

GENENTECH USA, Drug Supply Chain Security Act Data Issues and Resolution Policy

Effective Date: May 27, 2025



Welcome to Genentech's Drug Supply Chain Security Act (DSCSA) Data Issues and Resolution Policy. This policy was created to help customers navigate working with Genentech when a data error occurs on a shipment, and falls under the obligations of the Federal Drug Supply Chain Security Act law.

This document is focused on DSCSA data issues and reporting. This policy is not associated with, and is out of scope of the Genentech USA, Return Goods Policy.

IF YOU EXPERIENCE A DSCSA RELATED ISSUE ON YOUR SHIPMENT IMMEDIATELY DO THE FOLLOWING:



**SEGREGATE AFFECTED
PRODUCT SHIPMENTS
IMMEDIATELY***



**REPORT DSCSA DATA ISSUES
IMMEDIATELY OR WITHIN 24
HOURS OF DELIVERY****

OVERVIEW

- Genentech is committed to collaborating with direct purchasers to minimize DSCSA data exceptions at the time of shipment.
- Occasionally, these exceptions may arise, and we aim to work together to resolve any future Data Issues, ensuring that our medicines reach patients efficiently.
- These guidelines address potential exceptions when passing, or failing to pass, the necessary information as required by the Drug Supply Chain Security Act (DSCSA). The covered data exceptions (addressed as "Data Issues" through this policy) below include:
- Product received with No Data
- Data received with No Product
- Packaging & Labelling Issues (damaged or unreadable barcode or label)
- Other Data Misalignment (e.g. formatting, barcode/label mismatch, or missing data).
- The purpose of this policy is to explain Genentech's approach to managing DSCSA-related Data Issues and share how we would like to collaborate with your company for their swift and effective resolution.



- This policy applies to all customers, including wholesale distributors and dispensers, who purchase directly from Genentech.
- We ask customers to work with Genentech in good faith to comply with and implement any current and future obligations as described in Title II of the Drug Quality and Safety Act “DQSA”, known as Drug Supply Chain Security Act (“DSCSA”).
- To ensure patient safety, upon receipt and identification of a DSCSA Data Issue, please segregate the affected product immediately and report the Data Issue immediately or within 24 hours of receipt of the product.
- Please collaborate closely with Genentech to resolve a DSCSA Data Issues within ten (10) business Days



PLEASE ADHERE TO DSCSA REGULATIONS

- Genentech asks customers to comply with the requirements of the Drug Supply Chain Security Act (“DSCSA”), including without limitation, requirements related to the transmission of serialized transaction data in electronic format from Genentech.
- In accordance with and to the extent required by state and federal law, customers shall create and maintain all records, manifests or other documentation, in electronic and/or written form, necessary to evidence the chain of ownership of any Products purchased from Genentech and shipped, resold or provided to another trading partner or customers.
- Genentech asks customers to work in good faith with Genentech to comply with and implement any current and future obligations as described in Title II of the Drug Quality and Safety Act “DQSA”, known as Drug Supply Chain Security Act (“DSCSA”), including but not limited to implementing resources, systems and processes needed to carry out a serial-level, interoperable exchange of DSCSA mandated transaction data, product verification, product tracing requirements in order to ensure supply chain security and compliance with all applicable DSCSA requirements.
- Genentech shall work collaboratively with customers to resolve any Data Issues within ten (10) business days or sooner. If that time frame is not feasible, Genentech will work with customers to resolve the Data Issues as soon as is practicable.
- For questions or concerns related to DSCSA, but not limited to, EPICS data onboarding, product verification, product tracing, EPICS data issues or exceptions, please contact the Genentech DSCSA team at GenentechDOSA-d@gene.com.

DSCSA DATA ISSUE REPORTING STEPS

1. Please Segregate Affected Product Shipments Immediately*

- a. Segregate all affected products and store them per labeled conditions.
- b. When segregating the product, keep a log of the temperature or use a temperature monitoring device throughout the time needed to resolve the Data Issue.
- c. The product must be segregated appropriately with corresponding temperature logs as proof it was stored correctly to be eligible for a Return Authorization. Any product that does not have proof of temperature storage will not be eligible for return.
- d. Customers should adhere to these storage instructions to maintain product integrity and ensure proper storage.
- e. Do not decline or return the package/shipment/truck delivery to Genentech, as it will not be accepted. Do not hold or stop trucks from delivering products to their next location.
- f. A Return Authorization request must be approved by a Genentech Customer Service Manager or Director and the authorized return paperwork must accompany the return. Customers will need a Return Authorization approval from Genentech to return products that may be subject to a DSCSA Data Issue.

2. Report DSCSA Data Issue Immediately or Within 24 Hours of Delivery**

- a. *Immediately or within 24 hours* of product delivery and upon identification of a DSCSA Data Issue send an email to the Genentech DSCSA Team at genentechdgsa-d@gene.com.
- b. Include as much detailed information as possible related to the Data Issue:
 - i. At a minimum, provide the issue submitter's name, facility name, contact information, facilities' technical point of contact (name and email), PO# of the order in question, a brief summary of the data inquiry or event, and any other applicable information.
 - ii. Provide key technical and business contacts capable of closely coordinating and responding within two (2) hours (during business hours), for any inquiries until issue resolution.
- c. If Genentech is not notified immediately upon identification of a Data Issue, or within 24 hours of product delivery,] it is assumed that the product was received and accepted along with the required DSCSA data.

3. Inventory Considerations

- a. After a reported Data Issue, if inventory is depleted and there is an urgent patient need for the affected product, please contact the Genentech Customer Service Team immediately.
- b. Genentech customers Service is open Monday- Friday 6 am - 5 pm PT (9 am - 8 pm ET) and can be reached at 800-551-2231. All inquiries will be acknowledged within one (1) business day.

4. DSCSA Data Issues Not Resolved in Ten (10) Business Days

- a. The Genentech USA Return Goods Policy is out of scope of DSCSA returns.
- b. If the reported Data Issue is not resolved within ten (10) business days (from the date of issue reporting), Genentech Customer Service will work directly with the purchasing customers to coordinate next steps (e.g. reorder, Return Authorization, credit) based on impact.
- c. Returns for DSCSA Data Issues are different from the returns referenced in the Genentech USA Return Goods Policy. The Genentech USA Return Goods Policy is independent and does not apply to DSCSA Data Issues.
- d. A Return Authorization request for DSCSA Data Issues must be approved by a Genentech Customer Service Manager or Director and the authorized return paperwork must accompany the return. Customers will need a Return Authorization approval from Genentech to return products that may be subject to a DSCSA Data Issue. Genentech will make every effort to process the Return Authorization within 1 to 2 business days.
- e. For products requiring refrigeration or specific temperatures, the returning shipment must include temp tags or tag alerts that monitor the temperature.
- f. Once a Return Authorization is approved and product is returned, credit will be based on returned products and quantity and whether product is resellable based on appropriate storage conditions or must be destroyed.
- g. Genentech will not accept, nor will Genentech issue credit, for returned product to any Genentech location or one of our affiliate 3PL (third party logistics) partners unless it has been authorized to be returned by Genentech Customer Service with an accompanying Return Authorization.
- h. Call Genentech Customer Service Monday- Friday 6 am - 5 pm PT (9 am - 8 pm ET) at 800-551-2231 to start the process for a return.

OTHER IMPORTANT CONSIDERATIONS

- Genentech will not pay any fees associated with DSCSA Data Issues, unless contractually agreed upon in advance.
- Genentech will consider waivers for inventory managed products to adjust for any product delays in receiving shipment that may reduce the distributor or specialty pharmacies' ability to meet days on hand per the applicable distribution services or specialty services agreement.
- In the event of a catastrophic disaster or business continuity disruption, Genentech will ask customers to delay shipments or accept data manually, without penalties or fees, until the event can be resolved and normal business operations can resume.

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