

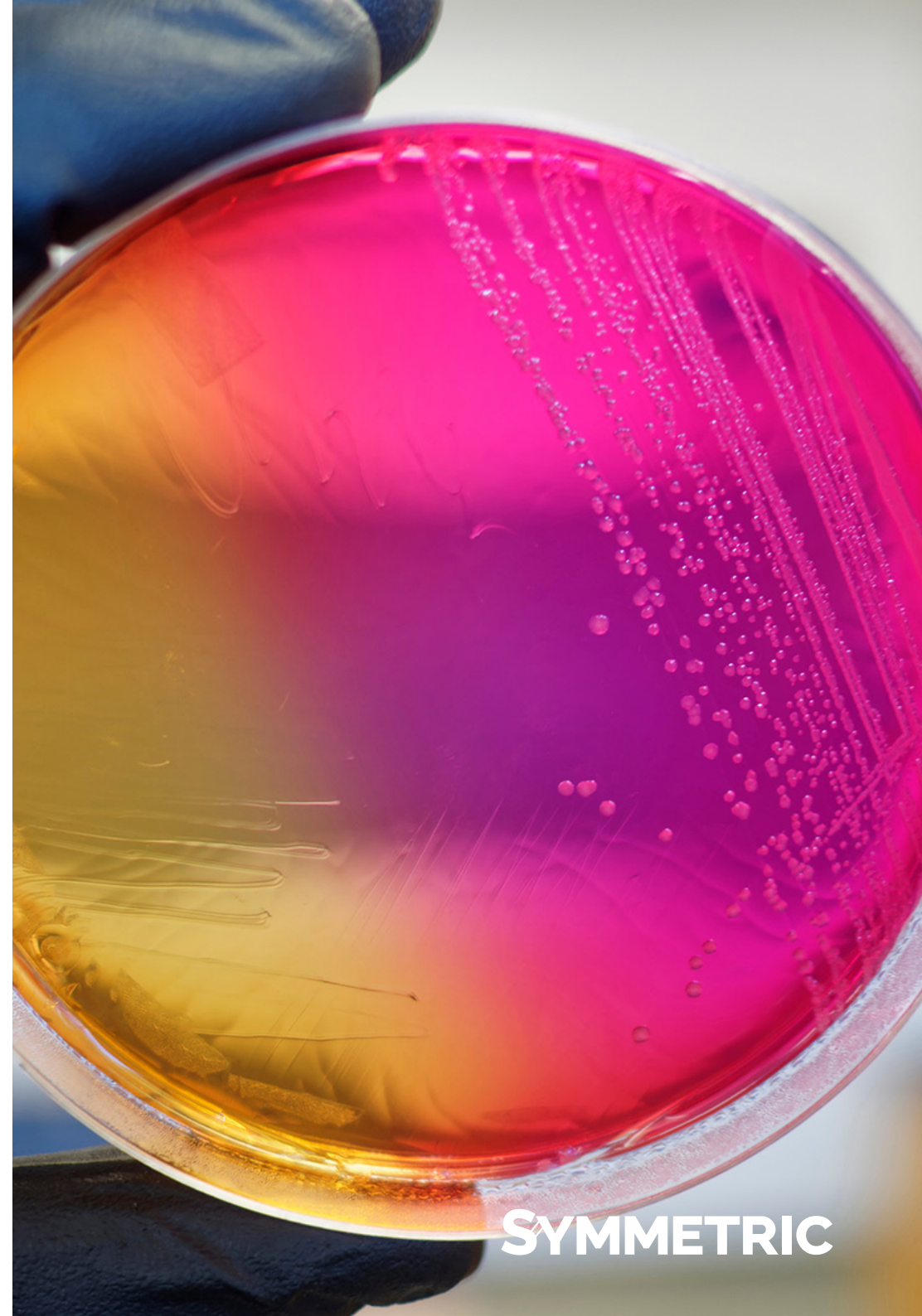
Sneak Peek

Contamination Control Strategy



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What utilities should be included in the CCS?

- Water (all grades), steam (all types), HVAC (all classes), air, nitrogen, other) gases, power(?).
- The assessment must include whether the utility potentially impacts on contamination of products by microorganisms, pyrogens and particulates.
- After the assessment, mitigation may or may not be required to eliminate or minimise the risk to the product by the relevant utility.

- What are the utilities' control and monitoring systems?
- HVAC may have been covered previously in relation to the facility and premises, if so simply refer to the previous comments and section references.
- The control and monitoring practices of water systems and gas systems are relatively easy to document, for example the correct selection and use of filters, checks on filter integrity.
- Power should not be overlooked as power loss can result in increased risk of particulate contamination from equipment failure as a result of the power interruption.

Raw material controls including in-process controls and CCS.



- Design controls examples: sampling area classification, entry and exit requirements, gowning requirements, sampling methods, etc.
- Procedural controls examples: cleaning frequency, LAF airflow and pressure control, gowning method, etc.
- Technical and organisational controls examples: types of samples and sample containers, cleaning practices of the sampling room, segregation of high-risk materials, ie samples supplied with delivery?
- Monitoring measures examples: sampling area bioburden data, raw material bioburden data, particulate levels in use and at rest conditions for sampling area, etc.

Registration

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