



MEDIA SPECIALISTS

providing solutions for industrial, clinical and research applications



IrvineScientific



*Leaders in
development and
manufacture of specialized
and classical media
for over 45 years.*

- *cGMP*
- *FDA-regulated*
- *CE-marked medical devices*
- *ISO 13485 certified*
- *Products for further
manufacturing use*
- *Products for research*



WITH YOU AT EVERY STEP

providing optimal conditions for mammalian cells

A partnership with Irvine Scientific opens the door to a wealth of knowledge and experience in media development, optimization and supply, as well as experience with regulatory requirements associated with supporting a therapeutic or medical device to market. In an ever-changing business world, you can be assured of a stable, long-term relationship with a company owned by the JX Group, a Fortune 500 company.

"We develop innovative products as well as custom solutions and services. We combine our specialist knowledge and experience together with a thorough understanding of the latest scientific data, typical workflows and regulatory demands."

Yuichi Nagano, President and CEO, Irvine Scientific

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READY FOR THE FUTURE

with innovative media solutions and services

PROVIDING THE OPTIMUM MEDIA FOR YOUR APPLICATIONS

As early as 1970, Irvine Scientific was providing media for research, industrial and clinical applications. From laboratories to large-scale production, and in fields as diverse as the manufacture of biotherapeutic drugs and the growth of embryos after *in vitro* fertilization, our products and services enable scientists and clinicians to generate sufficient numbers of fully functional, 'fit-for-purpose' mammalian cells.

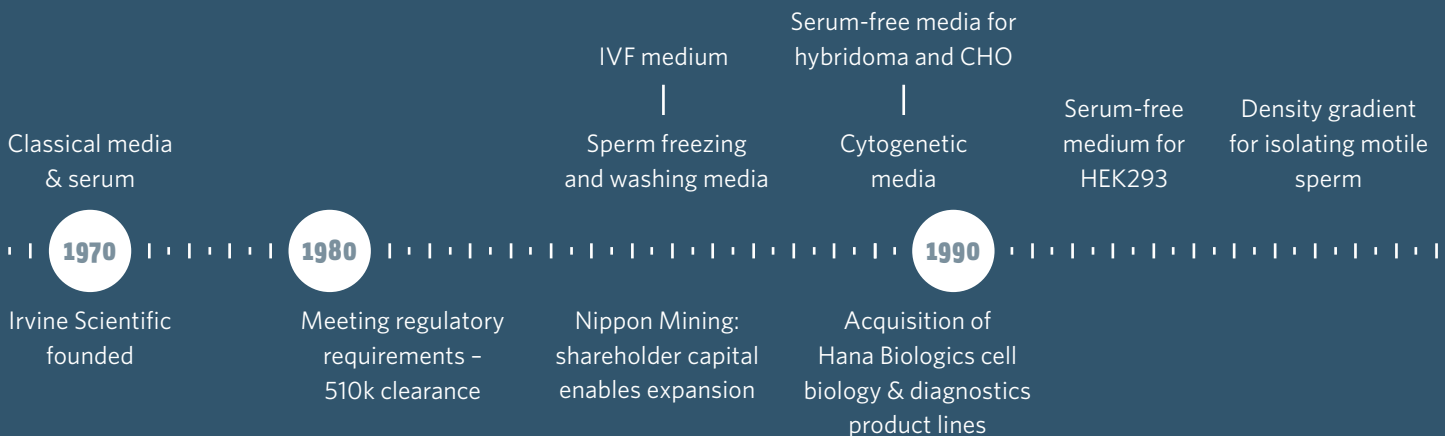
HELPING YOU AT THE CUTTING-EDGE

Irvine Scientific continuously meets demands for new, proprietary or customized media solutions for an increasing diversity of cell types. Whatever your area of work we can help to:

- **Maximize productivity during development and large-scale production of biologics**
- **Fulfill the potential for novel, cell-based therapeutics**
- **Contribute to successful outcomes in clinical diagnostics and reproductive medicine**

GIVING YOU PEACE OF MIND

Irvine Scientific products and services are developed according to the highest medical standards. Every product is subject to stringent Quality Systems unrivalled in the industry. Manufacture of proprietary and customized media is fully cGMP compliant. Replication of manufacturing facilities in USA and Japan ensures a rapid, uninterrupted worldwide supply of products with consistent, reliable performance.



"Technical and regulatory support has enabled our partners in different markets to pass smoothly and successfully through 510k, CE marking, Drug Master Files and drug approvals submissions."

Jessie Hsiao-Tzu. Ni, M.O.T., Ph.D., Chief Scientific Officer, Irvine Scientific



PVP for sperm immobilization Chemically-defined media for CHO Closed vitrification system for embryos Chemically-defined media for hybridoma Medium for continuous culture of human embryos Serum-free media for adult stem cells Chemically-defined media for MDCK and Vero cells Chemically-defined, DMSO-free cryopreservation for adult stem cells

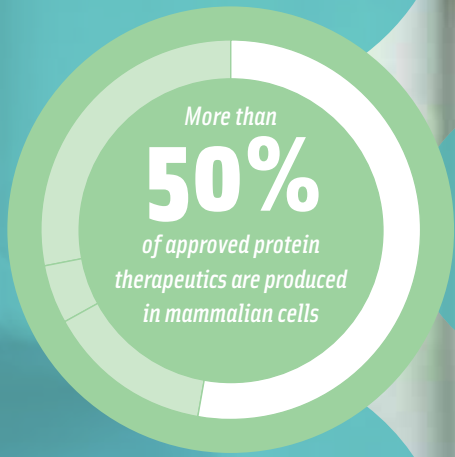
2000

CE marking ISO 13485 certification

2010

Production facility opened in Japan Production facility in USA expanded Media supplier for commercial antibody production in Japan ISO 9001:2008 certification for Japanese facility

JX Holdings formed:
(Nippon Oil Corp & Nippon Mining Holdings Inc)



In the last 40 years, the use of mammalian cells for the production of biologics has enabled modern medicine to treat and prevent serious illnesses, including cancer and autoimmune diseases such as rheumatoid arthritis.

Growth in the biologics market has created an unprecedented demand for cell culture media. With today's culture volumes ranging from micro-liters at lab scale to 20000 L tanks in production, and the acceleration of new therapeutics being brought into clinical trials, the market for cell culture is expected to grow rapidly.

Since introducing its first media solutions in 1970, Irvine Scientific has supported many companies on their path to market. This experience is continually fed back into an expanding and improving portfolio of products and services to provide higher performance and meet regulatory demands.



BIO- PHARMACEUTICALS

maximize productivity from development to large-scale production of biotherapeutics and vaccines

THE BalanCD PLATFORM - CELL-SPECIFIC MEDIA AND SUPPLEMENTS

Success in biologics development and manufacture is highly dependent on determining optimal culture conditions - in particular the quality and content of the medium and feed.

Developed to avoid many of the challenges faced during cell line development through process optimization and into commercial production, the BalanCD platform provides a selection of serum-free, chemically-defined, cell-specific media, together with their complementary supplements.

REDUCE DEVELOPMENT TIMES - RAPIDLY REACH REQUIRED YIELD AND QUALITY OF END-PRODUCT

Work efficiently and effectively by selecting the BalanCD medium platform best suited for your application.

TRANSITION SMOOTHLY THROUGH TO COMMERCIAL PRODUCTION

Unrivalled Quality Systems applied to cGMP and dedicated animal-component free manufacturing fulfill quality and reliability requirements. Comprehensive documentation including information from Supply Chain Management through Drug Master Files, is available to help meet regulatory requirements.

BE SURE OF RAPID, UNINTERRUPTED DELIVERIES

State-of-the-art facilities in California and Japan provide replication of media manufacture and Quality Systems and responsive, flexible production capacity.

"We supply media for several blockbuster biopharmaceuticals and are proud of our reputation amongst customers for facilitating a successful development process."

*Shawn Smith, Head of Sales and Marketing,
Industrial Cell Culture, Irvine Scientific*



*Accelerate the path
from development to production –
begin with a BalanCD medium
best suited for your application.*



Over
1000
cell-based therapeutics
are in clinical trials worldwide

The first bone marrow transplant, performed over 60 years ago, is one of the earliest examples of cell therapy. Today, T-cells are used in immunotherapy to combat cancer, while stem cells, with their unique ability to differentiate into specific cell types, are suggesting new ways to treat neurodegenerative diseases such as Alzheimer's, brain and spinal cord injuries, heart disease, diabetes and more.

Although one of the fastest growing industries in life science, scientists and clinicians face a significant challenge: primary stem cells do not live forever. As potential therapies move toward clinical trials, where cells are destined to be put directly into patients, the need to grow sufficient numbers with the required functionality using a safe, well-regulated process becomes paramount.

With over 45 years of experience in media development, Irvine Scientific is the ideal partner for scientists working at the forefront in developing cell-based therapies.

"Irvine Scientific has consistently provided our program with top-notch service and high-quality custom reagents at very short turn-around times. It's a pleasure to work with them since we can count on quick responses to allow us the greatest flexibility to our manufacturing needs!"

Andrew N. Cornforth Ph.D., Director of Manufacturing, Caladrius Biosciences, Inc.

CELL THERAPIES

fulfill the potential of novel, cell-based therapeutics

PRIME-XV MEDIA - PRODUCE HOMOGENEOUS FUNCTION FROM HETEROGENEOUS CELL SAMPLES

- **Select expansion and differentiation media to match cell type, cell source and final application**
- **Follow routine protocols verified for the most commonly-used cell types**
- **No more mixing or filtering - media are complete and ready to use**

GENERATE CONSISTENT, RELIABLE DATA THAT MEET INDUSTRY STANDARDS

PRIME-XV media are developed and verified following the latest, industry-determined standards and publications. They are produced in well-established, cGMP compliant facilities focused on risk mitigation and quality assurance to ensure consistency and continuity of supply.

GET FASTER TO MARKET WITH EXPERIENCED ASSISTANCE

For a smooth and efficient transfer to large-scale commercial production, continue to use Irvine Scientific manufacturing facilities. Having supported many customers through preclinical trials to final approval of drugs and medical devices, our specialists can help you at every step, providing technical advice, comprehensive documentation including Drug Master Files, and extensive regulatory support to assist moving your research to the clinic.

Select from a growing range of serum-free PRIME-XV media for expansion, differentiation and cryopreservation.





Worldwide, around

2,700,000

cytogenetic tests requiring media
are performed annually

With the development of new, complex genetic services and genetic testing, cytogenetic analysis continues to grow in importance, providing critical information for developmental research and clinical diagnoses.

Detection of chromosomal changes and abnormalities during pregnancy as well as in newborns, children or adults, can help to diagnose congenital conditions, such as Down's syndrome, and clinical conditions such as infertility.

In oncology, the diagnosis and treatment of certain cancers depend heavily on cytogenetic analysis of specific tissues such as blood, bone marrow or solid tumors to aid clinicians in staging, prognosis and treatment.

Building upon 25 years of experience and knowledge as a supplier to cytogenetic laboratories, Irvine Scientific developed CHANG media to meet the needs of modern diagnostics laboratories.

"We chose CHANG Marrow because it's comparable to, or even better quality, than other media."

Dr. Philip D. Cotter, Principal and Co-founder, ResearchDx., a leading Contract Diagnostics Organization for biopharmaceutical and diagnostic industries

CLINICAL DIAGNOSTICS

Time- and cost-efficient cytogenetic analysis

CHANG MEDIA FOR SUCCESSFUL ANALYSIS

Even the most challenging cells from a heterogeneous patient sample must be able to grow. Focused on performance, leading cytogenetic laboratories now choose CHANG media. Each medium is designed to optimize growth of a specific cell- or tissue-type and thereby reveal analyzable metaphases and interphases.

Manufacturing to the highest quality standards ensures consistency, minimizes the need for QC testing and meets regulatory demands.

GET FASTER ANSWERS

CHANG Amnio for cells from amniotic fluid, chorionic villi and tissues. Ensures faster growth, a high mitotic index and good morphology when compared to other commercially-available media.

IMPROVE DETECTION OF ABNORMALITIES

CHANG Marrow for bone marrow samples out-performs other commercially-available media in clinical studies and supports the growth of rarer, harder to culture cells often associated with malignancies.

USE THE MITOGEN OF YOUR CHOICE

CHANG Medium MF is a mitogen-free medium that facilitates the analysis of peripheral blood cells in constitutional and acquired investigations.



*Complete and ready to use
(no more mixing), CHANG media are
supplied in volumes designed
to minimize waste.*

REPRODUCTIVE MEDICINE

improve workflow efficiency and contribute to increased pregnancy rates

Since the first in vitro fertilization or 'test tube' baby was born in the UK in 1978, advances in reproductive medicine have enabled people around the world to have their own children. In 2013, Europe alone reported over half a million treatment cycles.

Irvine Scientific has been a well-recognized supplier of innovative media solutions and laboratory supplies to the reproductive medicine community (also known as A.R.T. – assisted reproductive technologies) for almost 30 years.

With an estimated one in six couples likely to experience some form of infertility problem during their reproductive lifetime, there is continuing pressure on clinical laboratories to increase pregnancy success rates, reduce the need for repeat treatment cycles and offer cost-effective treatment.

"My experience with Irvine Scientific's Continuous Single Culture has been nothing short of transformative for my IVF results."

*Michael B. Matilsky PhD, HCLD,
IVF Laboratory Director, BocaFertility,
U.S.A.*



SPERM



SEPARATION (A)



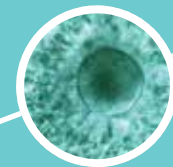
WASHING (B)



PREINCUBATION (C)



OOCYTE DENUDATION



PREINCUBATION (C)



RINSING (B)



OOCYTES

RETRIEVAL (B)

LEAD THE FIELD WITH NEW GENERATION PRODUCTS

Since 2012, Irvine Scientific has offered a new generation of products that integrate smoothly into typical laboratory workflows.

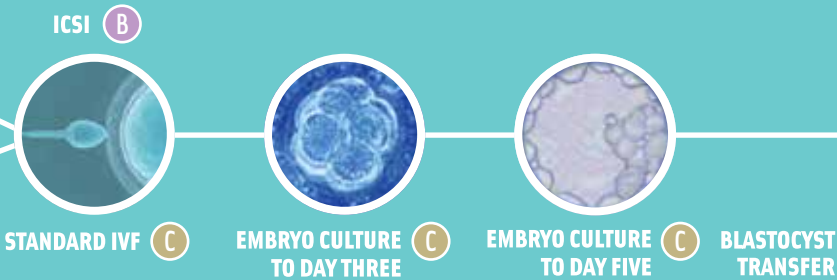
To improve the chance of a successful pregnancy, the viability of oocytes and sperm must be maintained, while embryos must be grown under conditions that minimize stress and encourage healthy growth. With optimized, multi-application media solutions to fulfill these requirements, laboratories can now:

- **Collect and maintain high quality sperm and oocytes to help improve fertilization rates**
- **Grow embryos in an uninterrupted, stress-free environment**
- **Improve laboratory efficiency**

SAFETY AND REGULATORY DEMANDS ASSURED

All products are subjected to the most stringent QC controls, including proprietary bio-assays, to ensure safety. Quality and regulatory management systems ensure compliance with the broadest scope of regulatory requirements, including ISO 13485:2012, FDA's QSR, European Medical Device Directive (93/42/EEC).

MORE THAN 5 MILLION BABIES HAVE BEEN BORN
WORLDWIDE SINCE THE FIRST IVF BABY IN 1978



MEDIA SERVICES

faster to market with an experienced partner

As research ideas become potential commercial realities, the focus grows on providing optimal culture conditions while ensuring regulatory compliance and mitigating the risks involved with bioproduction. Selecting an Irvine Scientific Media Service can give you instant access to over 45 years of knowledge and experience in media development and the associated regulatory requirements of the industry.

LET US DESIGN THE MEDIUM THAT EXACTLY MEETS YOUR REQUIREMENTS

From media screening and selection through to cGMP production, you will work with Irvine Scientific professionals with proven experience in supporting customers from preclinical trials through to final approval. Utilizing a well-established rational selection and optimization process together with access to an extensive media library ensures an efficient, cost-effective and time-saving development process.

USE OUR EXPRESS MEDIA SERVICE FOR RAPID PROTOTYPING

Normally provided within 10 working days, this service offers flexible, small-scale, non-GMP media production of liquid and powder formulations. By using the same raw materials sourced and quality-controlled as for our large-scale GMP manufacturing, this approach greatly facilitates the step from research to process development activities.

MEDIA DEVELOPMENT AND OPTIMIZATION

Save time and costs – access over 45 years of knowledge and experience

RAPID PROTOTYPING

Use our Express Media Service for flexible, small-scale, non-GMP production of media prototypes

MEDIA SCREENING AND SELECTION

Save time in development with expert support

ANALYSIS

Save resources and time – outsource spent media testing, receive advice on protocol and media optimization

MANUFACTURING SERVICES

work with a reliable, versatile partner

Irvine Scientific is a media supplier for production of multiple blockbuster biopharmaceuticals.

"Irvine has become our trusted commercial manufacturer. We have established a good working relationship throughout all departments. They are responsive, willing to work with our constraints and ready to adapt to our changing needs."

*Satish Chandran, CEO,
Somahlution Inc., U.S.A.*

RAPID, UNINTERRUPTED SUPPLY OF LIQUID AND POWDER MEDIA

Recognized for highly responsive turnaround times, state-of-the-art facilities in California and Japan provide prescribed redundancy of media manufacture, including designated cGMP and animal-component free work areas and equipment.

PRODUCTION AND PACKAGING OF PROPRIETARY AND CUSTOMIZED MEDIA

Offering a flexible production capacity (liquids from 100 L to 10,000 L, powders up to 3000 kg or more), liquid media is then filled into vials, bottles or bioprocess containers within aseptic filling suites.

UNRIVALLED QUALITY SYSTEMS MEET MARKET REQUIREMENTS

A robust Raw Material Program, detailed manufacturing procedures, and adherence to a stringent Quality Management System ensure lot-to-lot consistency.

CLASSICAL MEDIA

produce high quality results using premium products

Developed during the 1950s, many classical media are still used for routine cell culture in academic, industrial and clinical laboratories.

GROW CELLS UNDER OPTIMAL CONDITIONS TO OBTAIN RELIABLE INFORMATION

Select the products best suited for your specific cells and final application. Choose from a broad range of media, supplements and reagents.

GENERATE CONSISTENT RESULTS

Industry-leading manufacturing and quality systems ensure lot-to-lot consistency. Shelf lives of at least two years and an easy reserve/hold policy secure your future work.

*cGMP compliant
manufacturing meets
regulatory demands.*

Irvine Scientific develops and supplies products and services wherever our expertise in the growth and handling of mammalian cells can contribute to the health and well-being of mankind – today and in the future.



Over 45 years of knowledge and experience



Innovative products, solutions and services



Unrivalled quality systems

Irvine Scientific is a wholly owned subsidiary of the JX Group. Managed by JX Holdings, Inc., a Fortune 500 company, the JX Group mission is to contribute to the development of a sustainable economy and society through innovation in the areas of energy, resources and materials.



www.irvinesci.com

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