Chronicle™ automation software

Chronicle™ automation software is a cloud-based fit-for-purpose solution designed to optimize process development and manufacturing. It provides a unified digital platform to monitor your facility manufacturing operations and supply chain logistics. Electronic batch records trace every manufacturing step, and automation increases productivity. In addition, digitizing records reinforces good manufacturing practices (GMP) compliance and improves sample security. Electronic standard operating procedures (eSOPs) manage deviations, promote adherence, and provide training. Chronicle software has been independently audited against GAMP™ 5, 21 CFR Part 11, and EU Annex 11.

Chronicle automation software can support two different environments, the cell therapy and the biologics environment, to better fit your specific needs.

Main features of Chronicle software include:

- **Electronic batch records.** Implement electronic batch records, which help you comply with regulatory requirements.
- **eSOP operator support.** Save operator time and reduce mistakes with electronic-standard operating procedures (eSOPs). They can adapt to changing conditions, perform calculations, and integrate instrument data.
- **Release by exception.** Review deviations efficiently with automated workflows able to support release by exception.
- **Batch scheduling.** Schedule your batch manufacturing by reserving equipment, products, consumables and operators, and checking availability on a built-in calendar.
- **Maintenance control.** Manage service records for all your instruments with full history, document management, and automated preventive-maintenance notifications.
- **Barcode traceability.** Trace your products and consumables with stock control, through scanning and barcode label printing.
- **Connect and visualize third-party instrument data.** Utilize the Gateway folder watching capability to upload and visualize PDF files from Cytiva and third-party instruments.

Cell therapy environment

Chronicle automation software connects Cytiva cell therapy instruments and selected third-party instruments for real-time monitoring and automatic upload of results.

Features specific to the cell therapy environment:

- **Instrument monitoring:** Monitor all connected instruments from inside or outside the cleanroom with real-time lab dashboards, email, and SMS alerts.
- **Parameter groups:** Save time by using Chronicle software to centrally define, approve, and deploy parameter groups (freezing and thawing profiles) to Sefia™ S-2000, VIA Freeze™ and VIA Thaw™ instruments.

Fig 1. Chronicle software connects Cytiva's cell therapy instruments (shown here) and third-party instruments.

Biologics environment

Chronicle automation software connects to a selection of Cytiva instruments used in the FlexFactory™ manufacturing platform for automatic upload of post run results. Results from other Cytiva and third-party instruments can be uploaded as pdf format to the batch record.

Fig 2. Biologics environment of Chronicle software connects Cytiva's instruments (shown here) and third-party instruments.

cytiva.com

cytiva

Electronic records increase productivity and reduce errors

Automating a unit operation with an eSOP reduces hands-on time and the risk of human error. Digitizing the whole workflow with an electronic batch record helps raising productivity while reinforcing GMP compliance. In process development, connecting devices to a central data storage simplifies the collection of data, and comparison of large numbers of data points.

Fig 3. Operators can scans a reagent label to identify lot number and expiration date.

Real-time instrument alarms accelerate incident response

Chronicle software helps you to manage manufacturing operations, both in your facilities and across your supply chain. Real-time dashboards with SMS and email notifications allow your staff to respond quickly*

* Dashboards and notifications differ between cell therapy and biologics environments.

Fig 4. A Chronicle dashboard shows the live status of every instrument in the cleanroom.

cytiva.com/celltherapy

Planned digital transformation

Start digital transformation early by selecting a solution that matches your needs and can evolve together with your processes. You can select either a pre-GMP or GMP account, and then select user-packages for additional users. This allows you to adopt digital solutions as early as process development, scaling with you throughout commercialization.

Table 1. Chronicle software accounts set up

	Pre-GMP	GMP
Recommended use	Manufacturing automation and the ease of tech transfer for a pre-GMP environment	Optimized for GMP-manufacturing at scale
Hosting	Via secure cloud — shared with other pre-GMP users	Via secure cloud — private, dedicated to one account
Software updates	Automatically applied when available	Only applied at customer's request and approval
Includes	Virtual Chronicle software gateway	• Virtual Chronicle software gateway • Validation support package • Access to a sandbox account (same version as the GMP account) • Access to a pre-GMP account (with unlimited users, for as long as the GMP subscription is active) • Standard service-level agreement (SLA)
Pricing	• Pre-GMP base annual subscription • *Optional* annual subscription for 5,10, or unlimited number of additional users	• One-time hosting setup fee • GMP base annual subscription • *Optional* annual subscription for 10, 25, or unlimited number of additional users

Contact your local Cytiva representative to learn more and to organize a demo.

Ordering information

Products	Product code
Chronicle Pre-GMP base annual subscription	29734890
Chronicle Pre-GMP annual subscription for 5 additional users	29734891
Chronicle Pre-GMP annual subscription for 10 additional users	29734892
Chronicle Pre-GMP annual subscription for "unlimited" number of users	29734893
Chronicle GMP hosting setup	MYC_60001
Chronicle GMP base annual subscription	29734894
Chronicle GMP annual subscription for 10 additional users	29734895
Chronicle GMP annual subscription for 25 additional users	29734896
Chronicle GMP annual subscription for "unlimited" number of users	29734897