eCoA & eCoC

eCertificates

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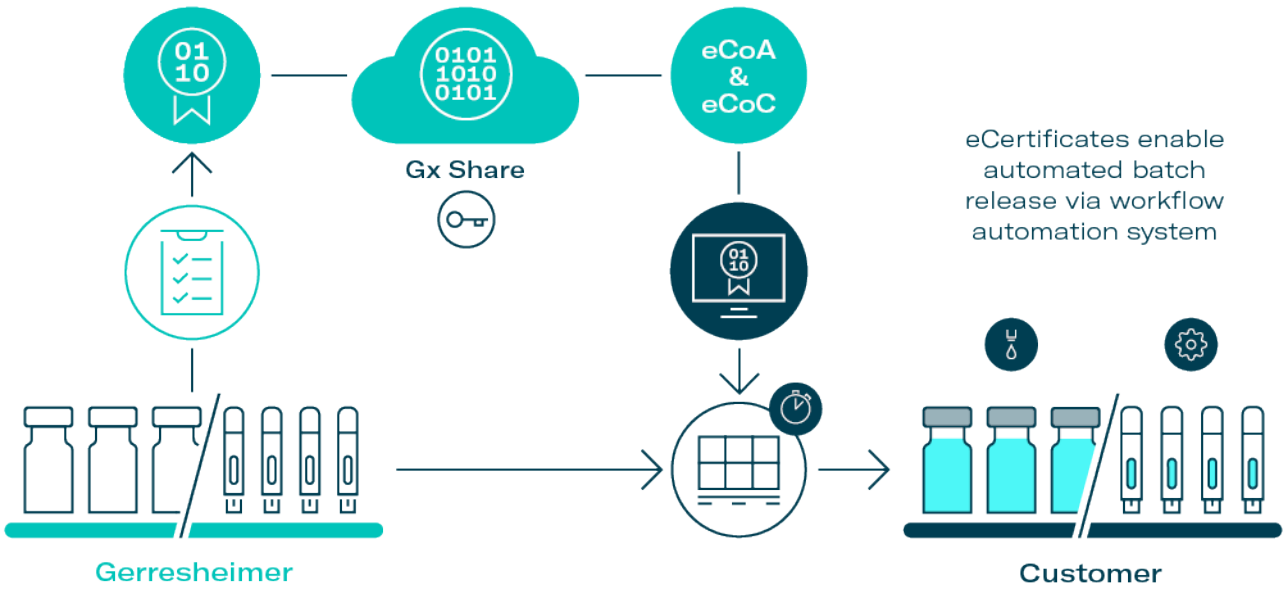
Automated electronic CoA and CoC management



Optimize inventory, minimize manual quality control

With eCertificate management, structured, machine-readable electronic Certificates of Analysis (CoA) and/or Certificates of Conformity (CoC) are generated immediately after batch verification. The certificates are validated and securely exchanged via web platform or Application Programming Interface (API) directly to a customer quality system.

By implementing an automated workflow, quality control effort is reduced and batches can be immediately released to assembly or fill & finish lines. This enables safety stock and inventory dwell time to be reduced and production delays avoided, which in turn frees up working capital.

Examples of cost saving potential for delivery of injection devices for assembly

Annual saving on inventory carrying cost

Assuming inventory can be reduced from 10 days to 1 day

SAVE $246K

Batches/year x inventory value x carrying cost rate (20%) x days saved / 365

Annual saving on quality documentation process

Assuming manual effort of 8h is reduced by 80%

SAVE $64K

Batches/year × hours saved per batch × hourly rate ($100)

Annual saving on production continuity & safety stock

Assuming delay due to issues with manual CoA handling

SAVE $60K–$0.5M

5% of batches delayed by 3 days x value at risk (3x inventory value per day) / 365

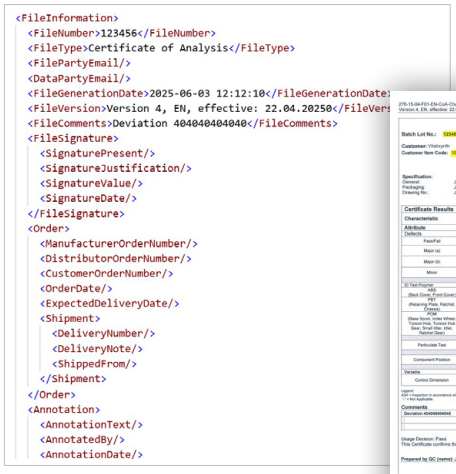
Calculation based on 100 batches of 500‘000 devices with a value of $1/pc manufactured per year and kept in inventory

Customize to meet your needs

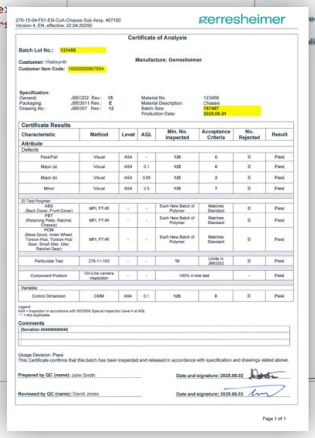
We work in collaboration with your team to customize and develop an optimal process to meet your individual needs.

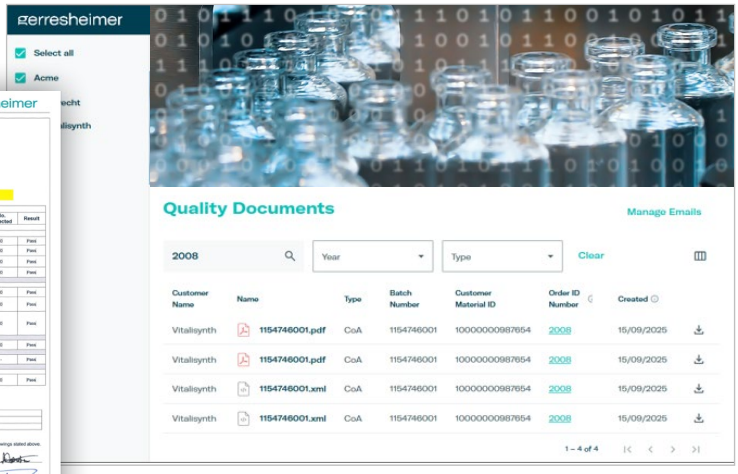
Define	Implement	Deploy
– Agree data parameters (i.e. production date, pass/fail data...) – Define secure data transfer method (i.e. web, API...) – Select data format (i.e. XML, JSON)	– Develop and validate using agile methodology – Implement a joint pilot – Optimize process and software – Release software	– Assess results and risks against customer requirements – Continuously deliver data and optimize processes as needed – Roll-out according to agreed plan – One-time or recurring fee may apply

eCertificates customized to your needs via our Gx® Share customer support portal



Machine readable formats for eCertficates such as Extensible Markup Language (XML)



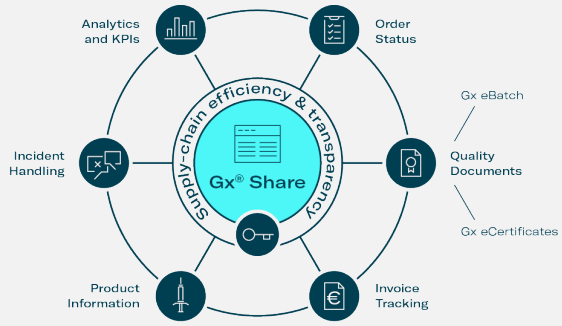


XML and PDF versions of eCertificates are available from Gx Share and can also be directly transferred to a customer quality system via APIs

Further enhance quality processes & planning

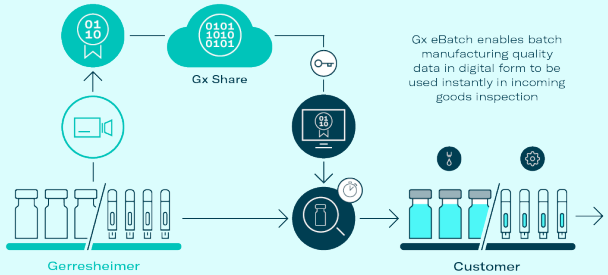
Gx Share
Digital customer portal

Our secure digital customer portal is a single point of truth for customers. It enhances supply chain agility and transparency by providing order information, incident status and quality documents. It also enables data integration through APIs.



Gx eBatch
Data-driven quality control

Quality data for a primary packaging batch is automatically, securely transferred to a customer quality system. This eliminates the cost & effort of incoming inspection, improves root cause analysis, and enables prediction of future quality.



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