



ORGANIZATION:

Baylor College of Medicine, Center for Cell and Gene Therapy

INDUSTRY:

Cellular Therapy

The logo for Baylor College of Medicine consists of the text 'Baylor College of Medicine' in a white, serif font, centered within a dark blue square.

Background:

The Center for Cell and Gene Therapy (CAGT) at Baylor College of Medicine, Texas Children's Hospital, and Houston Methodist Hospital provides an infrastructure to rapidly translate novel cell and gene therapy protocols from the laboratory to the clinic. The comprehensive approach of the center brings a wide variety of scientists and clinicians together to develop strategies for the treatment of cancer, HIV, neurological and cardiovascular diseases.

Regulated By: FDA and FACT

The Challenge:

CAGT found document control using a manual, paper based system difficult, cumbersome and time consuming. To develop, build, and maintain this type of management system was extraordinarily labor-intensive, and taking valuable time away from the ongoing Quality Assurance activities. Dr. Adrian Gee, Ph.D., Director of Quality Assurance and Professor at Baylor College of Medicine, described a system in which "...pieces of paper went out to be signed by various individuals and it was almost impossible to know where they were in the system and whose desk they were on at any particular time."

Why ECL2 and Q-Pulse?

"I've been involved in a number of institutions that have tried to get their record keeping and record management into line electronically", states Dr. Gee. "Traditionally they have brought in a programmer that knows everything about IT, but does not understand what we do, how we do it and what we are trying to achieve." When Dr. Gee discovered that the ECL2 Staff had managed Quality Systems in cellular therapy and understood their specific needs, the partnership with ECL2 was established.





ECL2 intuitively knows the needs of a cell therapy lab because the consultants have the same background. They understand what we are talking about and can relate to it when we say we need to do things a certain way.



Dr. Adrian Gee, Ph.D.,
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The Solution:

Utilizing Q-Pulse's various and interlinking Modules, the CAGT Quality Management system now has speed, agility and the ability for analysis and change. Additionally, the personalized ECL2 implementation training has made the transition easier than they had anticipated.

"The one-to-one aspect of the ECL2 Implementation process is very helpful to us", states Dr. Gee. "There is flexibility within the Q-Pulse system to allow us to do things in slightly different ways with which our organization is more familiar. Having [ECL2's] expertise to tailor Q-Pulse to do those kinds of things is extremely useful to us." ECL2 intuitively knows the needs of a cell therapy lab because the consultants have the same background. They understand what we are talking about and can relate to it when we say we need to do things a certain way."

The ECL2 client relationship does not end after implementation. "The nice thing has been if [we] have an issue [we] are able to contact the ECL2 folks and sort it out, so if a problem arises we can get a quick solution to it. This kind of one-to-one communication and training are invaluable."

In addition, Dr. Gee went on to say that "...having everything available to everybody when they need it from one location is an extraordinarily more efficient system ... it's so much easier if everybody knows it's in Q-Pulse; staff can do a search for it and up it comes. Then they can print it out if needed. [Before Q-Pulse] we had occasional panics where apparently something had gone missing and it takes time to track it down. Now we don't have to worry about that because we've learned that anything we think that is of remotest importance goes into Q-Pulse and we know where it is."

Additional Services - Validation:

Baylor College of Medicine, Center for Cell and Gene Therapy also enlisted the services of ECL2's validation services. ECL2 developed custom validation documents, specific to CAGT's system configuration. This saved a significant amount of time and resources which would have been required without the assistance of ECL2.

"There is just no way we could do validation ourselves.", states Dr. Gee. "It's just so nice to have that done properly by people who know exactly what they are doing so we can show it to the FDA and have confidence that they are not going to have an issue with it. We wouldn't know where to start to do it properly."

**For more information on Q-Pulse please visit our website at
www.ECL2.com or contact us directly at 469.828.5006
or by email at inquiries@ECL2.com.**