



**Global Harmonization Working Party**



**Introduction of Proposed Final Document :  
Guidance to Supplier Audit for Medical Device  
Manufacturers**

(being assessed within GHWP member  
country/region)

**GHWP/WG7/F003:2023**

**Work Group 7**

**Ning Li (Becky Li)**

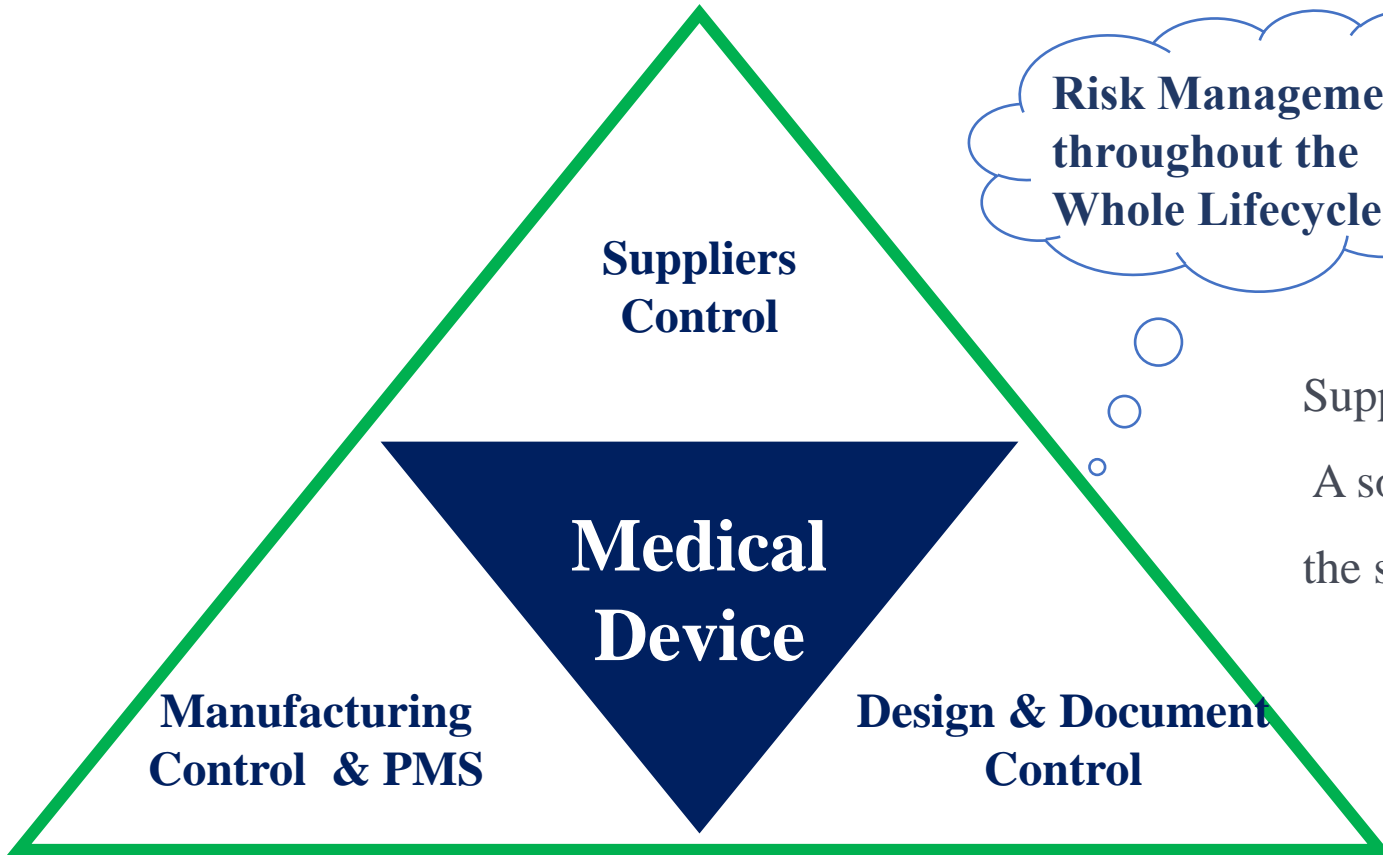
**Sr. Director of QS and Regulatory Affairs**

**Micro-Tech (Nanjing) Co., Ltd.**

- Over 20 years working experience, served as R&D engineer, operations, purchasing engineer, quality and regulatory affairs person in charge.
- Deputy Secretary-General of the Medical Device Packaging Professional Committee of the China Association for Medical Devices Industry.
- Member of the Standardization Technical Committee of the Medical Device Polymer Products Professional Branch of the China Association for Medical Devices Industry.
- Member of the Third Drug Vigilance Professional Committee of Jiangsu Pharmaceutical Association.

**MICRO-TECH (MT) was founded in China in 2000. MT has set up several subsidiaries in US, Germany, Netherlands, UK, France, Japan, Thailand and so on. We are committed providing high-quality products and services to hospitals and clinics around the world, advancing the quality of care, improving patient outcome.**

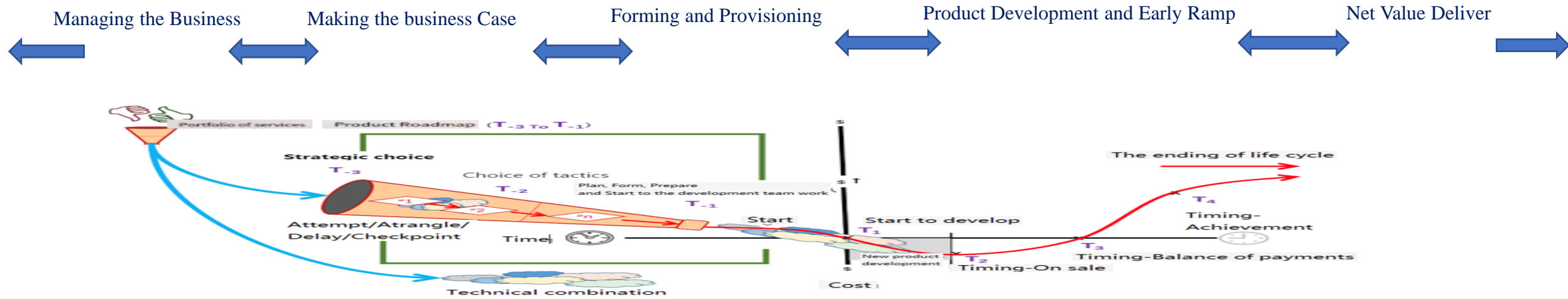




Suppliers control takes an important role in the supply chain.

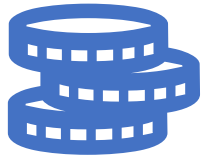
A sound and reliable supply chain achieved will better support the sustainable development of industry.

## Process Map: Risk and the Product Lifecycle



<ul style="list-style-type: none"> <li>•Risk in the economy</li> <li>Macro risks</li> <li>•Risk of not understanding the marketplace</li> <li>•Risk of poor selection of technology</li> <li>•Risk of poor portfolio management</li> </ul>	<ul style="list-style-type: none"> <li>•Technology risks</li> <li>•Market risks</li> <li>•Risk of competition</li> <li>•Risk of a disruptive new product</li> </ul>	<ul style="list-style-type: none"> <li>•Risk of prioritizing the wrong project</li> <li>•Resource risk</li> </ul>	<ul style="list-style-type: none"> <li>•Risk of not understanding customer needs</li> <li>•Resource risk</li> <li>•Supplier risk</li> <li>•Manufacturing risk</li> <li>•Quality risk</li> <li>•Materials risk</li> <li>•Reliability risk</li> </ul>	<ul style="list-style-type: none"> <li>•Risk of a poor introduction to the market</li> <li>•Risk of the product not being ready to sell</li> <li>•Risk of poor support</li> <li>•Risk of a fatal bug</li> </ul>	<ul style="list-style-type: none"> <li>•Supplier risk</li> <li>•Manufacturing risk</li> <li>•Competitive risk</li> </ul>
Managing the business	Strategy Implementation	Tactical Selection of Project	Product Development	Product Introduction	Maturity

## Risk and Challenge on Materials and Components Purchasing



Large purchasing fare  
in total



Low purchasing fare  
per unit/year



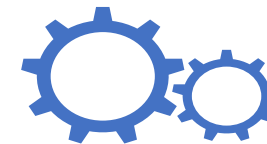
Supplers in world wide for  
example China, USA, Europe,  
UK, Japanese and so on



Too many kinds of raw  
materials and  
componnents



Different kinds of  
suppliers



Different level of  
materials and supplier

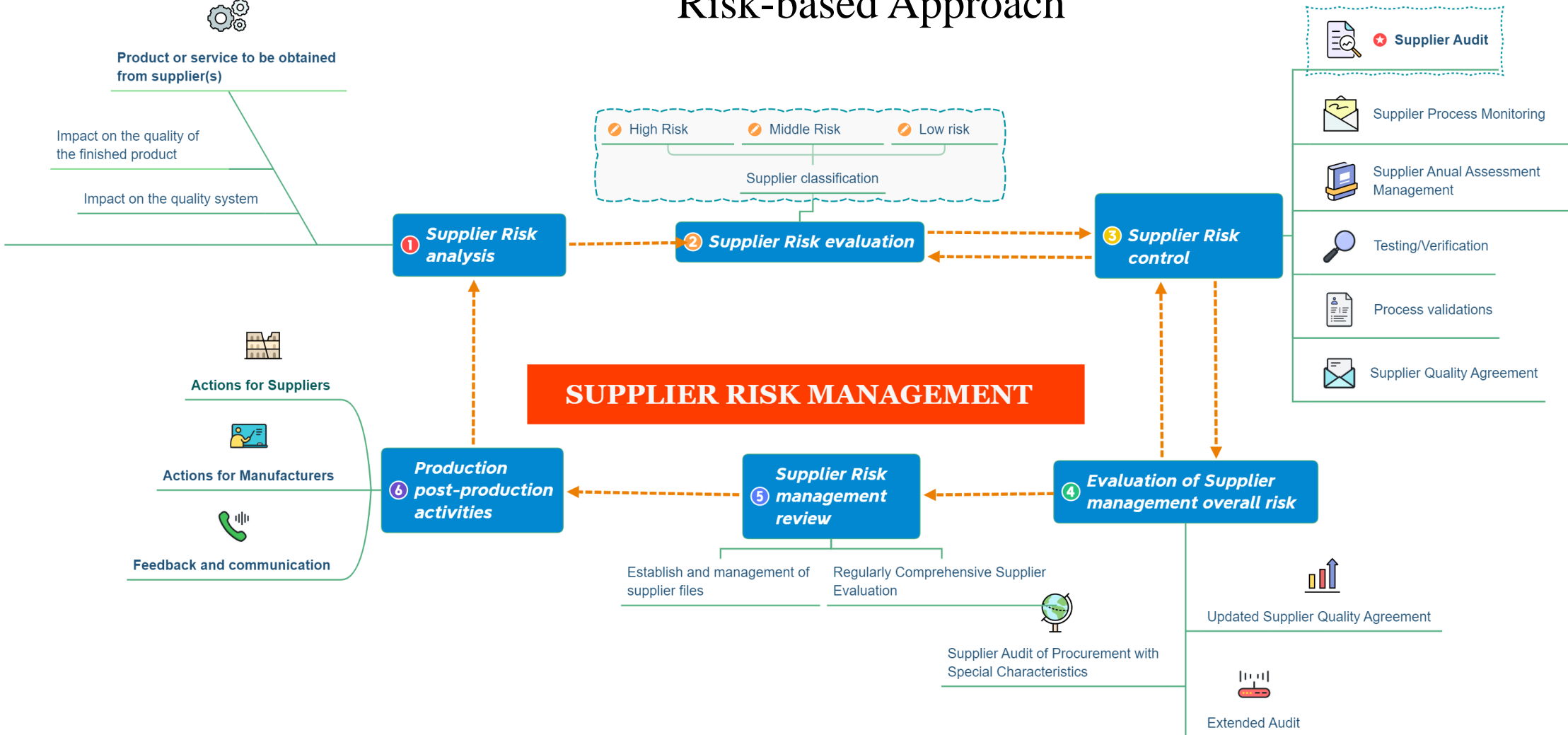
## Standards and Guidance Collection & Adoption

- T/CAQ 10108-2018 Supplier Audit Guidance
- Guidelines for Supplier Audit of Medical Device Manufacturers (NMPA regulation ([2015] No. 1)
- ISO 19011:2018 Guidelines for auditing management systems
- ISO 13485:2016 Medical devices - Quality management systems -Requirements for regulatory purposes
- SG3 (PD)/N17R7 Quality Management Systems - Medical Devices - Guidance on Supplier Controls for Products and Services

## Comparision and Analysis

- Guidelines for Supplier Audit of Medical Device Manufacturers (NMPA regulation ([2015] No. 1)
- SG3 (PD)/N17R7 Quality Management Systems - Medical Devices - Guidance on Supplier Controls for Products and Services
- GHWP/WG7/P003:2023 Guidance for Auditing Supplier to Medical Device Manufacturers

# Risk-based Approach

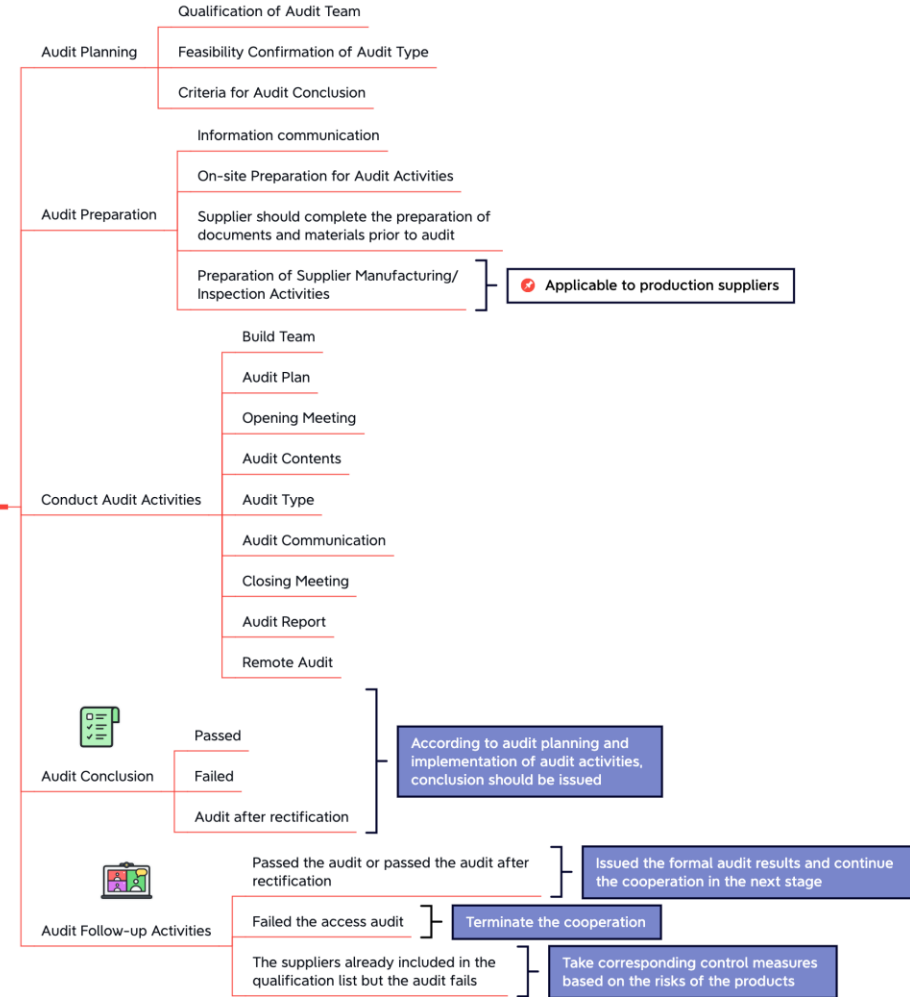


# Overview

All activities are based on Risk Management

## Guidance to Supplier Audit for Medical Device Manufacturers

### Audit Activities



### Supplier Audit of Procurement with Special Characteristics

- Supplier of animal-origin raw materials
- Supplier Providing Sterilization Services
- Supplier of Allogenic Raw Materials

### Supplier Selection and Management Procedure

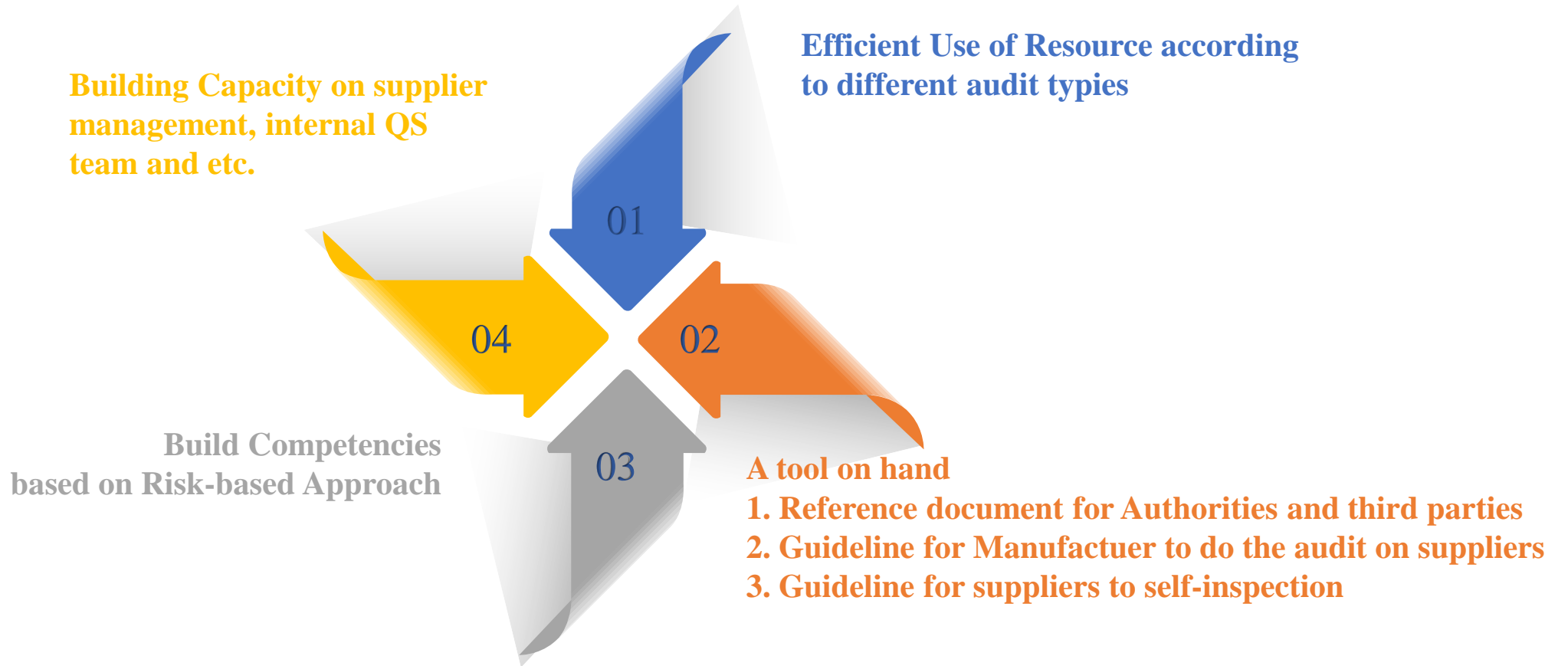
- Comprehensive Access Audit of Potential Suppliers
- Process Monitoring
- Assessment Management

### Key Points of Audit

- Document Audit
- On-site Audit
- Change Management Audit
- Extended Audit



## Benefit & Opportunities





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**THANKS!**