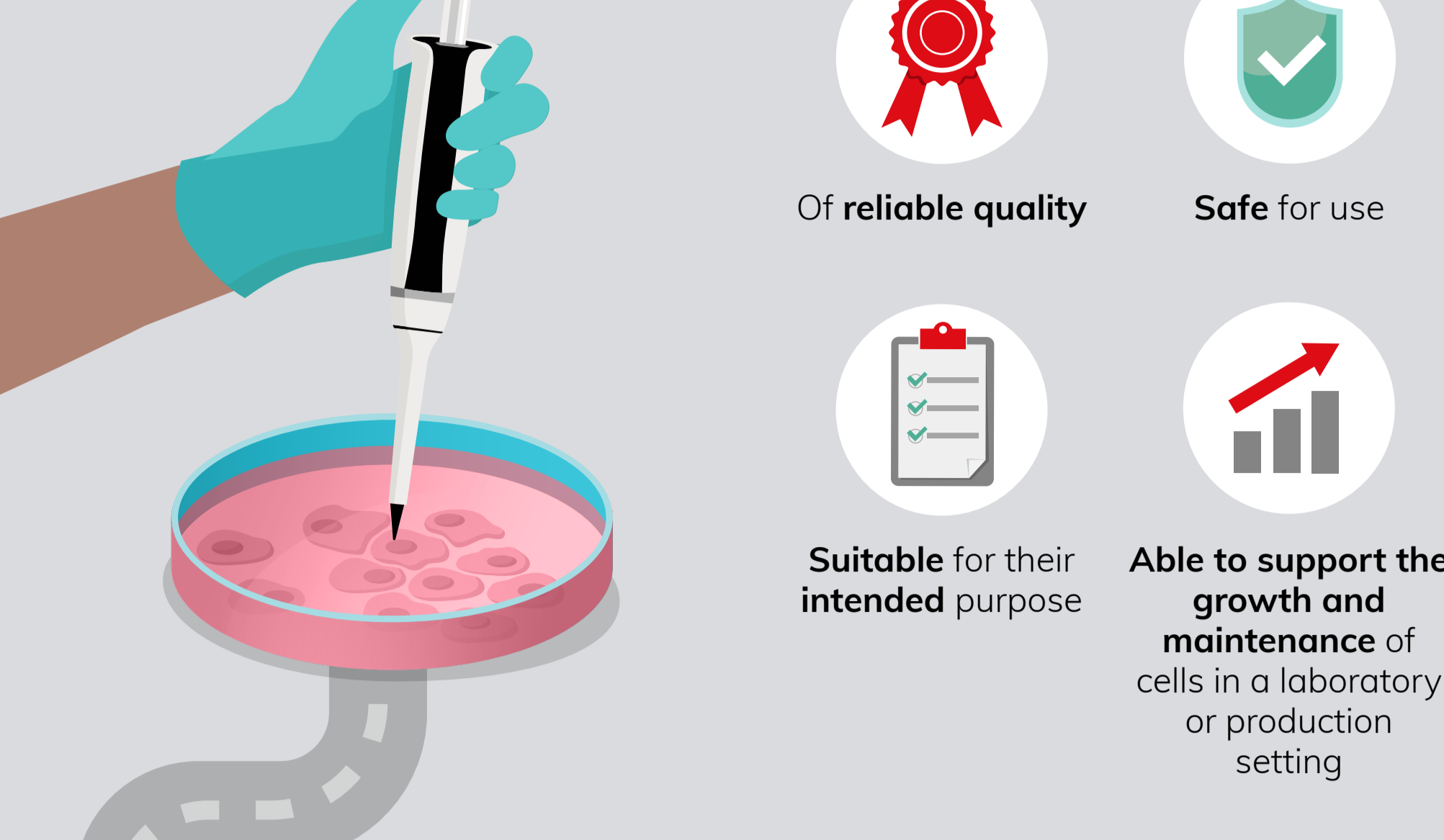


Ensuring Good Manufacturing Practice in supply chain processes

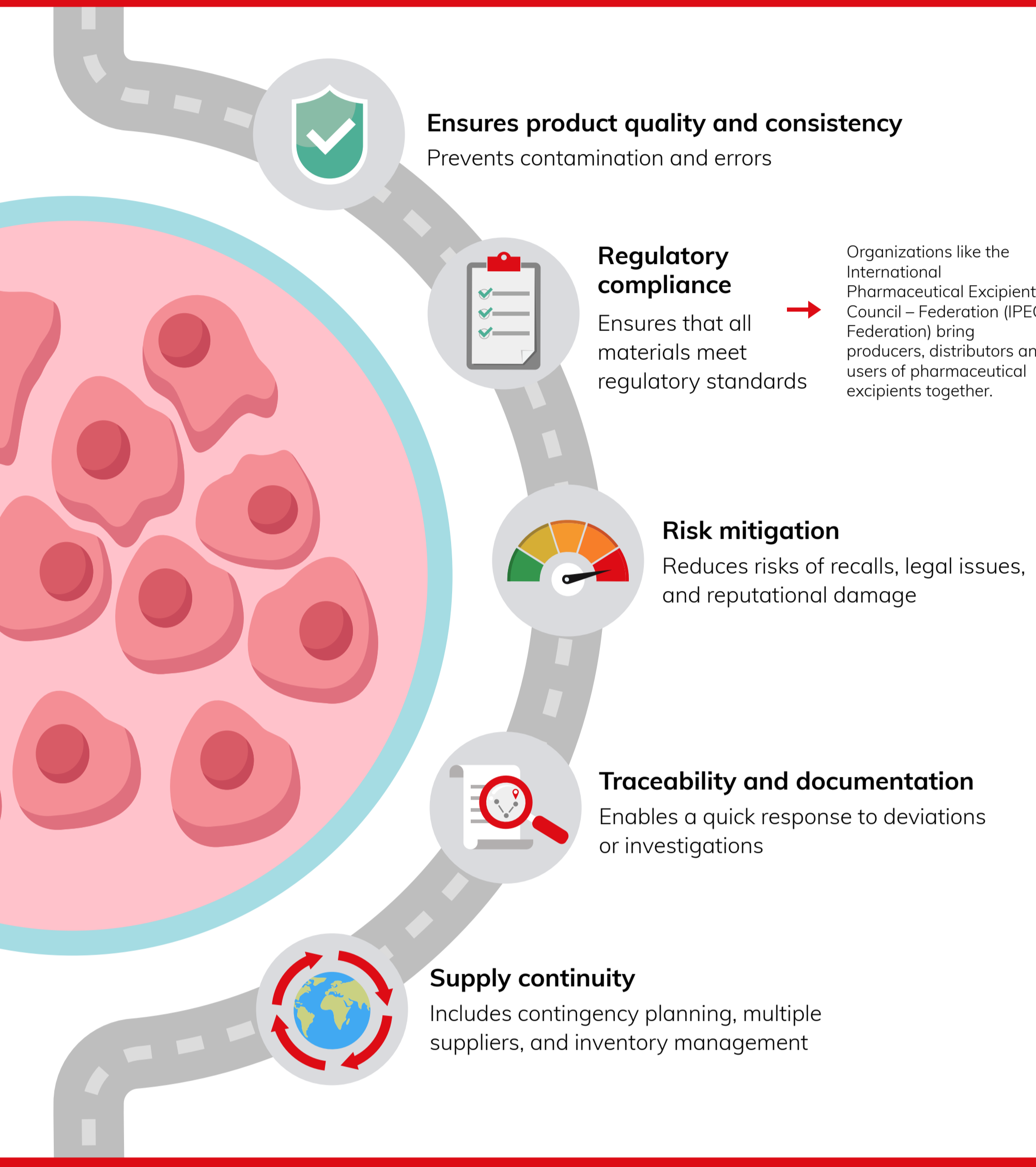
What is GMP?

Good Manufacturing Practice (GMP) comprises a set of regulations ensuring that products are consistently produced and controlled according to quality standards.

In the context of cell culture media, the EXCiPACT™ GMP standard for Excipients/Pharmaceutical Auxiliary Materials (PAMs) ensures that the cell culture media are:



Why is a qualified supply chain essential for GMP cell culture products?



Ensures product quality and consistency
Prevents contamination and errors

Regulatory compliance

Ensures that all materials meet regulatory standards

Organizations like the International Pharmaceutical Excipients Council – Federation (IPEC Federation) bring producers, distributors and users of pharmaceutical excipients together.

Risk mitigation

Reduces risks of recalls, legal issues, and reputational damage

Traceability and documentation

Enables a quick response to deviations or investigations

Supply continuity

Includes contingency planning, multiple suppliers, and inventory management

Recommended GMP requirements in supply chain



Supplier qualification and management

- Conduct regular audits to ensure supplier compliance
- Establish clear agreements outlining GMP responsibilities
- Monitor supplier performance continuously

Raw material and component sourcing

- Test incoming materials for identity, purity and quality
- Maintain detailed records for material traceability
- Store materials under controlled conditions to prevent degradation



Packaging and labeling

- Ensure accurate labeling with batch numbers and expiry dates
- Use tamper-evident packaging to protect product integrity
- Implement serialization for product traceability



Manufacturing process control

- Validate processes to ensure consistent product quality
- Identify and mitigate risks to prevent contamination
- Regularly maintain and calibrate equipment



Storage and transportation

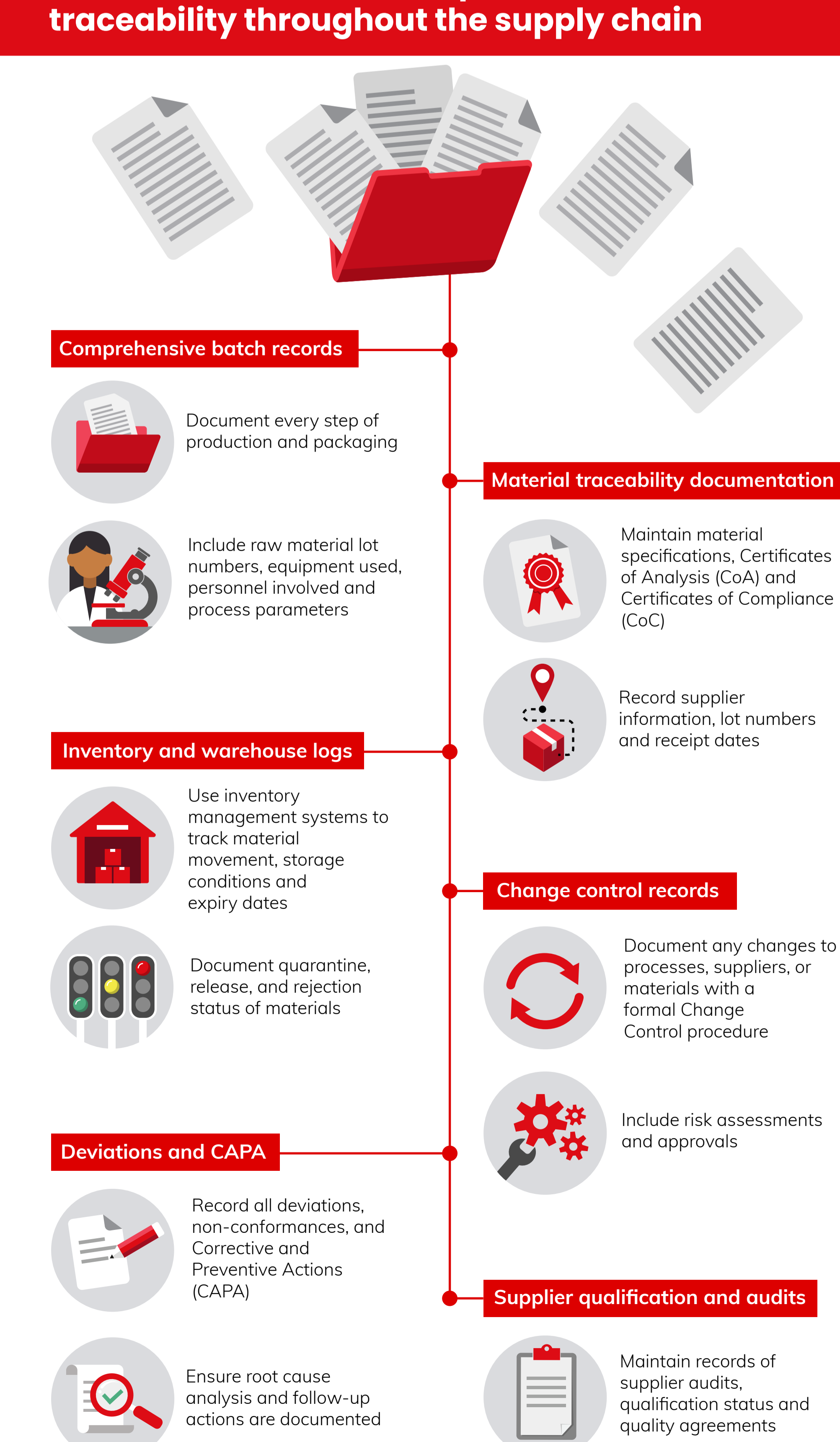
- Continuous monitoring of storage conditions like temperature
- Maintain clean, pest-free and organized facilities
- Manage cold chain logistics for temperature-sensitive products



Distribution and supply chain integrity

- Maintain comprehensive records of product movement
- Conduct audits of logistics partners
- Establish contingency plans for emergencies

Essential documentation practices to maintain traceability throughout the supply chain



Comprehensive batch records

Document every step of production and packaging



Include raw material lot numbers, personnel involved used, equipment used and process parameters

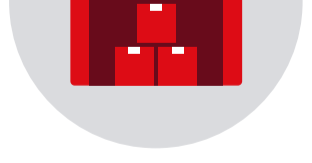


Inventory and warehouse logs

Use inventory management systems to track material movement, storage conditions and expiry dates



Document quarantine, release, and rejection status of materials



Deviations and CAPA

Record all deviations, non-conformances, and Corrective and Preventive Actions (CAPA)



Ensure root cause analysis and follow-up actions are documented



Material traceability documentation

Maintain material specifications, Certificates of Analysis (CoA) and Certificates of Compliance (CoC)



Record supplier information, lot numbers and receipt dates



Change control records

Document any changes to processes, suppliers, or materials with a formal Change Control procedure



Include risk assessments and approvals



Supplier qualification and audits

Maintain records of supplier audits, qualification status and quality agreements

