

Security of supply program for chromatography media

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Introduction

Manufacturing of biopharmaceuticals is a large commitment to the public health and helps save the lives of millions of people. In view of global financial uncertainties and recent natural disasters, such as the earthquake and tsunami in Japan 2011, we are reminded of how vulnerable today's supply chains can be to unforeseen external incidents (Fig 1).

Chromatography media (resins) are a critical raw material for manufacturing of biopharmaceuticals. As chromatography media usually are single-sourced, its supply security is of key concern for the pharmaceutical industry.

This poster presents the comprehensive security of supply program implemented at GE Healthcare Life Sciences (Fig 2).

The first part of this program covers flexible and high-capacity manufacturing to enable timely deliveries of high-quality media, year after year.

The second part of the program covers our emergency preparedness for severe incidents that potentially affect our manufacturing capability (Fig 3).

The third part covers our supply chain sustainability, comprising rigid standards for supplier qualification and management.



Fig 1. Unforeseen external incidents, such as the earthquake and tsunami in Japan 2011, remind us of how vulnerable today's supply chains can be. Photo courtesy of AFP PHOTO/JIJI PRESS/TT.

Security of supply program

Part 1

From the manufacturing site in Uppsala, GE Healthcare has provided high-quality chromatography media since 1959. The Uppsala site has one of the world's largest manufacturing capacities of media, with an annual production of more than 300 000 liters. We continuously expand our manufacturing capacity. Recently, we invested more than 100 million USD in production upgrades to meet the growing demand for our products. The site comprises two independent multipurpose manufacturing facilities.

Part 2

To minimize the risk and to mitigate the impact of a potential serious incident at our manufacturing site, we have implemented a business continuity plan (BCP) following industry standards.

The BCP covers a strategic reserve of chromatography media used in registered processes for the manufacturing of human therapeutics and vaccines. The reserve can be used as a backup inventory in case of supply interruptions during the recovery time following a

potential major incident at our manufacturing site or at the site of any of our suppliers.

The strategic reserve contains more than 70000 liter media, representing more than 60 products, and is kept in locations geographically separated from our manufacturing site. The strategic reserve 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.

Part 3

In case of an interruption in our own supply chain, we can make use of the strategic reserve to enable deliveries of chromatography media for registered manufacturing processes.

In addition, we have identified at least one second supplier for most of our critical and important raw materials, to maintain a continuous production during an emergency. Going forward, we will identify and implement second suppliers for all critical raw materials that exhibit the highest estimated financial impact.

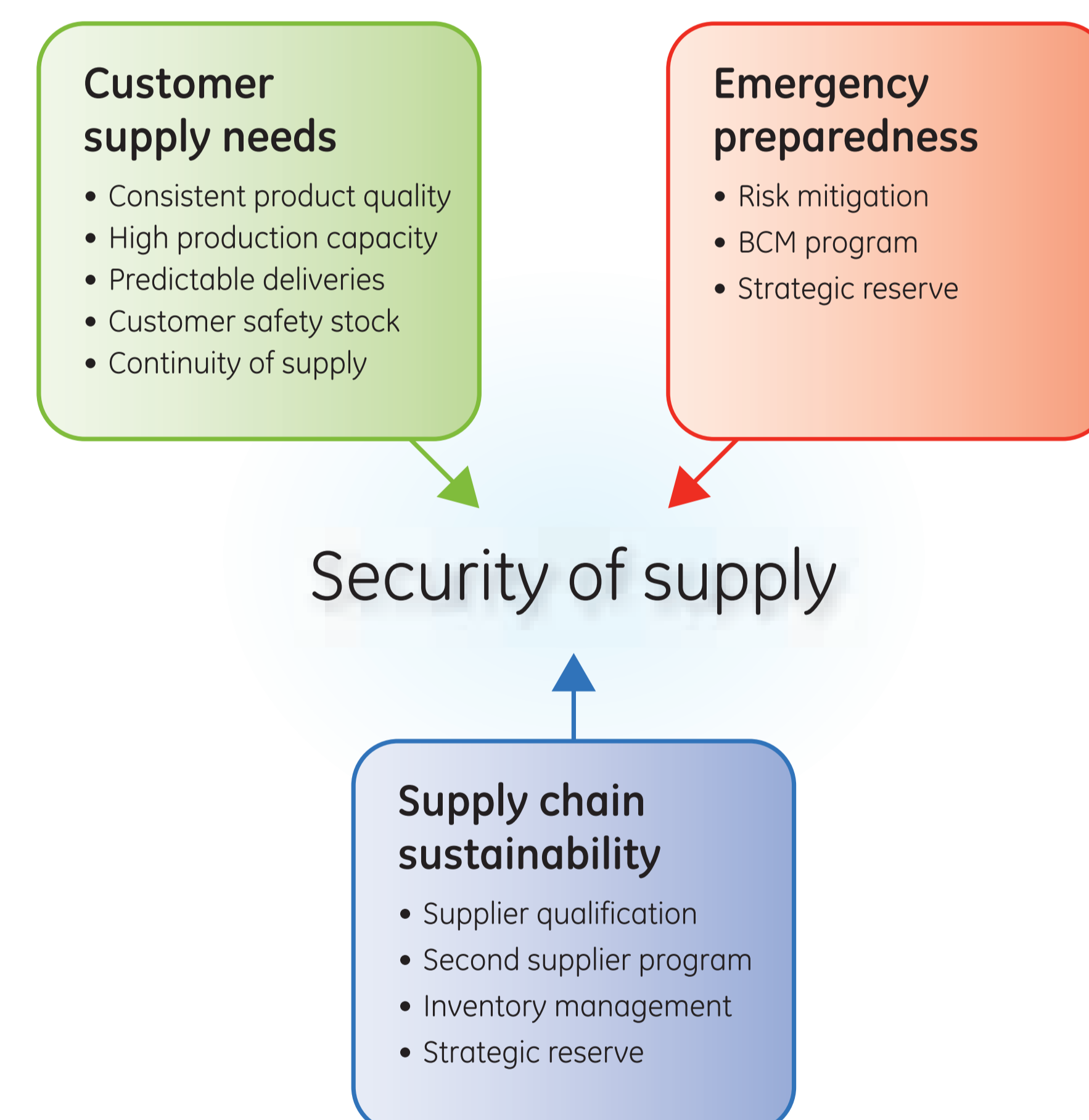


Fig 2. GE Healthcare's security of supply program.

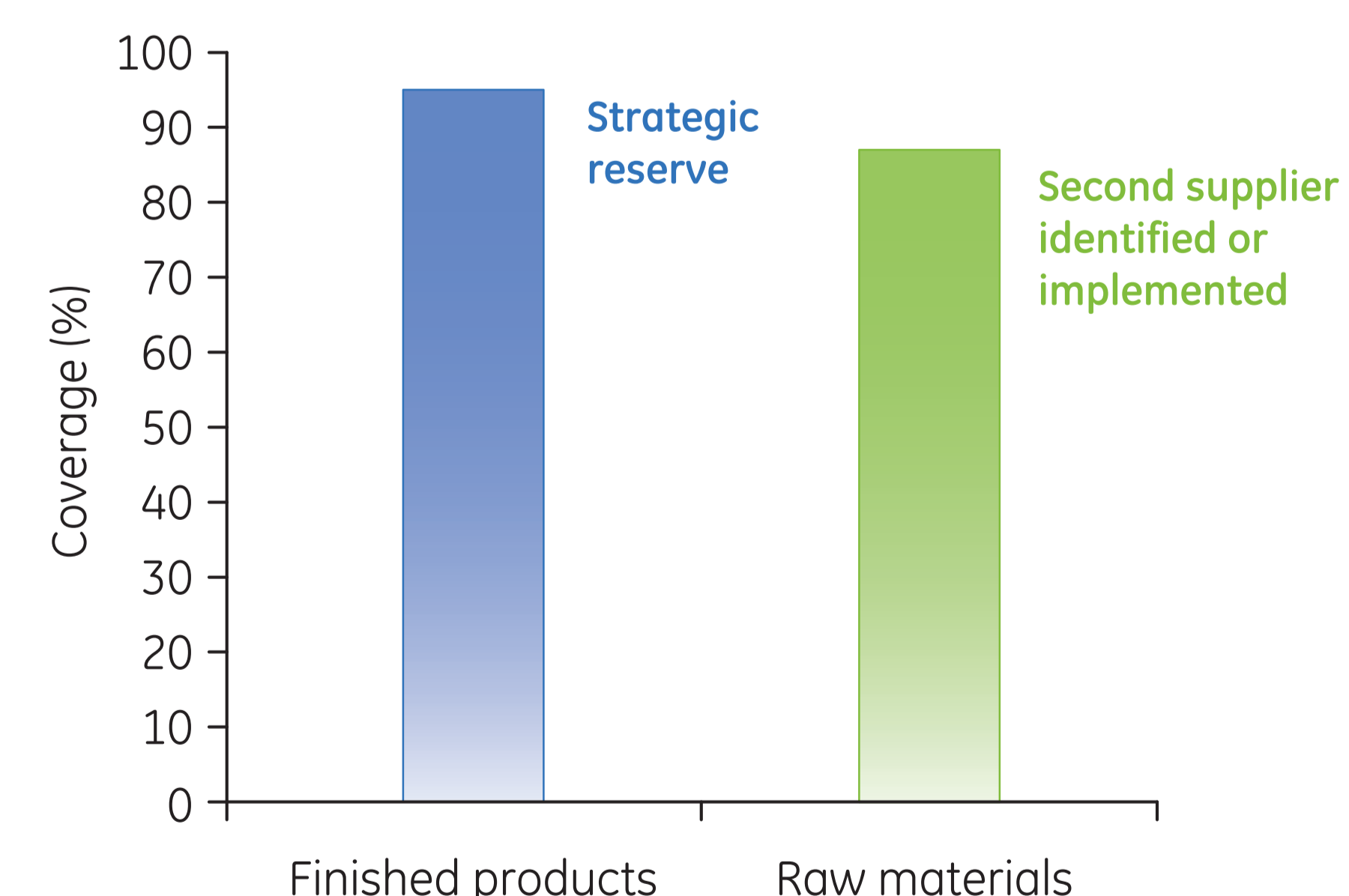


Fig 3. Emergency preparedness for chromatography media used in approved and registered processes. Left bar shows approximate percent of media covered by the strategic reserve. Right bar shows fraction of critical or important raw materials, used in production of chromatography media, for which second suppliers are identified or implemented.

Summary

GE Healthcare has implemented a comprehensive, three-part security of supply program to help our customers maintain manufacturing of vital biopharmaceuticals, even under unforeseen circumstances.