



## Evaluate Your **Cell & Gene Therapy** Contamination Control Program

**Are you confident in your cell and gene therapy production environment?**

**Use these questions to evaluate your contamination control and product safety processes:**

- ▶ Is your current manufacturing process scale up/out-ready with a GMP-compliant facility?
  - Is your contamination control program audit-ready?
- ▶ Do you manufacture or intend to manufacture at a CDMO or use your own cleanroom facility?
  - Are you prepared for your next phase of development?
- ▶ Have you evaluated the contamination risk of using an open system vs closed system?
- ▶ Have you evaluated the contamination risk from the environment surrounding your open/closed system?
  - Have you analyzed the contamination risk from ancillary materials?
  - Have you considered the costs/benefits of an isolator vs. a cleanroom?
- ▶ Do you know how to address the parts of your process that have the highest risk of exposing cells or products to contamination?
- ▶ What parts of your process currently involve or are expected to utilize a validated decontamination process?



### ABOUT ECOLAB

**Ecolab delivers cleanroom confidence. Our science-driven innovation puts our biopharmaceutical manufacturing customers at the forefront of compliance, product safety and operational excellence.**

We offer leading-edge programs that is proven to meet the sensitive and rigorous demands of cell and gene therapy manufacturing. Our portfolio of cleaning and advanced contamination control products is supported by proactive service and technical expertise.

Ecolab supports contamination control design and strategy from clinical trials to commercial manufacturing. This can reduce your costs of changes in scale and ensure consistency in your patient and product protection.

When you partner with Ecolab, you'll be assured and confident, you have assessed your risk profile and taken pivotal steps to help ensure it's under control.

**IF YOU WOULD LIKE TO DISCUSS CONTAMINATION CONTROL SOLUTIONS, CONTACT AN ECOLAB CELL AND GENE THERAPY SPECIALIST**

#### WORLDWIDE HEADQUARTERS

1 Ecolab Place, St. Paul, MN 55102 USA [www.ecolab.com/lifesciences](http://www.ecolab.com/lifesciences)

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