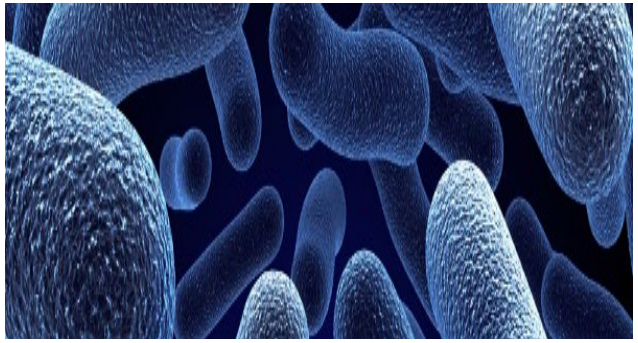
Australian Government
Department of Health
Therapeutic Goods Administration

Clean Room Requirements for Biologicals

A General Overview of contamination control



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TGA Health Safety Regulation

Outcomes

- General understanding of Clean rooms and their role in contamination control
- General understanding of how Personnel play an essential role in contamination control
- General understanding of how Critical Materials entering cleanrooms can be a source of contamination
- General understanding of Decontamination Programs for contamination control
- General understanding of the importance of environmental monitoring programs in contamination control

Contamination Control and Clause 300

- **Clause 300**:- Premises, facilities and equipment should be located, designed, constructed, adapted, maintained, and suitable for its intended use. Their layout and design should aim to ***minimise the risk*** of errors and permit ***effective cleaning*** and maintenance in order ***to avoid contamination***, build up of dirt and, in general any adverse effect on the quality of the products.
  - In order to ***minimise the risk of microbiological and particulate contamination***, the manufacture of ***sterile products***, or ***products required to have a low bioburden***, should be subject to special ***environmental controls*** (e.g. clean rooms, biological safety cabinets). Where required, applicable code ***clauses in Annex 1 of the mandated Code of GMP for Medicinal Products*** should apply.
  - Premises, facilities and equipment which, is critical to the control of processing should be formally qualified.

Other applicable Contamination control Clauses: 305, 306, 308, 332, 333, 800, 818, 821, 901, 913

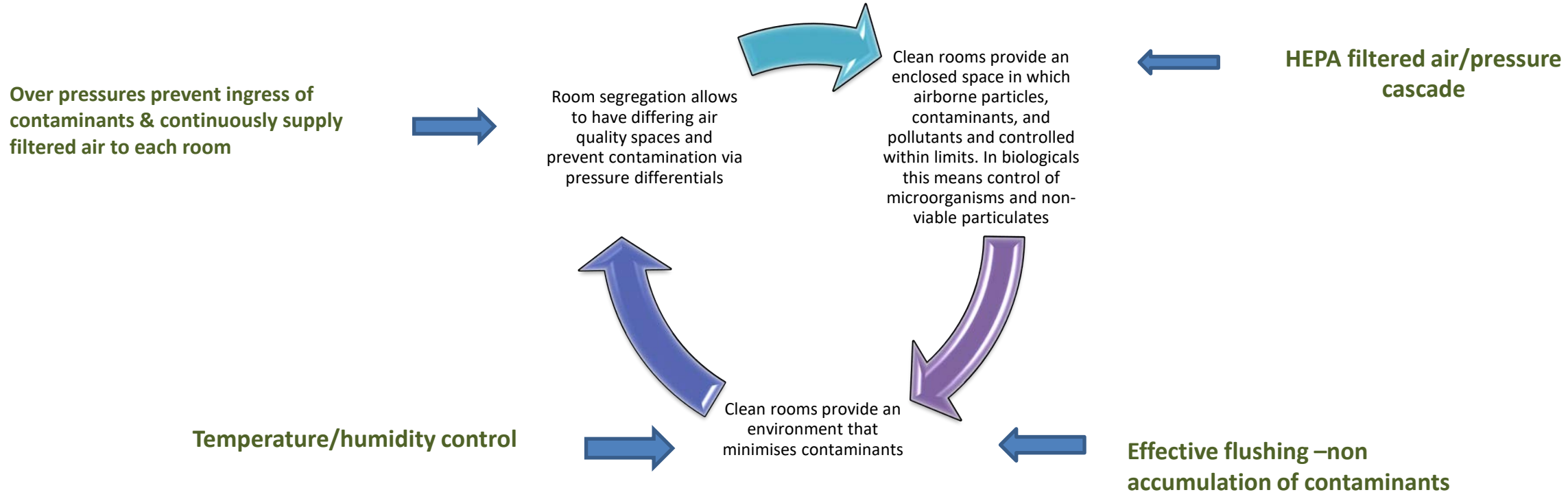
Clean rooms and Clause 300

- ARTG registration:
- Sterile Product- Annex 1 applicable (Class 3 and 4 biologicals)
- Non-Sterile Products (low bioburden)- aseptic minimal manipulation- (Class 2 biologicals)- effective risk based contamination controls required to prevent contaminating products during processing and storage in line with cGMP:

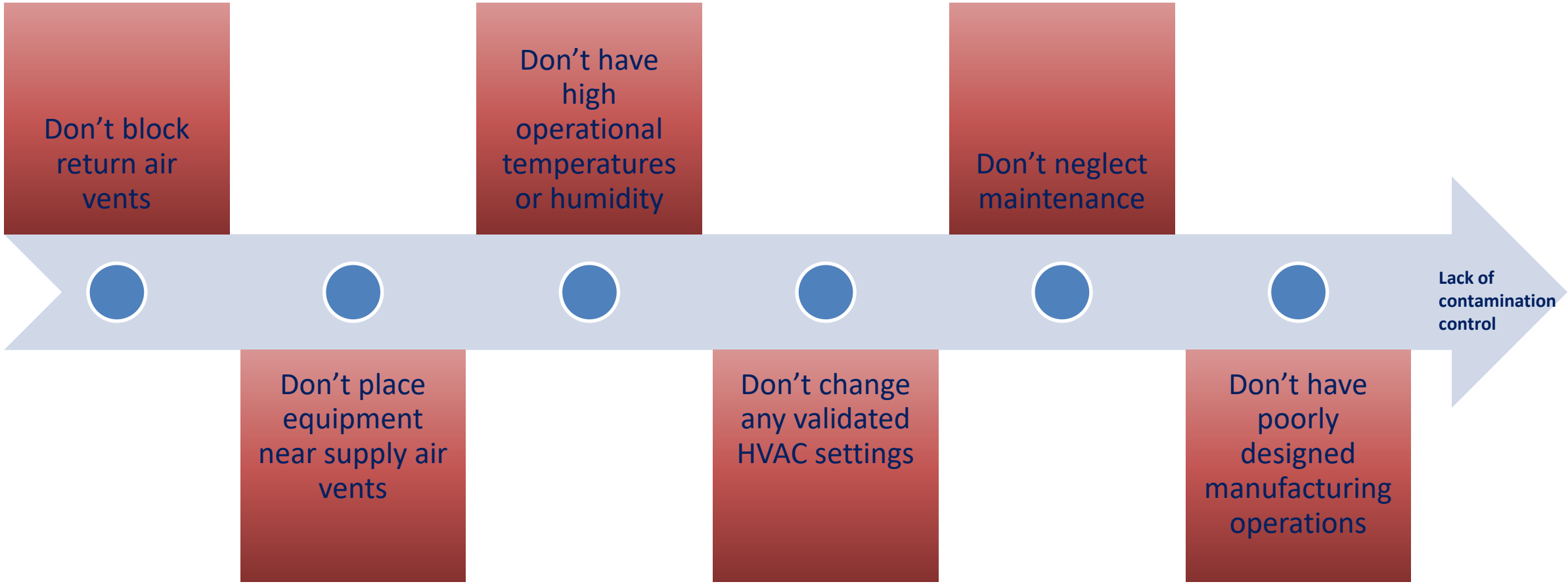
Clean rooms vital to contamination control

Clean room controls

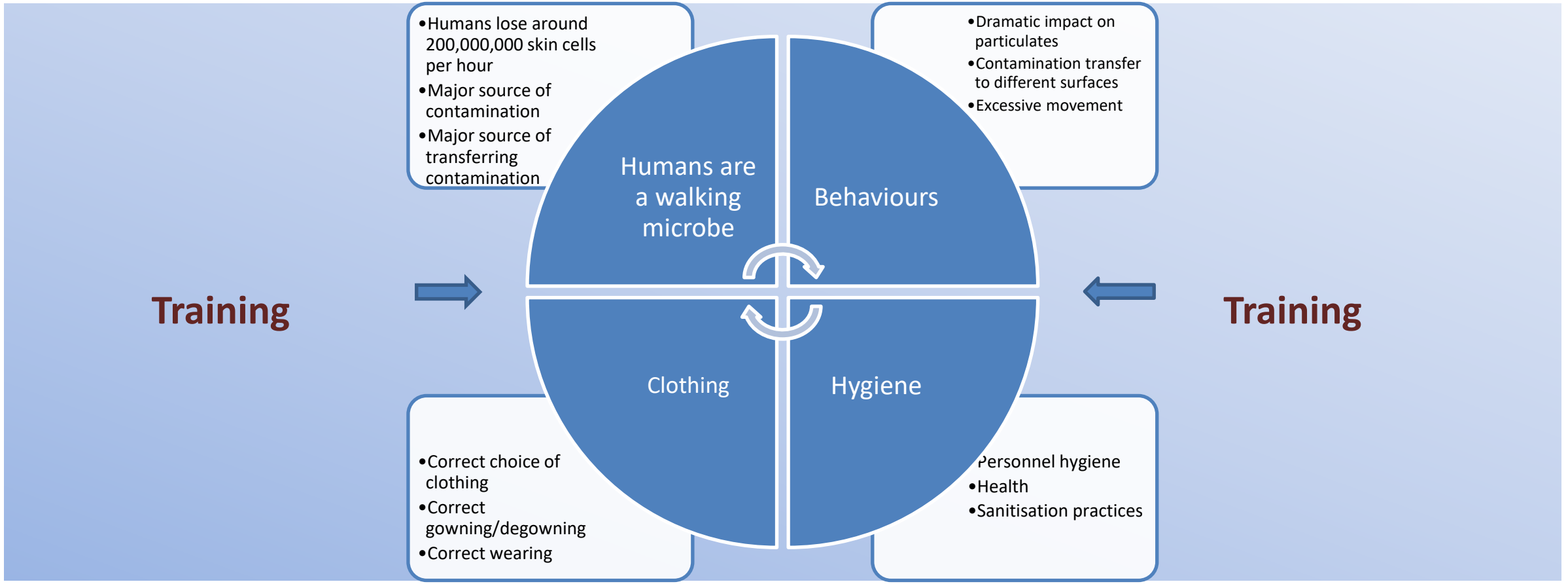
What clean rooms do



The ‘Don’ts’ of clean rooms

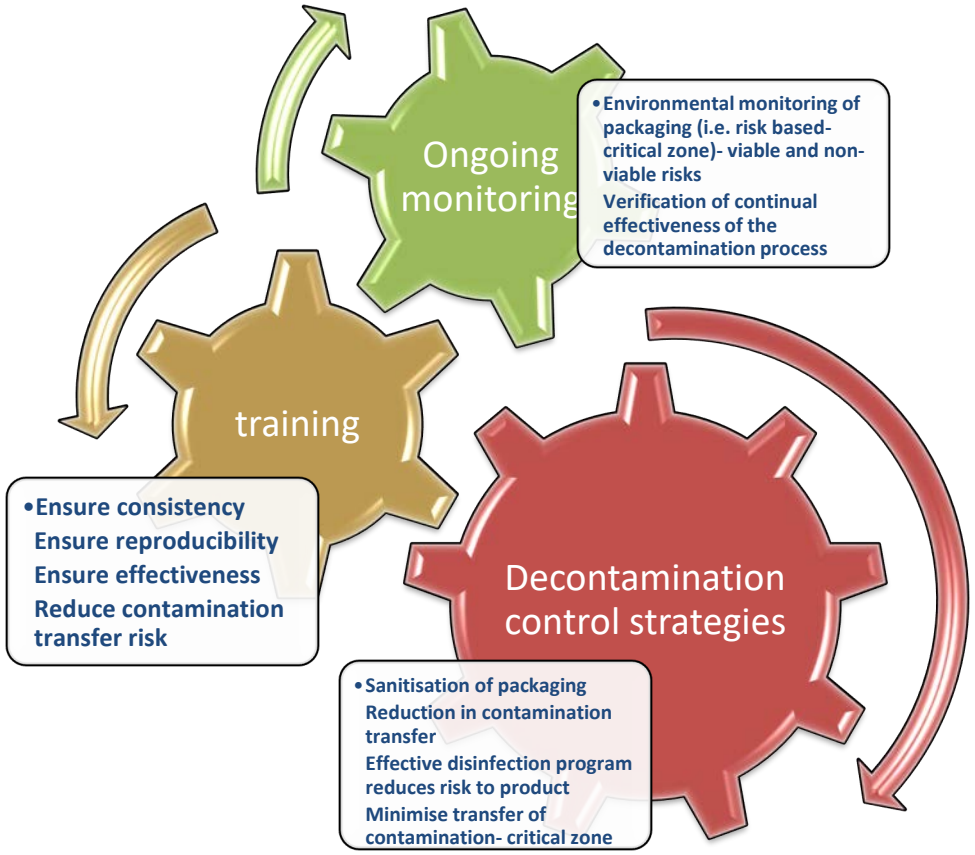


Personnel- A clean room nemesis

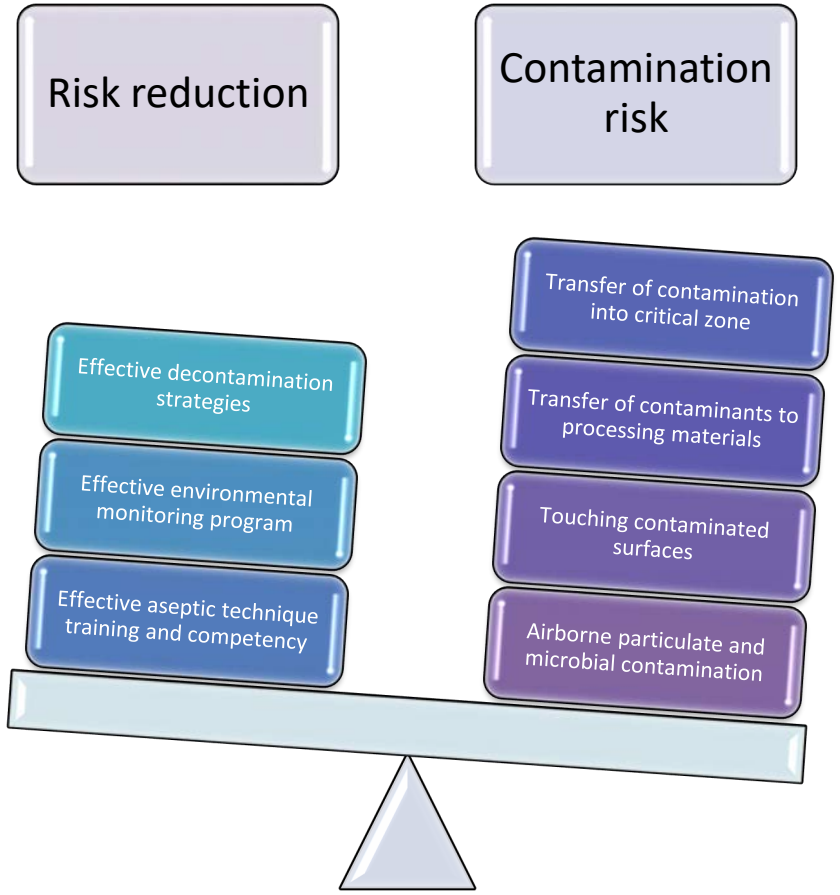


Critical materials- Ghost contaminant

Critical materials- contamination controls

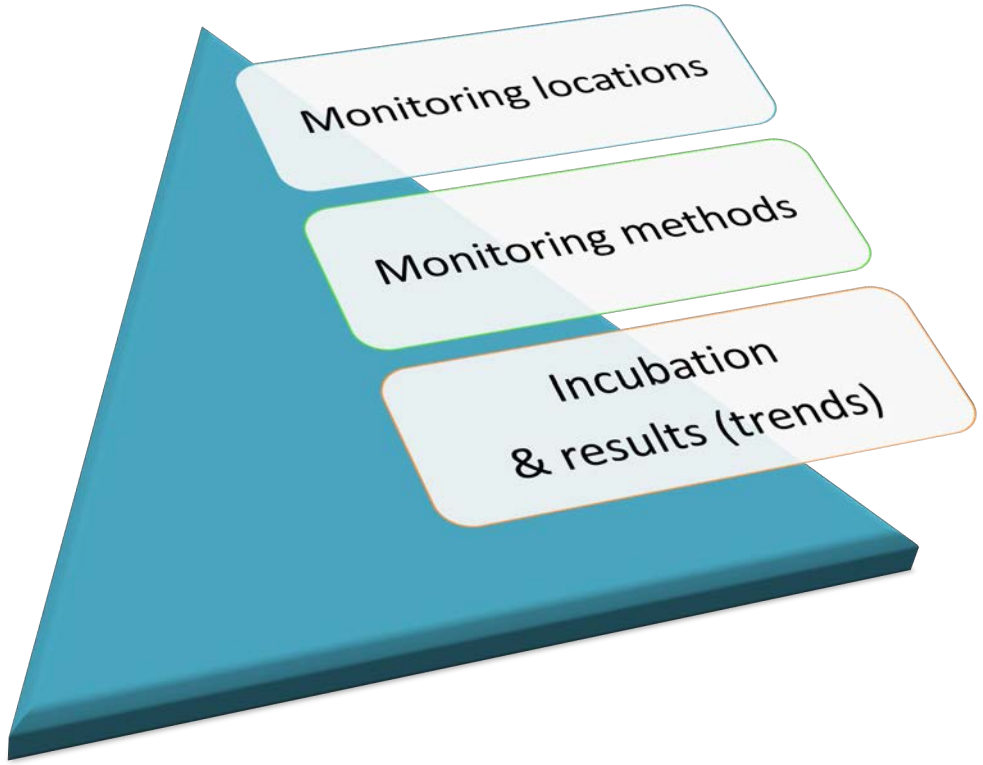


Critical Role of Decontamination



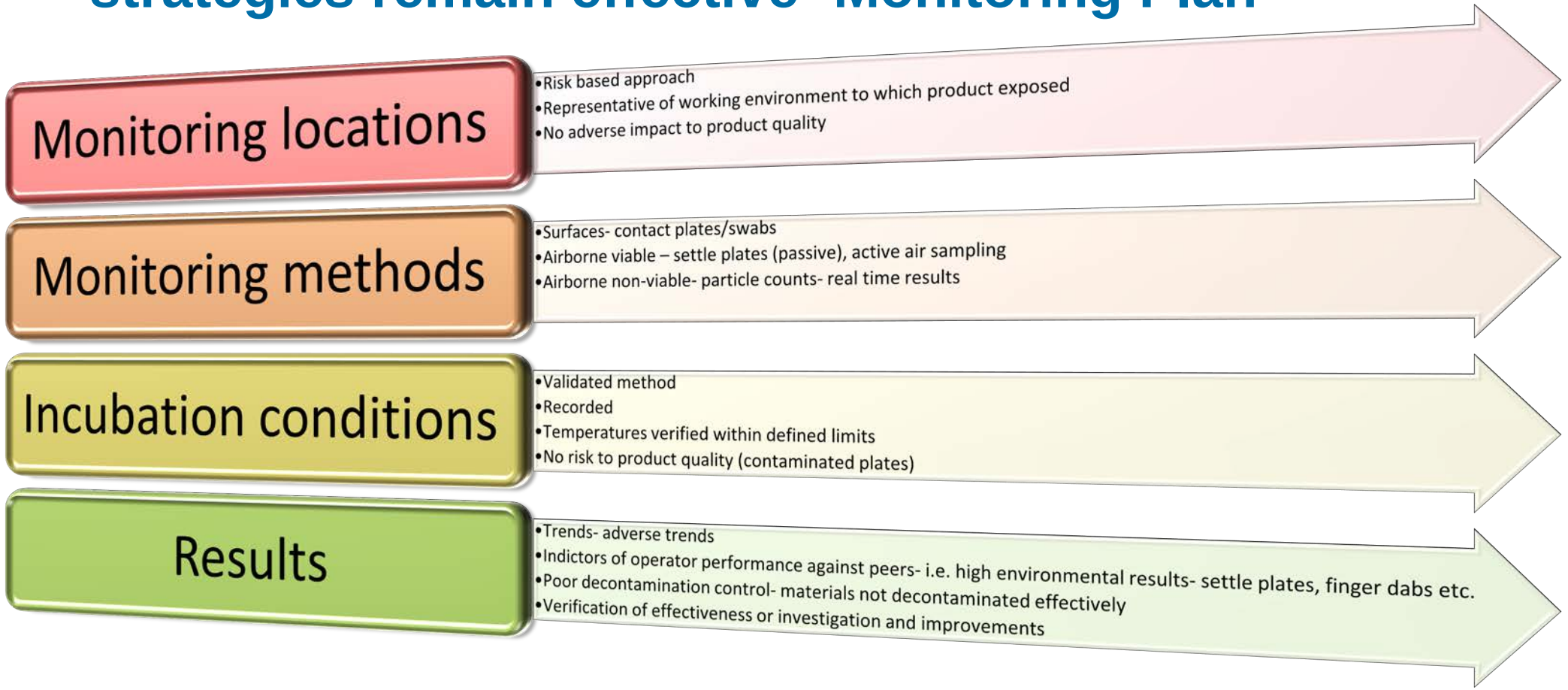
Environmental Monitoring- verifies contamination control strategies remain effective

Monitoring Plan

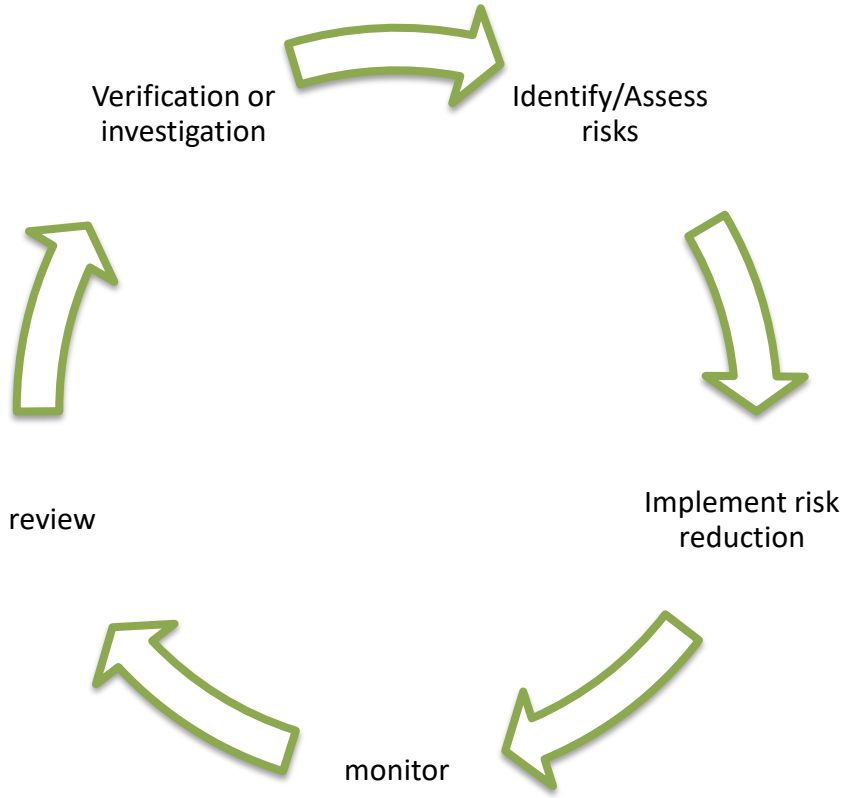


Effective control or investigation & process improvements

Environmental Monitoring- verifies contamination control strategies remain effective- Monitoring Plan



Lifecycle approach to contamination control



Contamination Control

Know your vulnerabilities (contamination risks)

- Do you know all your vulnerabilities?
- How have you assessed these vulnerabilities?
- What are your top vulnerabilities?

Keep vulnerabilities visible

- Can you automatically detect your vulnerabilities?
- What systems do you use to be proactive?
- Do you have effective tools to assess vulnerabilities?
- Do you have sufficient resources to assess, implement, monitor and mitigate vulnerabilities?
- Do your monitoring tools enable proactive action to adverse trends?

Continually monitor & assess risks

- Do you continually assess effectiveness of the control strategy monitoring systems?
- Do you reopen completed risk assessments when deviations & OOS recur?
- Do you take a proactive approach to outcomes of monitoring results?

Trend analysis

- What trend analysis tools do you use?
- Do you take action when trends display an upward trend before limits are exceeded?
- Are you able to identify and trend key contamination sources?

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