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# GENETIC ENGINEERING NEWS

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## COMPANY UPDATE

### Irvine Scientific Expands its Strategic Mission

Irvine Scientific (Santa Ana, CA) entered the life science market in 1970, catering sera, blood-based components, and classic cell culture media to a seedling biotechnology industry. In the 1980s, with the advancement of in vitro fertilization, they established themselves early as one of the leaders in reproductive media and continue in that arena today.

Their evolution did not stop there, emphasizes a company official. "Over the interim years, we've combined our mastery of advanced media for human embryo culture with capabilities in serum-free media formulation," says Tom Fletcher, director of R&D and an employee of 18 years.

Today, Irvine's newly expanded world-class manufacturing facility provides large-scale custom media manufacturing for the biopharmaceutical industry. In this capacity, Irvine also collaborates with process development



Irvine Scientific's 1,800-kg custom ball mill was designed to accommodate large powder runs with ease.

teams in optimizing cell growth and productivity for specific processes.

"We are pursuing our objective of becoming the supplier of choice for cus-

tom media formulation, optimization, and contract manufacturing," says Fletcher. "Our focus rests not only in assisting with the creation of life

through advanced reproductive media, but also in enabling the expression of protein-based therapeutics to help maintain life.”

Their new logo speaks to this full-circle story, according to Fletcher. “It embodies the essential aspects of Irvine

Scientific, our purpose, and our products,” he explains. “The logo’s new colors are life-based—blue for the color of the sky as well as the water from which all life was born and green for its association with growth.”

The mark is comprised of circular elements representing cells, which are the building blocks of life, and Irvine Scientific’s core focus. Within the mark these round elements are growing, suggesting cellular growth and development. And the word “Scientific” in the name Irvine Scientific is now more prominent.

“This is because our proprietary technology and expertise have grown immensely since 1970,” adds Fletcher, who says that advancing the science of cell culture through media formulation to specific targeted applications is Irvine Scientific’s daily work.

“To keep ourselves on the forefront of media development for both the assisted reproduction and the biopharmaceutical industries, we retain two separate scientific advisory boards comprised of thought leaders from around the world,” notes Fletcher.

### Expanded Vision

The current profile of Irvine Scientific on the biopharmaceutical front is that of a company with recently expanded and validated large-batch media manufacturing facilities that are now online. The company’s new levels of capacity are merely the latest step in a greater vision of expansion, according to Wendell Lee, Pharm.D., vp of regulatory affairs and quality assurance.

“We currently have a comfortable excess of capacity, but our projections show that this will not be the case for long. Our commitment is to initiate the next phase of expansion at such a time as

current capacity reaches 65%, with a target of completion of that phase before current levels reach 90%,” notes Dr. Lee. “This will ensure that service levels are never an issue for our customers.”

He says the company sees an ever increasing need for qualified and capable large-scale manufacturers of custom media that can be delivered either in bulk powder or flexible liquid packaging of 200-L to 500-L units.

“We manufacture media for our biopharma clients in the same facility and with the same staff that handles our Class II products for assisted reproduction.

“This facility meets ISO 9001 and EN46001 Quality Standards and our WFI system produces finished water that exceeds USP guidelines as well as stringent new European standards,” explains Dr. Lee. He adds that Irvine Scientific provides advanced media and related products to over 90 countries.

### Customer Categories

Tom Fletcher notes that the company’s customers fall into three basic categories: those who have a cell line and need a medium defined from scratch; those who have a medium but realize it isn’t producing the results that they require and thus need it optimized; and those who have their optimal formula and simply want large quantities manufactured.

“We serve all three,” he says, adding that the solutions Irvine Scientific provides are specific to customer requirements and are largely custom variations of either their serum-free or their chemically defined media.

In the last several years, Fletcher has witnessed a large increase in the need for serum-free and animal-compo-

## AT-A-GLANCE Irvine Scientific

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### PRINCIPALS

**Mike Kelly, Ph.D.**  
president and CEO

**Tom Fletcher**  
director of research &  
development

**Gary Nelson**  
director of operations

### NUMBER OF EMPLOYEES

100

### FOCUS

Irvine Scientific sells products in a variety of markets, including media and other related cell culture systems, specialty bulk sera products (as components for the diagnostics market), and media for the cytogenetics laboratory, as well as a complete product line for the reproductive laboratory.

nent-free media. Serum is a complex collection of chemicals and un-known constituents that could carry pathogens and other contaminants. "It's better to avoid it," points out Fletcher.

Similarly, more customers are requesting chemically defined media, as "it's a step up in sophistication and improves safety and reproducibility," he explains. **GEN**



Irvine Scientific's large-batch-volume, serum-free and animal-component-free media suite features a 16-station high-throughput fill line for flexible packaging of volumes 50 L and greater.

**OUR POINT**

**of difference**

**is a focus on**

**DETAILS**

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