

SANYO Biomedical Reference

Baylor Institute for Immunology Research



Overview:

Nicolas Taquet, MS is the technical director at the Baylor Institute for Immunology Research (BIIR) in Dallas, Texas. In 2004, he became the project manager to oversee the design, construction, and qualification of an entire large-scale vaccine manufacturing facility for Phase II/III clinical trials. Dendritic cells (DCs) are a unique group of white blood cells that are able to capture and process antigens for presentation to T cells, resulting in primary immune response. Described as the cells that control the immune response, DCs also trigger a response to invading infectious agents by activating macrophages, natural killer (NK) cells, NKT cells, and eosinophils. The Institute recently built a BSL-3E (BioSafety Level 3 enhanced) lab to study DC interactions with infectious agents.

SANYO Product Solution: (25) -86 Freezers, (80) CO2 incubators including: MCO-36AIC, SRL-6111, MDF-U53VC

Application: Dendritic Cell Immunology Research

BIIR has manufactured vaccines for clinical trials in dedicated Class 10,000 (ISO 7) cleanrooms. The facility can accommodate multiple Phase II clinical trials or potentially one large-scale Phase II/III trial. Current vaccines being produced for clinical trials at BIIR are for stage 4 melanoma and HIV patients in which patients' own DCs are cultivated and matured to provide a patient-specific treatment. The cleanroom design was driven by selecting equipment that would accommodate most of the existing and anticipated DC vaccine processes and was flexible enough to house future changes in the required equipment. The facility can accommodate 500 patients (12,000 individual vaccine vials) per year.

SANYO Advantages:

- "Each freezer holds extremely important samples: storage temperature consistency is critical for our research".
- All of the freezers are quiet and chamber temperature is fast to recover even with multiple door openings.
- "Sanyo incubators are equipped with CO2 infrared sensors so that the incubator chambers do not require any ambient humidity from a water pan, thus minimizing the contamination risk."
- Quick CO2 injection time, unit immediately returns to 5%.
- Small, stackable units make it easy to segregate different culture media.
- Sanyo equipment is easy to monitor with an alarm system (access ports for temperature/CO2 probes are well designed).



MCO-36AIC and MDF-U53VC

Competitive Analysis:

After considering the likely vaccine production processes that rely on short-term cell culture, the decision was made to incorporate the incubators within the cleanrooms of the production suite. Some CMOs argued against this in favor of placing the incubators in a centralized location, which would minimize overloading the production cleanrooms with incubation processes while segregating the potential contamination risk. Instead, BIIR chose to integrate enough SANYO incubators in each of the cleanrooms to accommodate a seven-day manufacturing schedule with cleaning and maintenance included. Because BIIR uses a closed cell culture system for the dendritic cell vaccine processes, media evaporation during the short-term incubation is not an issue. The culture bags are permeable to CO₂ but are waterproof.

“SANYO really won our business through service- going above and beyond. We were originally a Thermo facility, but SANYO’s service was excellent. SANYO assisted us with each installation of their equipment. When we had a condenser fan motor failure in some of our freezers, Steve Ivie, our sales rep and Michael Marciniak, National Sales Manager, proactively and immediately came down to our facility and replaced the motors in all of our condenser fans. We worked with SANYO to design a low pressure incubator for the US market by improving the tubing and the clamps. This allowed us to use a bulk CO₂ system with a central loop line for the building.”

“We don’t necessarily look for the lowest price; we are more concerned with finding a vendor that has a fast response time to any equipment malfunction.”

Industry Highlights and Current Research:

The GMP Core facility has produced over 400 vaccines since 2005. Additionally, the study of DCs has brought Baylor many major unexpected scientific discoveries, such as the understanding of lupus and the role of IL-13 in breast cancer, allowing them to apply their research and knowledge across multiple scientific disease studies. From a single drop of blood, BIIR can obtain information on over to 40,000 genes. By comparing blood from healthy volunteers with patients who have a specific type of pathology, they are identifying how different conditions skew the immune micro-environment. This has led to a patented treatment by correcting the microenvironment using existing drugs in juvenile arthritis. The study of cancer, autoimmune diseases, infectious diseases, and transplantation should enable us developing a targeted cure for a number of applications in the next few years. BIIR has raised over \$50 million in grants in the past 12 years.



SANYO MCO-36AICS in cleanroom #2

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**-Nicolas Taquet, MS, Technical Director,
Baylor Institute for Immunology Research**

Conclusions:

Immunology research facilities are a small niche industry, but are growing rapidly and are very rare in university settings. The institute’s core values are more similar to a biotechnology company than a traditional academic institution. Baylor is setting a new standard of excellence making cleanliness, equipment maintenance and regulation extremely important. We are honored that they chose SANYO for their strict cleanroom standards. The American Cancer Society has estimated that there will be 62,500 new cases and 8,500 deaths from melanoma in the US in 2008, and the CDC estimates that around 1 million people in the US are infected with HIV with around 56,000 new cases in 2006. If SANYO can play a part in minimizing those numbers and improving the quality of life around the world, we will.

Contact Info: Nicolas Taquet, MS, Technical Director
Baylor Institute for Immunology Research 3434 Live Oak St. Dallas, TX 75204

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