

## Background

**When the company's co-founders were PhD researchers, they saw the huge amount of paperwork that went into every batch record and thought there must be a better way. Together, they then developed a tool that they would want to use to collect data, reduce admin, and stay in control. The very first version of MyCellHub was born.**

Indeed, drug and therapy production processes as well as cleanroom processes, both for manufacturing and maintenance, need to meet very strict requirements. But regulatory paperwork associated with Good Manufacturing Practices (GMP) to produce cell & gene therapies is time-consuming and susceptible to human error. The complicated and lengthy paper-based documentation hampers the widespread availability of live-saving treatments. The complete production report for a single batch of a biotech drug easily takes 150 pages and the daily cleaning records of a cleanroom soon fill entire chambers full of paper. Yet, less than 10% of bio-therapeutic companies digitize their GMP operations.

That is why MyCellHub, a Belgian-based tech start-up headquartered in Leuven, was founded back in 2019: to help biotech companies and therapy providers streamline their lab and cleanroom operations by providing a toolkit for the digitalisation, data integration and data analytics of all their regulated bioprocess workflows.

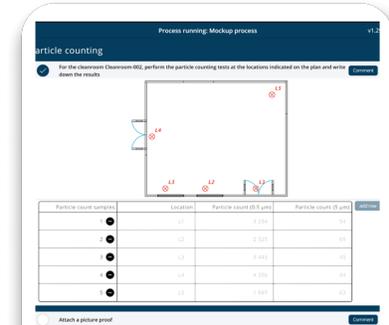
MyCellHub is an end-to-end SaaS platform for the management of GMP data. From batch recording and environmental monitoring to cleanroom cleaning, the company's toolkit gets rid of paperwork to reduce errors, streamlines quality compliance and provides data-driven optimization for your operations. The company's team considers that batch records are too important not to be intelligent. The platform is about making batch records intuitive and interactive. It is about unlocking insights for life-transforming treatments and helping democratize access to cell & gene therapies.

## Solution

MyCellHub offers operational 'software as a service' (SaaS) solutions to digitalize the whole process lifecycle of GMP-regulated workflows. Digitalization is key for streamlining cleanroom operation and ultimately a widespread adoption of the most powerful therapies.

The MyCellHub platform consists of the following two parts:

**A mobile application** specially designed to provide operators in cleanroom and laboratory environments with interactive work instructions. These help prevent mistakes and deviations while carrying out complex processes. By making use of the camera of the tablet for barcode scanning or by automating calculations the app makes data capturing both faster and with a higher data integrity compared to paper.



**A data-management browser application** that centralizes all process data recorded via the mobile app and provides a helicopter view of what's going on in the facility. This platform allows to plan and follow up processes, generate reports and analytics, but also keeps track of fluctuations in inventory in real-time.

## Benefits

By implementing and leveraging the MyCellHub platform, biotech companies can save up to 40% in costs associated with cleanroom cleaning operations, up to 81% time in manual documentation work, and up to 90% time in investigation workloads thanks to digital, real-time data collection and powerful, built-in audit trails.

Users can cut their quality control operation costs by 50+% with digital entries and automation and see their deviation rate drop by up to 65% thanks to interactive work instructions.

Additionally, the platform enforces data integrity and security, helps simplify regulatory compliance and optimize processes overall. Thanks to digital operations and workflows, reports such as environmental monitoring reports or electronic batch records can be automatically generated in simple clicks, saving operators countless work hours every month.