

# Chronicle automation software

## CELL THERAPY TECHNOLOGIES

Chronicle™ automation software is a fit-for-purpose digital solution designed to optimize complex cell therapy 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 has been independently audited against GAMP™ 5, 21 CFR Part 11, and EU Annex 11.

- **Electronic batch records.** Implement electronic batch records that comply with regulatory requirements
- **Release by exception.** Review deviations efficiently with automated workflows to support release by exception
- **eSOP operator support.** Save operator time and reduce mistakes with electronic SOPs that adapt to changing conditions, perform calculations, and integrate instrument data
- **Instrument monitoring.** Monitor all connected instruments from inside or outside the cleanroom with real-time lab dashboards, email and SMS alerts
- **Barcode traceability.** Trace your products and consumables with stock control, barcode label printing, and scanning
- **Maintenance control.** Manage service records for all your instruments with full history, document management, and automated preventive maintenance notifications
- **Procedure scheduling.** Schedule procedures by reserving instruments and checking availability on a built-in calendar
- **Integrated logistics.** Book and track temperature-controlled shipments in real time through our partnership with World Courier



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

## Electronic records increase productivity and reduce errors

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



**Fig 2.** An operator scans a reagent label to identify lot number and expiration date.

## Real-time instrument alarms accelerate incident response

Chronicle automation software connects Cytiva's cell therapy instruments and third-party instruments. This software helps you to manage manufacturing operations in your facilities and across your supply chain. Real-time dashboards with SMS and email notifications allow your staff to respond quickly.



**Fig 3.** A Chronicle dashboard shows the live status of every instrument in the cleanroom.

## Plans for every stage of development

Get started with digital early by selecting a plan that matches your stage of development. Pre-GMP, GMP, and Enterprise software packages allow you to adopt digital solutions as early as process development and can scale with you throughout commercialization Access Chronicle on a pay-per-use basis using credits. Choose the credit bundle that meets your needs. Options from 25 credits to 50 000 credits are available.

**Table 1.** Chronicle packages

	Pre-GMP	GMP	Enterprise
Recommended use	Explore the benefits of manufacturing automation	Optimized for GMP manufacturing at scale	Customers manufacturing more than 5000 doses per year
Hosting	Secure cloud – shared with other pre-GMP users	Secure cloud – private, dedicated to one customer	Customized*
Software updates	Automatically applied when available	Only applied after customer validates in a sandbox	Customized*
Includes	Virtual Chronicle gateway	Virtual Chronicle gateway; Validation support package; 5 year data retention-option to extend	Customized*
Pricing	Outcomes-based – no fixed costs; pay per batch or procedure	Outcomes-based – annual fee plus pay per batch or procedure	Enterprise – packages to minimize cost for customers able to invest upfront

\* Contact us for bespoke packages including customized hosting, on-premise and hybrid installations. Enterprise requirements may also include nonstandard instrument integrations or specific service commitments.

Contact your local Cytiva representative to learn more and to arrange a free trial.

**cytiva.com/celltherapy**

For local office contact information, visit [cytiva.com/contact](http://cytiva.com/contact)

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