our production recovery phase. Controlled order intake has successfully been used by GE Healthcare in the prioritization process during the supply shortage of Sephacryl™ following the Tsunami incident 2011. By controlled order intake, a sales stop will be implemented to enable distribution of media only for approved manufacturing processes. Customers will need to specify which registered manufacturing process the chromatography medium is intended for, volumes historically used, as well as estimate a nonbinding forecast. Withdrawals from the strategic reserve will be based on urgency and prioritized case by case. The prioritization will favor the immediate use of the medium in an approved manufacturing process, to enable the supply of pharmaceuticals to the public.

## **Q. What is the difference between the strategic reserve and the customer safety-stock service?**

**A.** The strategic reserve is a back-up inventory of chromatography media, should anything happen at our manufacturing site in Uppsala, Sweden or at the site of any of our suppliers of critical raw materials that severely impacts our manufacture ability. The reserve is not earmarked for any specific customer. The customer safety stock, on the other hand, is a dedicated inventory, earmarked for a specific customer, and held to a monthly fee in GE Healthcare's inventories. The main purpose of the safety stock is to enable fast deliveries in case of urgent customer needs.

## **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.** Our goal is to cover all customer needs of media, used in the manufacturing of human therapeutics and vaccines, during business recovery following a serious incident. The content of the strategic reserve will be reviewed annually and adjusted based on customer information regarding media 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 GE Healthcare's suppliers?**

**A.** Yes. The strategic reserve can be used in case of 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 GE Healthcare's business continuity plan.

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First published Feb. 2014

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