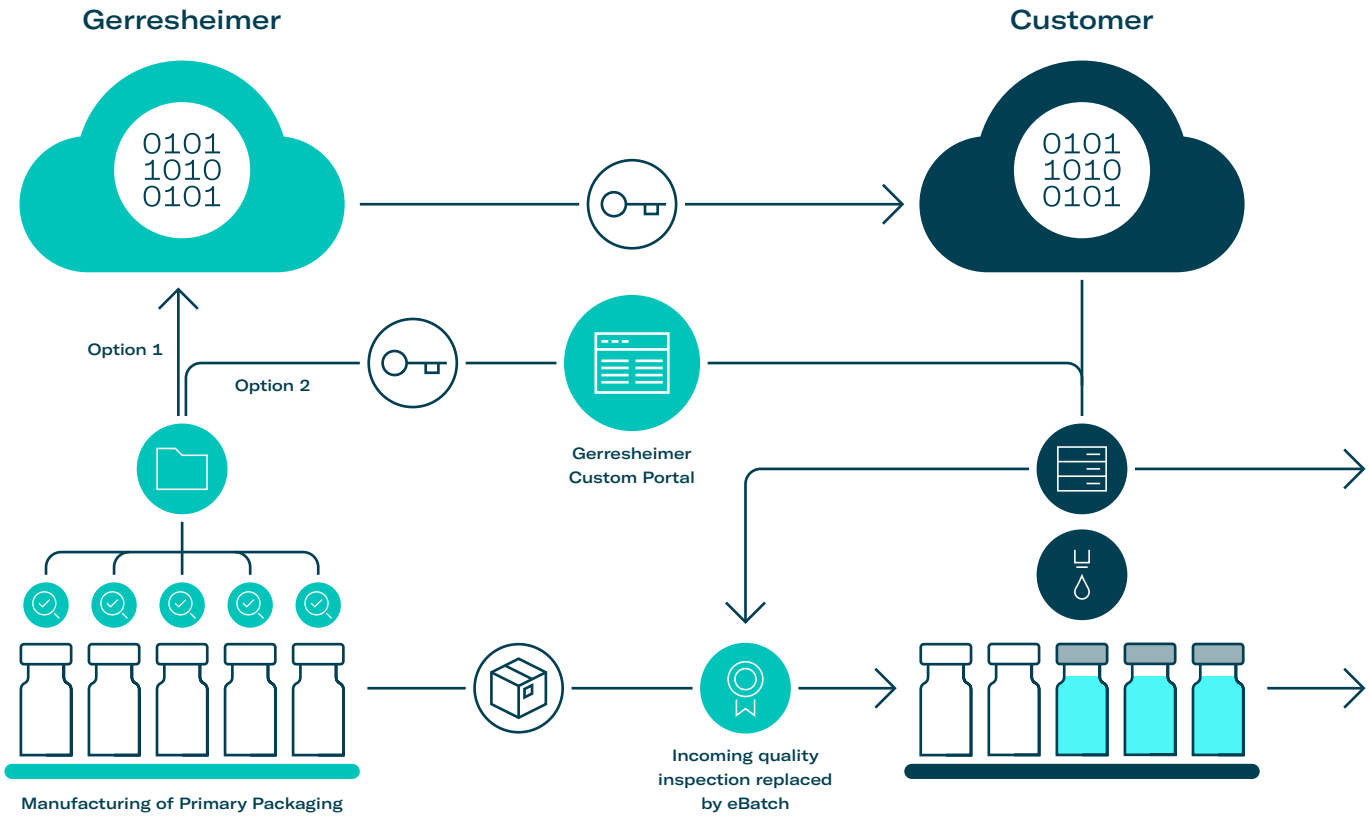
Gx® eBatch

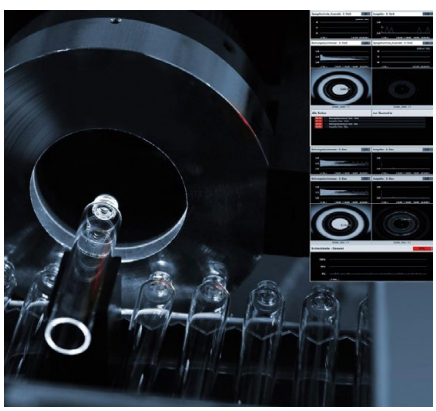
gerresheimer
innovating for a better life

Data-driven quality control



Increase confidence & efficiency through manufacturing steps via digital transfer of customized batch quality data

Gx® eBatch enables digital transfer of customized batch manufacturing data directly to pharmaceutical customers, eliminating the need for incoming batch inspection, streamlining production steps and enabling data analytics.



Assurance of parenteral primary packaging quality: Secure digital transfer of customized manufacturing quality data for a primary packaging batch provides transparency and quality assurance without the need for incoming quality inspection before transfer to the fill line.

Optimization of operational efficiency: Eliminating incoming inspection enables JiT delivery. A batch can be immediately released and transferred to the fill line, saving the time and costs associated with inspection and inventory.

Improved root cause analysis: If there are rejections further along the supply chain, the manufacturing batch data can be analysed to identify or eliminate potential root causes through advanced correlation analytics.

Prediction of future batch quality: Data can be further analysed and enriched with information from later supply chain stages. Machine learning and training data models, can be used to predict and optimize quality of future batches.

Customization to meet your needs

Define → **Implement** → **Deploy**

Our experts will set up workshops with you to define your specific requirements, including:

- Required data parameters and KPIs (i.e. CpK, STD)
- Secure data transfer method, automation level and frequency
- Data formats (i.e. XML, JSON, CSV)

We work together to implement the agreed parameters, analytics and delivery methods.

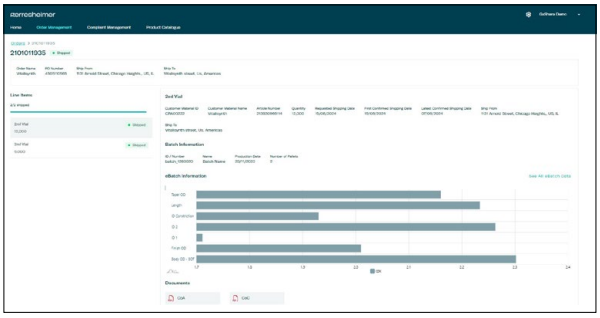
- Fast iterations and testing with agile methodology
- Data quality checks
- Data collection and pipeline development

The process is implemented and evaluated on an ongoing basis.

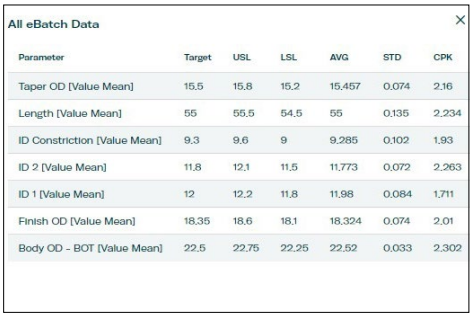
- Process assessment against customer requirements
- Continuous delivery of data and monitoring of quality
- Ongoing optimization

End-to-end customized Gx® eBatch solution

Example of data in .xml format



Overview of batch information in Gerresheimer customer portal



All eBatch Data

Parameter	Target	USL	LSL	AVG	STD	CPK
Taper OD [Value Mean]	15,5	15,8	15,2	15,457	0,074	2,16
Length [Value Mean]	55	55,5	54,5	55	0,135	2,234
ID Constriction [Value Mean]	9,3	9,6	9	9,285	0,102	1,93
ID 2 [Value Mean]	11,8	12,1	11,5	11,773	0,072	2,263
ID 1 [Value Mean]	12	12,2	11,8	11,98	0,084	1,711
Finish OD [Value Mean]	18,35	18,6	18,1	18,324	0,074	2,01
Body OD - BOT [Value Mean]	22,5	22,75	22,25	22,52	0,033	2,302

Example of data view in Gerresheimer customer portal

Benefits of Gx® eBatch at-a-glance

Increase confidence & efficiency through primary packaging manufacturing steps

- **Assurance of quality** through secure transfor of manufacturing quality data for each primary packaging batch
- **Optimization of operational efficiency & costs** as providing batch quality data digitally enables pharmaceutical companies to eliminate incoming inspection before filling and the associated time and costs of man hours and inventory
- **Improved root cause analysis** as quality data on the batch can be compared to failures in order to indentify potential causes
- **Prediction of future batch quality** by analyzing data over time to predict and optimize quality.

Further augment quality control with traceability

Reach 100% confidence by supplementing eBatch data with a full traceability solution

- Traceability enables each unique individual primary package together with its specific manufacturing quality data to be identified and tracked through the entire value chain, up to drug administration

Learn more about our traceability solutions

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