Expanding single-use biomanufacturing into new locations

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CY16920-08Oct20-CS

Expanding single-use biomanufacturing into new locations

As an industry, expanding biomanufacturing capacity to new locations is most often to support access to new markets. This could be as a contract manufacturer wanting to locate near a certain customer base or as a pharmaceutical or biotechnology company wanting to establish local in-house production.

Expanding to become an operation with multiple manufacturing sites also improves security of supply, offering the ability to manufacture the same product at more than one location, providing you have installed duplicate capacity.

Single-use technologies readily enable creation of duplicate biomanufacturing capacity, in addition to the benefits they bring by being both flexible and future-proofed.

When expanding single-use manufacturing into a new location, there are a number of key factors to ensure success.

"The teams worked very collaboratively to deliver the project in 14 months"

Paul Found,
Chief Operating Officer,
Fujifilm Diosynth Biotechnologies,
Billingham, UK

"The MHRA really engaged with us to help future-proof the facility"

Helen Bickley,
Head of Quality Assurance,
Fujifilm Diosynth Biotechnologies,
Billingham, UK

5 key considerations when expanding single-use biomanufacturing into new locations

1) Work collaboratively to increase efficiency

Working in collaboration is critical. This goes beyond collaborating with your colleagues and encompasses working closely with your suppliers. By developing an open relationship with your technology supplier, you can ensure that they understand your requirements and support your business needs.

As a contract development and manufacturing organization (CDMO), Fujifilm Diosynth wanted to add duplicate capacity in the UK, largely to mirror the capacity found at their Research Triangle Park facility in North Carolina, USA.

Having successfully installed GE Healthcare's BioProcess™ single-use platform technology at the North Carolina facility, GE Healthcare was the obvious partner for Fujifilm Diosynth's UK expansion project.

Working collaboratively, the team was able to deliver the UK's first cGMP single-use manufacturing facility in just 14 months at Fujifilm Diosynth's UK manufacturing site in Billingham. Getting the facility up and running in such a short timeframe was achieved due to efficient qualification, and technology and knowledge transfer processes between the sites.

This success would not have been possible without having the right people in place to support the project. You need the right combination of people, with the right experience and expertise to make such projects a success. Ambitious goals require high performing teams working seamlessly together.

2) Understand the local operating environment

Having knowledge of the local operating environment allows you to anticipate and address potential challenges before they arise. This is particularly important for meeting regulatory requirements, where unforeseen hurdles could dramatically impact the qualification timeframe and project delivery date if they have not been taken into account from an early stage.

If you are already operating in the country of your expansion project, you may be able to draw upon the expertise of your own local team. You could also benefit from the knowledge of external parties, such as suppliers, that have on-the ground operating experience to support your project.

For Fujifilm Diosynth, they already had a manufacturing site in the UK and wanted to expand this to include a single-use facility for mammalian cell culture biologics. Having internal expertise with working knowledge of the UK operating environment helped the wider project team understand what was needed to build and validate a local manufacturing facility.

They proactively engaged and included feedback from the UK's regulatory agency, the MHRA, in the initial project planning phase. Having visibility of the design and operating philosophy, the MHRA was able to help future-proof the facility. Fujifilm Diosynth was also able to incorporate customer feedback, and insights from GE Healthcare, to ensure they were taking a comprehensive approach.

"Having the ability to train offline enabled us to bring the go-live ahead of schedule by three months"

Helen Bickley

Consequently, Fujifilm Diosynth identified existing data that addressed local planning application requirements. This enabled them to speed up the qualification process and release valuable project resources that could then be allocated elsewhere. Overall, knowledge of the local operating environment meant a smoother implementation and qualification process.

3) Benefit from offline training

In order to bring a new manufacturing facility online quickly, your manufacturing operations personnel will need appropriate training. Ideally, they should be fully trained and ready to use the equipment as soon as it is installed. This can be achieved through offline training.

Fujifilm Diosynth wanted to fully validate their single-use biomanufacturing facility and bring it online as quickly as possible. They were able to benefit from GE Healthcare's global network of Fast Trak training centers, which meant their staff were trained offsite, in parallel with the activities happening onsite during the build.

The operating team traveled to Marlborough, Massachusetts, USA, to learn from GE Healthcare's single-use experts. Not only could they familiarize themselves with the systems being installed at their facility, but they also had the opportunity to discuss potential challenges and ways to address them. The operators were able to write procedures that were concise but detailed enough to enable effective and efficient training.

As a result, when the equipment arrived in the UK, the operations team was ready to use it. Being able to benefit from a comprehensive offline training program allowed Fujifilm Diosynth to start operations at the facility three months ahead of schedule and ensured smooth execution of the first manufacturing batch.

"We built upon GE Healthcare's experience in the design, commissioning, and qualification of single-use equipment to benefit our customers"

Paul Found

4) De-risk technology transfer

Technology transfer is widely recognized as a complex process, particularly for manufacturing biologics. There are means to de-risk the process, both from a compliance and time perspective, depending on the type of manufacturing capacity that you choose.

One of the benefits of single-use technology is the ease of technology transfer between sites compared to stainless steel manufacturing. This is especially true when utilizing the same technology platform and supporting processes for your duplicate capacity.

For Fujifilm Diosynth, their single-use expert team worked in collaboration with GE Healthcare to duplicate their single-use capacity from North Carolina, USA, to Billingham, UK. They worked together to ensure coordination between the sites, and built upon the experience that GE Healthcare has in the design, commissioning, and qualification of that equipment. Strong team work enabled them to deliver the project quickly and efficiently.

5) Ensure open communication

The value of honest and open communication should not be underestimated, both in delivering a project and beyond. If you are a company that is in any way a service provider, open communication is vital in ensuring that any issues are resolved quickly and smoothly.

As service providers in their respective fields, Fujifilm Diosynth and GE Healthcare both have a culture of embracing new technologies, and working openly and collaboratively with partners in order to be successful.

Right at the start of the project, the core single-use expansion project team agreed upon the importance of having an honest relationship and open dialogue so that they could tackle any potential issues head on.

When issues were encountered, the open communication and cultural fit between the companies enabled solutions to be rapidly developed and prevented any delays with getting the facility online.

> "As service providers, we both value the importance of open communications"
>
> **Paul Found**

Closing remark

In working collaboratively with your internal experts, single-use technology supplier, and local regulatory agency, you can efficiently create biomanufacturing capacity that meets all the necessary operating requirements. With a streamlined technology transfer and qualification process, strong coordination and communication between all parties, smart project planning, and parallel offline training, you too could be able to meet such ambitious project goals.

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29273656 AA 06/2017