

Manufacturing suites and facilities with integrated workflows and comprehensive services

Enterprise Solutions for Cell Therapy

FlexFactory | KUBio | Fast Trak Services | Digital Solutions



New promise brings new challenges

“Cell therapy has the potential to cure everything from cancer to diabetes. But we need to make it affordable and scalable.”

— Phil Vanek

General Manager for cell therapy growth strategy, Cytiva

As more cellular therapies move from clinical trial manufacturing to commercial production, regulatory considerations are a primary focus in the industry. It is important to ensure processes are automated, closed, and scalable for reproducible product quality.

Today’s workflows have many steps that are often performed manually in open systems. Such processes are difficult to scale and

lack the control needed to consistently generate a product with the desired quality attributes. They are also prone to contamination and variation. Decisions about adding capacity are complicated by the financial risk of building too early. To tackle these issues and make life-saving therapies more accessible, the industry needs a new way of thinking.



Industrial manufacturing with wraparound services

Industrializing cell therapies is a new arena, and speed is critical. To help you realize your commercialization timeline, Cytiva's solutions have expanded beyond biopharmaceutical manufacturing. Enterprise Solutions for Cell Therapy provides you with access to our end-to-end ecosystem of next-generation equipment, turnkey manufacturing solutions, and comprehensive services.

When you are looking to industrialize your process, consider our flexible solutions. We provide you with a single point of contact for project management, including sourcing of third-party equipment. FlexFactory™ suites and KUBio™ facilities integrate Cytiva's functionally closed processing equipment with semi-automation and digital solutions. This set-up provides process flexibility, so you can control and optimize your processes. Suites can be built new or by converting existing labs.

If you need an extra pair of skilled hands for process development, we can help you to optimize your protocol or convert to functionally closed processing. Our Fast Trak™ Services team also offers classroom and laboratory courses on cell therapy processing and procedure development, so your staff can get relevant training.

We will work closely with you to design and implement solutions that fit your needs, whether you are a startup launching a new clinical trial, a growing biotech, or an international company moving towards commercial manufacturing.



FlexFactory platform

Achieve reproducible and scalable manufacturing by adding integrated, functionally closed processing. Convert your lab or build a new suite.

A FlexFactory suite is designed for current good manufacturing practices (cGMP) manufacturing. The workflow includes controlled product thaw, isolation, activation, genetic manipulation/transduction, expansion, harvest, final formulation, and cryopreservation. The FlexFactory offering combines equipment, automation, connectivity solutions, and supporting services for a turnkey solution. Suites can be ready in 12 months for most applications.

Your FlexFactory can be configured to meet your needs. Based on your requirements, processing can be closed to reduce labor and manual errors. Functionally closed processing also manages the risk of contamination inherent to the use of flasks and open transfers between steps. You can choose a combination of equipment from us as well as other vendors. We provide advising and consultative services, including project management.



KUBio facility

KUBio comes with one or more FlexFactory suites, which you can configure. Build a complete and qualified facility at a new site in 22 months.

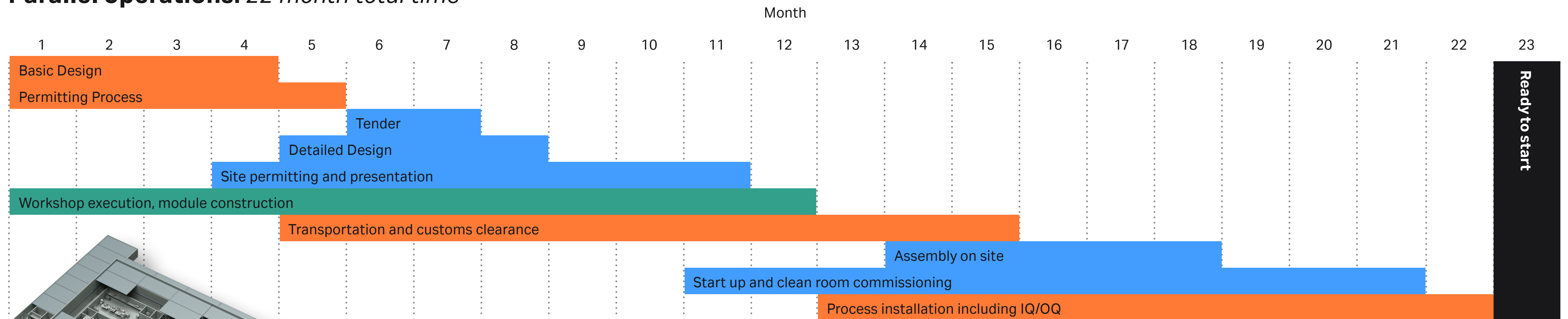
KUBio is our turnkey facility solution that provides reproducible, scalable cGMP-compliant manufacturing at a site of your choosing. Thanks to its pre-engineered construction, your KUBio facility can be operational in 22 months.

This comprehensive solution provides you with proven technical expertise and in-country assistance to resolve the unexpected.

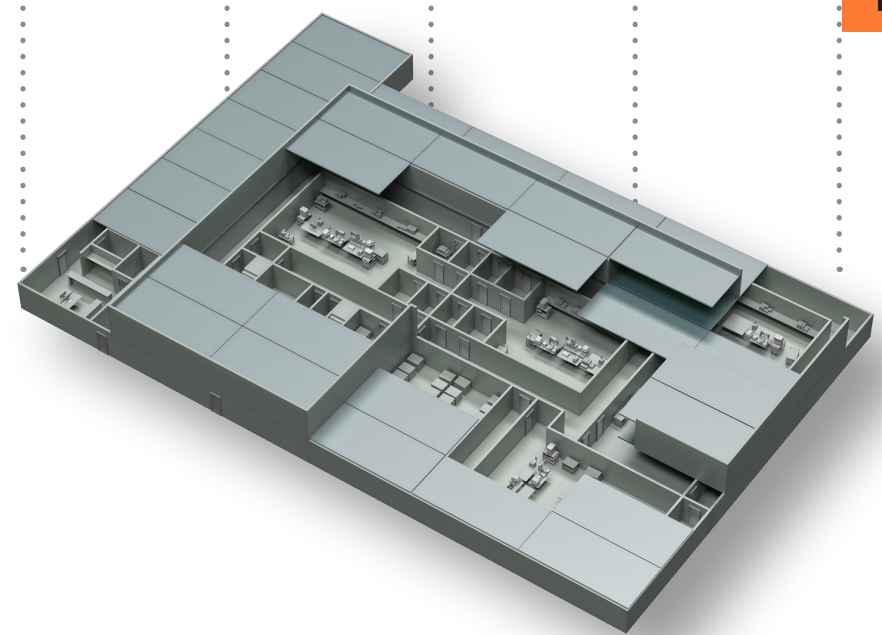
We will manage nearly every stage of your KUBio project, including off-site construction, transport, logistics, insurance, local labor and regulatory compliance, final construction, and qualification.

Your KUBio facility can include up to five FlexFactory suites. Suites can be configured to meet your needs. Production capacity for each suite is 150 to 800 doses per year depending on cell expansion time.

Parallel operations: 22 month total time*



*Depending on destination country



Fast Trak Services

Let us bridge the gap between research protocols and industrial manufacturing. Make sure your staff is ready on day one thanks to expert training.

Process development

If you need help with process development (PD), our teams in Toronto, Shanghai, and Marlborough/Boston are ready. Cytiva sites are fully equipped with closed and automated processing equipment.

Training and education

Empower your staff by sending them to our Fast Trak Advanced Cell Therapy Technology (CELLT1) course. This 4-day course provides a balanced mix of classroom and laboratory instruction on cell therapy processes and cell manufacturing under cGMP procedures. Practical laboratory sessions will provide beginning-to-end technical knowledge and training on industry-standard equipment and reagents. Course topics include tube welding and aseptic fluid transfer, cell counting and isolation, transduction and vectors, activation process and technologies, cell culture media development and design, cell expansion, perfusion applications, harvesting platforms, final formulation, and cryopreservation. Scale-up and scale-out, standard operating procedure (SOP) development, and process evaluation and optimization are also addressed. The course is designed to provide theoretical cell therapy process knowledge, identify bottlenecks, and troubleshoot your specific processes. Template SOPs can be provided if requested.

Fast Trak PD Services in collaboration with CCRM

These services are provided as a collaborative venture between Cytiva and The Centre for Commercialization of Regenerative Medicine (CCRM). The research and development (R&D) team is comprised of more than 40 scientists and engineers with expertise in advanced therapeutic cell technologies. Expertise centers around closing and automating T-cell manufacturing workflows, including cell isolation and activation, genetic modification, expansion, harvest, final formulation, and cryopreservation. Consumable assessment and cost-of-goods analysis is also offered, as well as viral PD services and manufacturing capabilities. PD services with multiple cell types, such as natural killer cells and pluripotent stem cells, are also available.

Digital Solutions

Integrating FlexFactory equipment with semi-automation and digital capability allows you to control and optimize your processes.

All major unit operations in the FlexFactory platform are automated, and automation software is integrated with the main software platform. A centralized data historian server is provided for data management and trending, allowing you to monitor the performance of your cell processing operations. Asset Performance Management (APM) uses the data infrastructure to provide you with early warnings that equipment or process is about to fail. Real-time, 24-hour alerts notify you of adverse trends in critical process parameters, allowing you to make proactive corrections to maintain product quality.



Our commitment to cell therapy

We are investing in cell therapy because we have seen its life-changing power in action.

With some recent acquisitions, we can now offer a wide range of functionally closed processing equipment throughout the cell processing workflow. These are brought together in our FlexFactory and KUBio offerings, which are well established for biopharmaceutical manufacturing. We continue to invest in products, tools, solutions, and services that will help you bring cellular therapies to those in need, making them more accessible and affordable than ever before.

We are also committed to collaborating with others in order to further the cell therapy industry as a whole. Among these collaborations are a joint venture to advance process development and manufacturing, and an independent technology company that uses advanced manufacturing and data analytics software to help industrialize cell therapy.



Photo credit: CCRM.

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