

# Celldex Therapeutics and FMT Plan for Prevention

**Celldex Therapeutics, headquartered in Hampton, New Jersey, is in the business of prevention. Researchers at Celldex, like their predecessor Jonas Salk, believe in the power of the body's immune system to combat any kind of disease.** If successful, Celldex will be one of the first companies to commercialize immuno-oncology products targeted to breast cancer and other oncology indications, which, worldwide, account for nearly two million new cases diagnosed in 2012 alone.



## EXPERIENCE AND EXPERTISE

Celldex Therapeutics planned to enter the commercial manufacturing space immediately, should the FDA approve one of its immuno-oncology products. To scale for this kind of rapid growth, the company infrastructure would have to be agile.

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—CHIP CATIN  
SENIOR VICE PRESIDENT & CFO  
CELLDEX THERAPEUTICS

Celldex hired PricewaterhouseCoopers (PwC) to gather information about software requirements and devise a vetting system for potential integration and implementation vendors that had experience working with life science companies. PwC suggested fifteen possible partners, among them FMT Consultants.

FMT, having worked with over 200 biotech companies, was the clear choice. "FMT had a number of clients with similar experience, plus they have clear expertise in Microsoft Dynamics GP," says Chip Catlin, Senior Vice President and CFO of Celldex Therapeutics.

## CELLDEX THERAPEUTICS

- › Spun out of Medarex (Bristol-Meyers Squibb) in 2005
- › Acquired four new companies since, bolstering their proprietary portfolio of research therapies
- › In 2012, listed on Deloitte's Technology Fast 500 for third consecutive year

## CHALLENGES

- › Acquire or upgrade ERP system to support company's future growth into commercial manufacturing & sales
- › Ready the ERP for future expansion, putting systems and processes in place
- › Find a CRM that would integrate with the ERP for in future phase
- › Find a plugin that will satisfy compliance reporting requirements and integrate with other solutions

## RESULTS

- › Upgrade current Dynamics GP system to latest version
- › Install Rockton Auditor to handle regulatory compliance
- › Install and configure ReQlogic to rapidly scale from clinical to commercial manufacturing

## OUTCOME

- › Microsoft Dynamics GP upgrade saved significant funds
- › Streamlined processes for clinical manufacturing are scalable to commercial manufacturing upon FDA approval
- › System is efficient and completely integrated
- › Quality Assurance is tighter, validated and fully traceable



## LEARNING TO SPEAK THE PROCESS

FMT Consultants sat down with Celldex's internal Quality Assurance (QA) team to learn their complex manual process speak. FMT was very careful to pay close attention to the seriousness of QA, as it is vital to a biotech company's success, within a regulated industry. "FMT learned our language very quickly once we educated them. They adopted the lingo and spoke it very fluently," says Catlin.

***"We consider FMT an extremely valuable partner to Celldex and don't anticipate any end to their support at all. We do have other integration projects with them still. We continue to look forward to a long-term relationship with FMT"***

—**JOHN CORRADO**  
IT DIRECTOR  
CELLDEX THERAPEUTICS

Once the QA aspect of the project was addressed, the next task for FMT was to attend to Celldex's manufacturing needs. Celldex was still in the clinical phase of manufacturing, but needed to be able to enter the commercial phase almost immediately, should one of its therapies be approved. To make that possible, FMT had to build two different manufacturing processes into one system.



## INTUITING THE SOLUTION

As PwC found that Microsoft Dynamics GP could meet all of Celldex Therapeutics's requirements for growth and scalability, FMT simply upgraded Celldex's Microsoft Dynamics GP system to the latest version. Then FMT installed and configured a plug-in, called Rockton Auditor, which could manage a newly streamlined QA process and fully integrate with other solutions.



Next, FMT installed another product called ReQlogic to manage the dual phases of manufacturing. John Corrado, IT Director for Celldex, says, "FMT was able to scale quite easily. They had done their design work very early in the process, coming to an understanding of what we did and what we envisioned we were going to be doing. They built that scalability into the process to ensure that the path we were going down was going to be something we could leverage when we go to the commercial manufacturing phase."



## REWARDED WITH OPPORTUNITY

The simple upgrade to the current version of Microsoft Dynamics GP saved Celldex time and money. Working together, FMT and Celldex arrived at a streamlined, tighter QA process with detailed reporting and documentation. The added plugin took what was once a disparate, siloed process and made it fully integrated. On the manufacturing side, Celldex is now agile and ready to cross over into commercial manufacturing immediately.

For phase two, FMT will build out the commercial manufacturing and sales components, layering on a robust CRM and other applications onto the current system before any products are approved.

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