

## Frequently asked questions related to the expansion of the Cytiva facility in Logan Utah, USA

We are committed to meeting the growing demand for HyClone™ cell culture media products by increasing capacity and further enhancing supply reliability through the expansion of Cytiva's Logan, UT facility. This expansion is designed to enhance our flexibility and efficiency in meeting this demand. It adds manufacturing suites and doubles the capacity of the current facility. We understand that our customers will have additional questions, so we provide answers to some of the common ones here.

### 1. What is the scope of the expansion?

The scope of the expansion of our cell culture media facility in Logan, UT includes increased capacity for large-volume liquid media and dry powdered media – both standard and custom products. The expanded facilities now feature a warehouse staging area to help maintain finished product temperatures prior to shipping, consolidated quality control labs, and new climate-controlled corridors. Impacted products include growth media and feeds, buffers, high-concentration fluids, and other process liquid products packaged in single use bags. Serum products and small-volume media are not impacted.

### 2. What change notifications have already been published?

A prenotification announcing the expansion plan was published on 09 August 2024. The formal change control notification (CCN) for large-volume liquid media was published on 05 December 2024. These documents are available to customers who are registered and subscribed to receive CCNs for any impacted products at [www.cytiva.com/rsf](http://www.cytiva.com/rsf). Notifications can be found under the CCN tab once logged in.

### 3. Will there be a separate change notification for dry powdered media?

Yes, in the second quarter of 2025 we plan to publish a separate CCN for dry powdered media and email it to existing customers who are subscribed to receive CCNs for any impacted products.

### 4. What is the process to subscribe to CCNs?

If you are not yet signed up for CCNs, log in to your account at [cytiva.com](http://cytiva.com) and subscribe at [cytiva.com/rsf](http://cytiva.com/rsf). To ensure continuity if roles change, we recommend subscribing with a general email address (e.g., [changenotifications@company.com](mailto:changenotifications@company.com)) that multiple people can access. Contact your regional sales office if you have questions.

### 5. Will a summary of the facility validation details be available?

The expanded liquid media manufacturing facilities and equipment will be validated and qualified to meet the requirements of ISO 13485. Once validation is completed, a CCN update will be published to provide the validation summary or instructions on how to access it. The CCN will be issued to all

customers who are subscribed to receive CCNs for any impacted products and available at [www.cytiva.com/rsf](http://www.cytiva.com/rsf) once published.

**6. When will the updated Validation Guides be available?**

We plan to release the updated Validation Guides to existing customers in Q4 2025 for liquid media products and Q4 2026 for dry powdered media. Validation Guides are available to existing and new customers upon subscription and approval at [www.cytiva.com/rsf](http://www.cytiva.com/rsf).

**7. Will there be an address change?**

The address for the cell culture media facility in Logan UT will remain the same: 925 West 1800 South Logan, Utah 84321. The Warehouse address will also remain the same: 965 W 1800 S Logan Utah 84321.

**8. Will the shelf life or expiry date of the product be affected?**

No, this will remain the same.

**9. Will the product Certificate of Analysis be affected?**

No, this will remain the same.

**10. Will the product label be affected?**

No, this will remain the same.

**11. How do I schedule a site audit?**

Please contact your Cytiva commercial representative to schedule a site audit.

**12. Are there any changes to order processing?**

No, you will continue to order through your local Cytiva entity.

**13. Will there be any changes to the part numbers for standard or custom products?**

Part numbers, specifications, batch records, and lot sequencing will remain consistent for all products.

**14. Will the Intended Use statement change?**

No, the statement will remain the same.

**15. Will there be a change to the sterile filtration step?**

Products will be filtered per the specifications, maintaining the same filter membrane type and pore size.

**16. Why is it important to approve the expanded manufacturing site for my custom products?**

Your approval positions us to better serve you and other customers by increasing production capacity, enhancing our capabilities and ultimately reducing lead times. This expansion offers the potential for enhanced reliability and speed in delivering both standard and custom orders.

**17. How can I update my custom specifications to add the expansion?**

Cytiva will provide details on how to update customer specifications post-validation.

**18. How will manufacturing lead times be affected by the expansion?**

With the expansion of this facility, we anticipate being better able to meet the growing demand for cell culture media products.

**19. Will there be changes in the raw materials used for producing standard or custom products?**

No, the same raw materials will continue to be sourced from qualified vendors.

**20. Where will my standard or custom product be produced?**

Standard products will be produced in both the current and additional suites after the new suites have been validated. Cytiva will assign the suites to be used for any given batch based on factors including scheduled batch size, capacity, and efficiency. For custom products where Cytiva has provided a notification, the same process will apply once you have approved the expanded manufacturing site for your custom products.

**21. Will the new suites be free of animal-derived components?**

Yes, for both liquid media and dry powdered media production.

**22. How can I stay informed about the progress of the expansion?**

Please contact our technical support team at [hyclone.techsupport@cytiva.com](mailto:hyclone.techsupport@cytiva.com).

[www.cytiva.com](http://www.cytiva.com)

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