

MEDIA KIT 2025



INDEX

Nucleic Acid Insights—your
content marketing partner
for life sciences

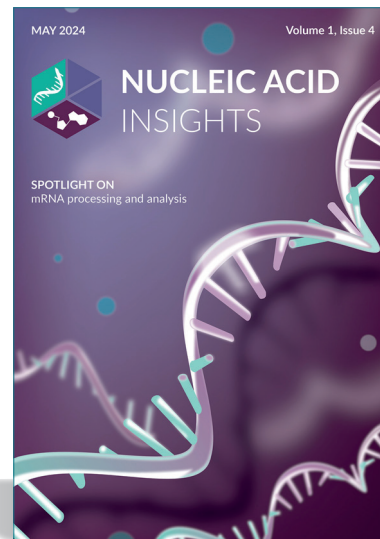
ABOUT	3	INTERVIEWS AND PODCASTS	18
WHAT CAN WE DO FOR YOU?	5	VIDEO PRESENTATIONS	20
USER DEMOGRAPHICS	7	INFOGRAPHICS	21
CALENDAR	11	SCIENTIFIC ILLUSTRATIONS	22
OPPORTUNITIES	13	EBLASTS	23
WEBINARS	13	PREMIUM SERVICES	24
EXPERT ROUNDTABLES	16	OUR OTHER PUBLICATIONS	25
ARTICLES	17		

ABOUT

Nucleic Acid Insights—an online, peer-reviewed, open access journal with a translational focus

Nucleic Acid Insights provides online, peer-reviewed, open access content with a translational focus.

Nucleic Acid Insights is specifically designed to provide the need-to-know information required to successfully navigate this rapidly evolving space—the go-to online resource keeping the field up to date with all the latest news, trends, issues, and breakthroughs across the nucleic acids area.



Nucleic Acid Insights covers all the major RNA and DNA technologies and modalities, including but not limited to: messenger RNA (mRNA); plasmid DNA; antisense oligonucleotides (ASO); phosphorodiamidate morpholino oligonucleotides (PMO); RNA interference (RNAi); small interfering RNA (siRNA); aptamers; micro RNA (miRNA); and guide RNA (gRNA).

These technologies are explored across a wide range of applications and related areas spanning the life sciences field, including: therapeutic drugs; prophylactic vaccines; associated delivery technologies (eg. LNPs), as well as guide RNA utilized in genome editing platforms; raw and starting materials; research tools; and diagnostics.

All content is available free of charge, and the written material is complemented by engaging formats such as webinars, infographics, animations, video, and podcasts

Nucleic Acid Insights provides a unique online content marketing and lead-generation opportunity

Is it important for your company to demonstrate its capabilities to scientists and/or business leaders making key technology platform decisions at an early stage in a product's development?

Do you need to generate qualified leads from companies involved in DNA or RNA manufacture?

Are you looking to provide educational materials to individuals focused on analytical, process, or clinical development?

Nucleic Acid Insights provides a unique online content marketing and lead-generation opportunity for:

- ▶ active engagement of key stakeholders from across the global community all year round;
- ▶ the chance to target organizations at varying stages of the R&D pipeline—universities, spin-outs, biotechs, pharma, hospitals, investors, and analysts;
- ▶ an alternative to the ever-more expensive conference market; and
- ▶ a means by which you can access the people making the key new discoveries, those individuals driving the delivery of safe and effective therapies to patients, and those manufacturing the RNA/DNA products of the future.

WHAT CAN WE DO FOR YOU?

We don't sell off-the-shelf solutions: all the packages we provide are tailored to your precise marketing, educational and business development objectives

We can:

- ▶ provide support in the development of your content marketing strategy and tactics for this sector, partnering with you in the development of your annual marketing plans;
- ▶ work closely with you to create quality written, video, and audio content of high value to your target audience;
- ▶ offer you opportunities to re-purpose scientific and educational content you have already developed and make it available to a global audience;
- ▶ raise your company's profile, demonstrate your capabilities, and enhance your reputation as a thought-leader in the sector;
- ▶ play a key role in your lead-generation activities;
- ▶ ensure your leading scientists are seen as subject matter experts throughout your target market; and
- ▶ create written content from video or audio, ideal for increasing the reach, longevity, and searchability of your data and other technical information.

We can partner with you to develop high-quality content to demonstrate your thought leadership

- ▶ Your own special focus issue or ebook on the topic of your choice
- ▶ Client case studies, interviews, and co-presentations
- ▶ Peer reviewed articles, as well as editorials and commentaries
- ▶ Video presentations and roundtables
- ▶ Podcasts
- ▶ Infographics and animations
- ▶ Webinars, both live and on demand
- ▶ Blog posting



USER DEMOGRAPHICS

We currently have
7,000 registered users

Data by sector

- ▶ Big pharma
- ▶ Academic institutions conducting early stage research as well as vaccine clinical trials
- ▶ Investors and analysts
- ▶ Biotech companies, including those at a relatively early stage of development. Our research shows that these earlier stage companies attend fewer industry conferences than those at a later stage, so *Nucleic Acid Insights* offers an unparalleled opportunity to target this particular audience
- ▶ Solution and service providers
- ▶ Government-funded organizations (such as NIH) and NGOs



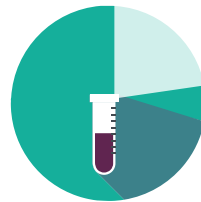
31%

BIOTECH



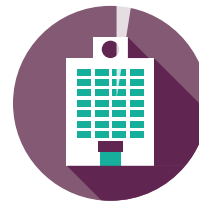
22%

ACADEMIC/
HOSPITAL



23%

PHARMA/
LARGE BIOTECH



2%

GOVERNMENT/
NGO



2%

INVESTOR/
ANALYST



22%

SOLUTION/
SERVICE PROVIDER,
including CROs
and CDMOs

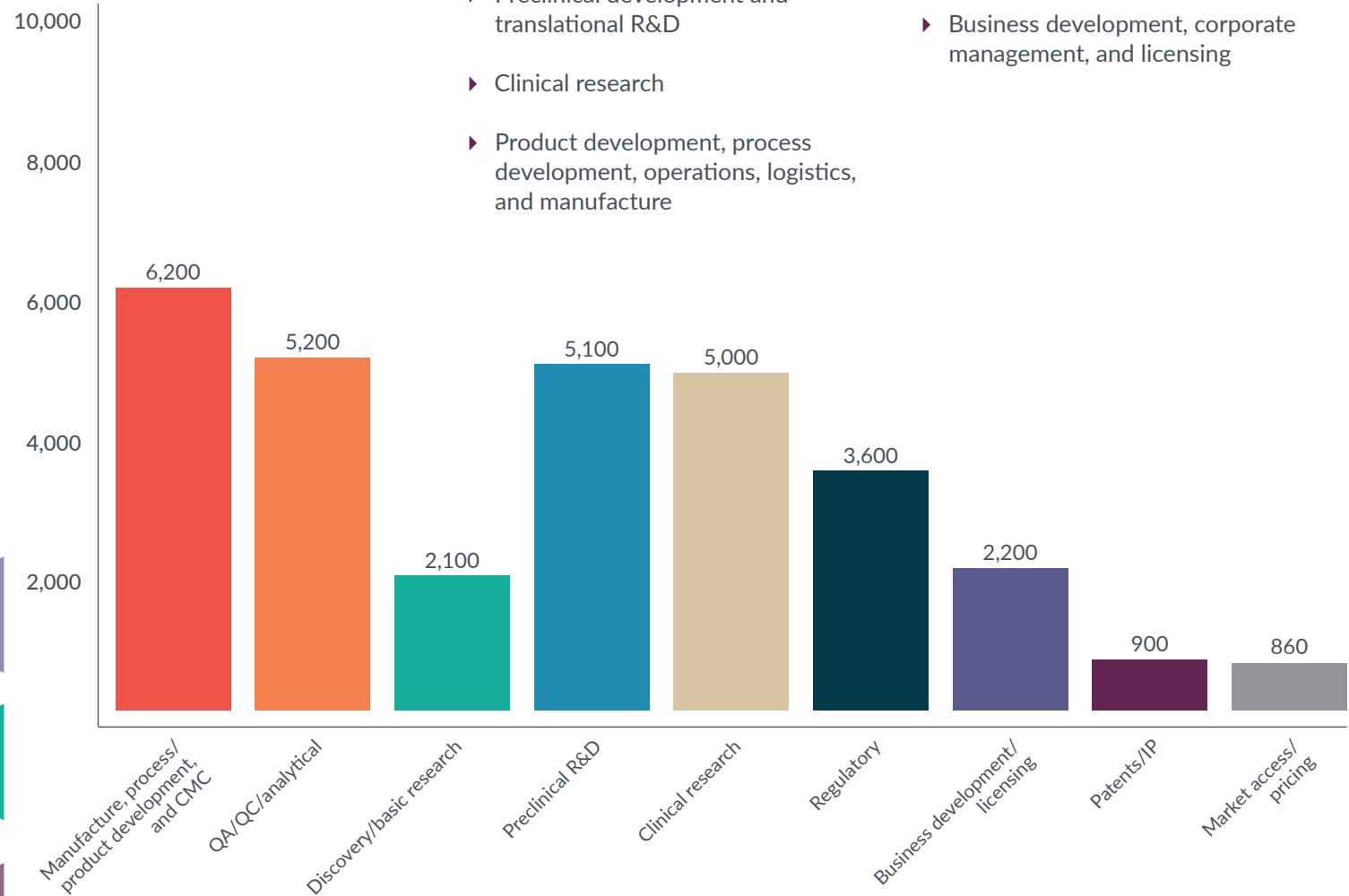


1%

CONSULTANT

Nucleic Acid Insights has a translational focus, featuring content of value to individuals along the R&D pipeline

Data by interest area and seniority

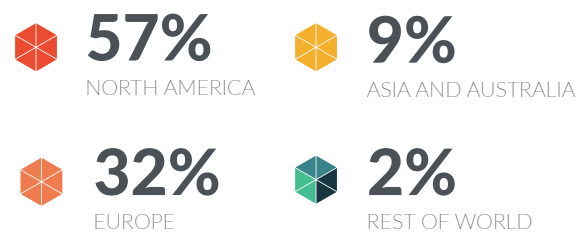


- ▶ Discovery and basic research
- ▶ Preclinical development and translational R&D
- ▶ Clinical research
- ▶ Product development, process development, operations, logistics, and manufacture
- ▶ Regulatory affairs, QA/QC, and validation
- ▶ Business development, corporate management, and licensing

Data by interest area
and seniority (continued)



Data by location



EDITORIAL CALENDAR

You are able to sponsor any of the Spotlights and/ or select an issue for the content we develop together

We also feature a number of topic-specific channels on our website:

mRNA; plasmid DNA;
oligonucleotides;
formulation and delivery



SPOTLIGHTS

Each monthly Spotlight focuses BioInsights members' attention on a particular topic or technology area. We leverage an array of formats to provide a comprehensive update on the key trends, challenges and breakthroughs in a given field: independently peer reviewed Expert Insights, Opinion pieces, Interviews, Webinars, Podcasts, FastFacts videos, and more...



CONTENT PILLARS

Content pillars allow us to zoom right in on specific aspects that are of special interest to BioInsights members, including mRNA, DNA, oligonucleotides, and delivery systems. Specifically themed content is added to each and every pillar on a monthly basis.



PODCAST SERIES

We select a key issue or challenge, then invite a range of stakeholders to proffer their opinions and share related learnings via the ever-popular, easy-to-consume podcast format.

NUCLEIC ACID INSIGHTS
EDITORIAL CALENDAR 2025

FEBRUARY	MARCH	APRIL	MAY	JUNE
New directions in application	Innovation in engineering and design	Manufacturing: upstream/synthesis	Platforming	Next-generation approaches to delivery
LNPs: what does the future hold?	Diagnostic/sensor applications	Analytics	Engineering and manufacturing	Upstream/synthesis
JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER
Analytics	New directions, new modalities	Downstream/purification: issues and ramifications	Delivery	Manufacturing: downstream/purification
Getting beyond the liver		Preclinical tools and technologies	Stability	At the interface of synthetic biology and DNA

CROSS-PILLAR EDITIONS

Special editions addressing key questions and challenges across the spectrum of nucleic acids



CONTENT PILLARS

mRNA

Formulation and delivery

Oligonucleotides

DNA

Nucleic Acid Insights provides you with fantastic opportunities to:

- ▶ Educate your target market about your company's expertise, capabilities, and experience
- ▶ Share your latest data with organizations looking for partners and service providers in your field
- ▶ Profile your executives and scientists as thought-leaders and KOLs
- ▶ Generate qualified leads from across the global sector
- ▶ Increase awareness of your company's role in nucleic acid R&D

OPPORTUNITIES

Any of our options can be tailored to match your current marketing and business development priorities

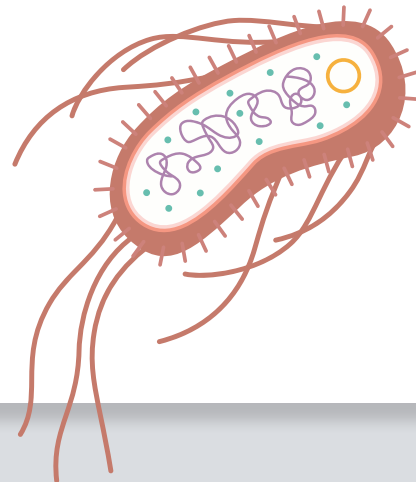
We offer a broad range of options to help you reach your target audience, any of which can be tailored to match your current marketing and business development priorities. These include interviews, expert roundtables, podcasts, webinars, articles, video presentations, infographics, e-blasts and more.

WEBINARS

Webinars can stand alone or can be included in a Spotlight, depending on the topic and timing fit

Our 2025 webinar schedule is filling up fast

Contact jamie.cox@insights.bio to discuss options and availability



Presenting a webinar with *Nucleic Acid Insights* gives you an efficient and cost-effective way to:

- ▶ generate qualified leads from amongst the global nucleic acid community;
- ▶ demonstrate your company's expertise and capabilities;
- ▶ stimulate discussion around a topic of significant importance to your customers;
- ▶ educate individuals on crucial regulatory, scientific or technical issues; and
- ▶ make a noise around a new product or service offering launch.

Presenting a webinar with us is an efficient and cost-effective way to generate qualified leads

Our webinar packages include:

- ▶ as much support as you need in terms of topic selection and agenda development, format selection, and speaker panel identification and invitation;
- ▶ full hosting and technical support, including planning calls with panelists and rehearsals as needed;
- ▶ a comprehensive promotional plan, including multiple email shots to our database, website and newsletter marketing, and social media;
- ▶ a moderator from our editorial team to ensure the webinar runs smoothly on the day;
- ▶ registration and attendee lists for the webinar;
- ▶ a report on the questions submitted during the live webinar so you can follow up directly with individuals afterwards and continue the discussion;
- ▶ hosting of the webinar recording on an indefinite basis with ongoing lead generation;
- ▶ webinar recording provided to you for hosting on your own site; and
- ▶ the option for us to publish an article based on the transcript of the webinar, repurposing your presentation into written format and making it search engine friendly.

We don't sell off-the-shelf solutions. All the packages we provide are tailored to your precise marketing, educational and business development objectives.

You can view all of our on-demand webinars [here](#)

Here are some examples of previous webinars for our clients:



Feb 11 2021 ON DEMAND
Fitting product to process: raw materials customization for cell therapy manufacturing success
Thursday 08:00 PST / 11:00 EST / 16:00 GMT / 17:00 CET

Format

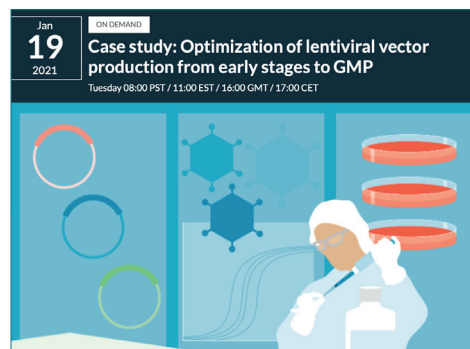
Panel-style webinar with accompanying transcript-based article

Client

Bio-Technie

[VIEW THE WEBINAR HERE](#)

[READ THE ARTICLE HERE](#)



Jan 19 2021 ON DEMAND
Case study: Optimization of lentiviral vector production from early stages to GMP
Tuesday 08:00 PST / 11:00 EST / 16:00 GMT / 17:00 CET

Format

Presentation-style webinar with Q&A

Client

Polyplus-transfection

[VIEW THE WEBINAR HERE](#)



Feb 10 2022 ON DEMAND
TESSA technology: A new era for AAV manufacture
Thursday 08:00 PST / 11:00 EST / 16:00 GMT / 17:00 CET

Format

Live30 webinar: a 30 minute webinar focused on new technologies and their applications

Client

Mirus Bio

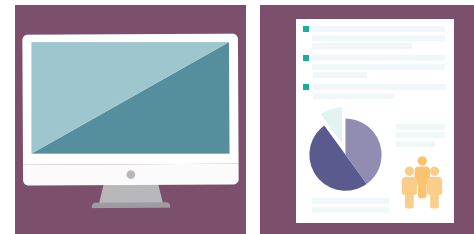
[VIEW THE WEBINAR HERE](#)

EXPERT ROUNDTABLES

Here are some examples of expert video roundtables for our clients:

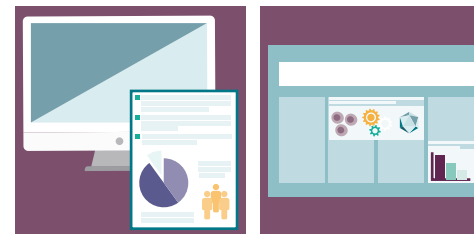
On-demand video expert roundtables provide powerful tools for you to generate qualified leads and/or position your thought leader(s) at the heart of the debate around a topic of key importance to your company.

Our editorial team works closely with you to identify over-arching topics and discussion points, and to convene a panel of KOLs. We then liaise with the panel to define the final list of questions for discussion, record the video, and, edit the roundtable itself, and then produce a full article based on the transcript.



Format
Video (l.) and article (r.)

Client
Thermo Fisher Scientific



Format
Video plus article (l.) and poster (r.)

Client
Corning



INTERVIEWS AND PODCASTS

Here are some examples of interviews for our clients:

Interviews are a great way to raise awareness within the nucleic acid community, with minimal resource requirements from your team.

We can interview up to three of your scientists, executives, partners or clients, with the resulting video, podcast and/or written version included in an issue of the online journal.

Format

Video and written

Client

Merck

Format

Podcast and written

Client

Merck/Millipore Sigma



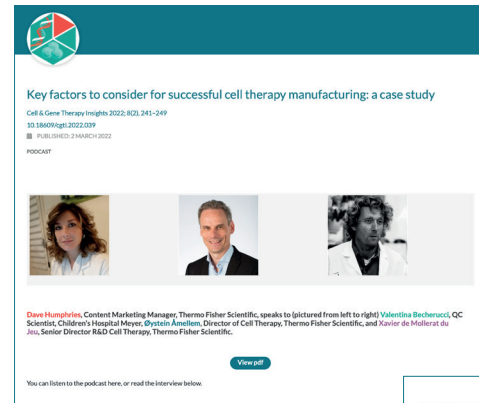
WATCH THE VIDEO AND
READ THE ARTICLE HERE



HEAR THE PODCAST AND
READ THE ARTICLE HERE

Podcasts in a variety of formats and lengths can also be produced, either in series or as one-offs

Here is an example:



Key factors to consider for successful cell therapy manufacturing: a case study
 Cell & Gene Therapy Insights 2022; 8(2): 241-249
 01/06/2022; 2022-03-01
 PUBLISHED: 2 MARCH 2022
 PODCAST

Dave Humphries, Content Marketing Manager, Thermo Fisher Scientific, speaks to (pictured from left to right) **Valentina Bacherov**, QC Scientist, Children's Hospital Meyer, **Deyan Anselmi**, Director of Cell Therapy, Thermo Fisher Scientific, and **Xavier de Mollerat du Jui**, Senior Director R&D Cell Therapy, Thermo Fisher Scientific.

You can listen to the podcast here, or read the interview below.

Format
 Serial podcast and written interview

Client
 Thermo Fisher Scientific

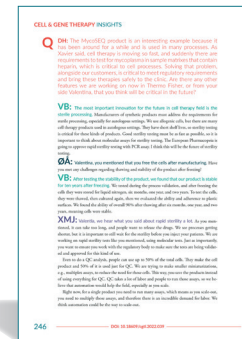


CELL & GENE THERAPY INSIGHTS
 PODCAST INTERVIEW

Key factors to consider for successful cell therapy manufacturing: a case study

Dave Humphries, Content Marketing Manager, Thermo Fisher Scientific, speaks to **Valentina Bacherov**, QC Scientist, Children's Hospital Meyer, **Deyan Anselmi**, Director of Cell Therapy, Thermo Fisher Scientific, and **Xavier de Mollerat du Jui**, Senior Director R&D Cell Therapy, Thermo Fisher Scientific.

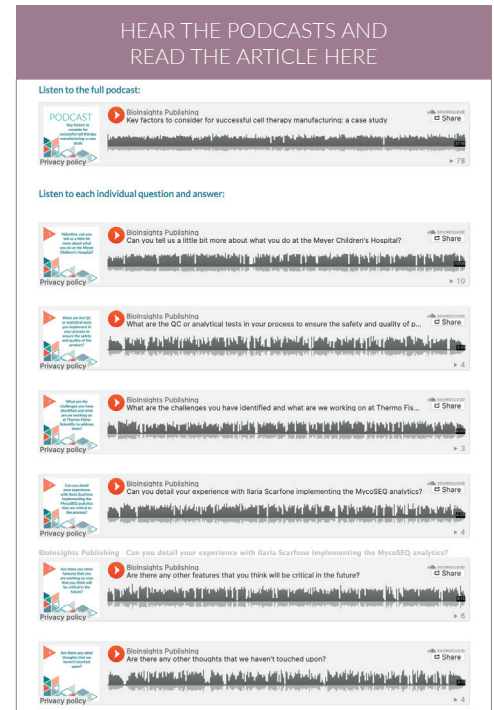
Q: Today, we'll be discussing the key factors to consider for successful cell therapy manufacturing. Valentina, can you tell us a little bit more about what you do at the Meyer Children's Hospital?



CELL & GENE THERAPY INSIGHTS

Q: The MycoSEQ product is an interesting market because it has been around for a while and is used in many processes. As a former cell therapy manufacturing professional, what are the key factors to consider for the cell therapy manufacturing process that contain elements which are critical to cell production, including the processes, the equipment, the materials, the regulatory requirements, and bringing these elements safely to the clinic. Are there any other factors you are working on now at Thermo Fisher, or have you seen Valentina, that you think will be critical in the future?

VB: The most important innovation for the future of cell therapy will be the continuing development and use of AI. AI is going to be used in many ways, from the design of the process to the optimization of the process. It will be used to optimize the process, to reduce the time to market, and to improve the quality of the product. It will be used to optimize the process, to reduce the time to market, and to improve the quality of the product. It will be used to optimize the process, to reduce the time to market, and to improve the quality of the product.



HEAR THE PODCASTS AND READ THE ARTICLE HERE

Listen to the full podcast:
 Biointights Publishing
 Key factors to consider for successful cell therapy manufacturing: a case study

Listen to each individual question and answer:
 Biointights Publishing
 Can you tell us a little bit more about what you do at the Meyer Children's Hospital?

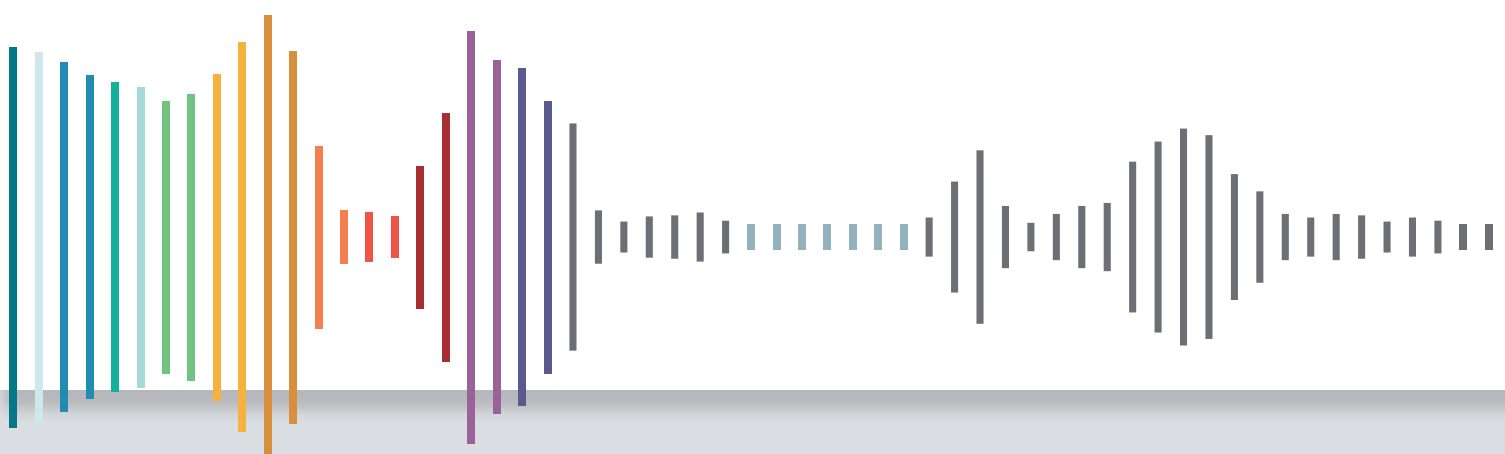
Biointights Publishing
 What are the QC or analytical tests in your process to ensure the safety and quality of p...

Biointights Publishing
 What are the Challenges you have identified and what are we working on at Thermo Fi...

Biointights Publishing
 Can you detail your experience with Iarla Scarfone implementing the MycoSEQ analyt...

Biointights Publishing
 Are there any other features that you think will be critical in the future?

Biointights Publishing
 Are there any other thoughts that we haven't touched upon?



VIDEO PRESENTATIONS

Our FastFacts work well for educational and lead generation purposes

Here are some examples of Fast Facts videos for our clients:

Our FastFacts videos are 10–15 minute edited presentations, accompanied by a poster summarising the key learning points. They are designed for the presentation of app notes, validation data, case studies, scientific posters, or product demonstrations.

TESSA technology: a new paradigm in AAV manufacturing
 Cell & Gene Therapy Insights 2020, 4(8), 1225
 10.18699/cgt.2020.1225
 PUBLISHED 1 OCTOBER 2020

FASTFACTS

Ryan Cawood

Watch the video or read the poster to learn:

- Benefits and drawbacks of current AAV viral vector production methods
- How Tetra-cysteine Enabled Self-Sterilizing Adenovirus (TESSA) allows efficient, scalable AAV manufacturing
- Results from studies comparing TESSA with conventional methods

About the speaker
 Ryan Cawood received his PhD from Cornell in 2015, after working first as a design engineer and then as a scientist at the company was to simplify and standardize the process of DNA engineering called "CRISPR-Cas9". He then worked for the next three years as a research scientist at the company where he worked on the development of the "CRISPR-Cas9" platform through his research on the development of new biological tools. This culminated in a series of patents in the field of a cloning solution procedure using a combination of proprietary technologies in through design, recovery, development and manufacture of a novel biological tool.

Client
OXGENE

FASTFACTS

TESSA technology: a new paradigm in AAV manufacturing

The discovery of a novel, self-sterilizing AAV vector production platform using a tetra-cysteine enabled self-sterilizing adenovirus (TESSA) allows efficient, scalable AAV manufacturing. This platform is designed to simplify and standardize the process of DNA engineering, which is a key challenge in the development of AAV-based gene therapies. The TESSA platform is designed to be used in a variety of settings, including large-scale manufacturing and small-scale research.

KEY TAKEAWAYS:

- TESSA technology allows for efficient, scalable AAV manufacturing.
- TESSA technology simplifies and standardizes the process of DNA engineering.
- TESSA technology is designed to be used in a variety of settings.

OXGENE

GMP compliant residual PEIpro® test: one step closer to commercialization
 Cell & Gene Therapy Insights 2020, 4(10), 1455.
 10.18699/cgt.2020.1455
 PUBLISHED 10 NOVEMBER 2020

FASTFACTS

Watch the video or read the poster to learn:

- Why perform residual PEIpro testing?
- How are cells and raw materials quantified and detected?
- How does the Residual PEIpro test guarantee specific and accurate quantification of PEIpro?

About the speaker
 Maja is a Senior Scientist in Chemistry at Polyplus-transfection. With a PhD from the University of Strasbourg and post-doctoral experience at Harvard Neuro-Oncology Center, she is currently focused on the development of innovative targeted delivery solutions.

Client
Polyplus-transfection

FASTFACTS

GMP compliant residual PEIpro® test: one step closer to commercialization

In the last few years, the cell and gene therapy industry has seen an explosion in the number of clinical trials based on the use of cell and gene therapy. This has led to a significant increase in the demand for GMP compliant residual PEIpro testing. This poster highlights the importance of this testing and provides a detailed overview of the Residual PEIpro test, which is a simple, accurate, and reliable method for quantifying and detecting residual PEIpro in cell and gene therapy products.

KEY TAKEAWAYS:

- Residual PEIpro testing is essential for GMP compliance.
- The Residual PEIpro test is a simple, accurate, and reliable method for quantifying and detecting residual PEIpro.
- This test is designed to be used in a variety of settings.

Polyplus-transfection

Simplifying AAV protein analytics with Maurice
 Cell & Gene Therapy Insights 2021, 7(1), 217
 10.18699/cgt.2021.217
 PUBLISHED 28 APRIL 2021

FASTFACTS

Chris Heeger PhD

Watch the video or read the poster to learn how to achieve faster, better analysis of integrated Maurice CE-SDS PLUS systems, including:

- CE-SDS analysis of AAV protein purity
- MSF analysis of AAV charge heterogeneity

About the speaker
 Dr Chris Heeger, Director of Application Science for the Analytical Solutions Division, has been instrumental in the development of Maurice CE-SDS PLUS systems. He has been working on this project since 2015, starting as a Lead Applications Scientist, and subsequently further building the Maurice CE-SDS PLUS systems. He has also been instrumental in the development of the Maurice CE-SDS PLUS systems, which are designed to simplify and standardize the process of AAV protein analytics.

Client
Protein Simple

FASTFACTS

Simplifying AAV protein analytics with Maurice

The Maurice CE-SDS PLUS system is a powerful tool for simplifying AAV protein analytics. It is designed to provide fast, accurate, and reliable analysis of AAV protein purity and charge heterogeneity. This poster highlights the key features and benefits of the Maurice CE-SDS PLUS system, which is designed to be used in a variety of settings.

KEY TAKEAWAYS:

- The Maurice CE-SDS PLUS system simplifies AAV protein analytics.
- The Maurice CE-SDS PLUS system provides fast, accurate, and reliable analysis.
- The Maurice CE-SDS PLUS system is designed to be used in a variety of settings.

Protein Simple

Identify and select optimal T cell phenotypes
 Cell & Gene Therapy Insights 2021, 7(1), 81.
 10.18699/cgt.2021.081
 PUBLISHED 22 FEBRUARY 2021

FASTFACTS

James Loung

Watch the video or read the poster to learn:

- What are the challenges facing adoptive cell transfer (ACT)?
- How can we identify the best T cells for adoptive therapy?
- How can multidimensional, functional assays on single T cells help develop powerful and effective ACT?

About the speaker
 James Loung is an accomplished scientist who works with a distinguished team of researchers in the industry leading global product portfolio. He currently serves as the VP of Research and Development for the company's research and product development. He is also the General Manager of Cell and Gene Therapy at Therion Therapeutics, a leading biotech company focused on the development of novel cell and gene therapy products.

Client
Berkeley Lights

FASTFACTS

Identify and Select Optimal T Cell Phenotypes

Adoptive cell transfer (ACT) is a powerful strategy for cancer immunotherapy. However, the success of ACT depends on the selection of optimal T cell phenotypes. This poster highlights the challenges facing ACT and provides a detailed overview of the methods used to identify and select optimal T cell phenotypes. This includes the use of multidimensional, functional assays on single T cells to help develop powerful and effective ACT.

KEY TAKEAWAYS:

- Identifying and selecting optimal T cell phenotypes is crucial for successful ACT.
- Multidimensional, functional assays on single T cells help develop powerful and effective ACT.
- The use of single T cell analysis is essential for identifying and selecting optimal T cell phenotypes.

Berkeley Lights

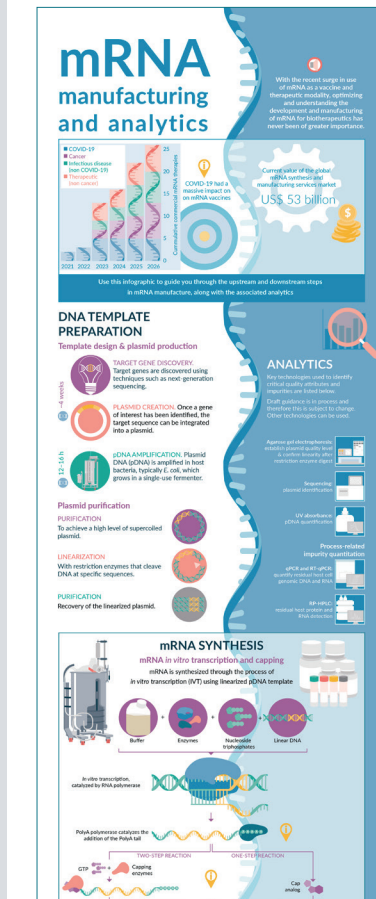


INFOGRAPHICS

Here are some examples of infographics that we have produced for our clients:

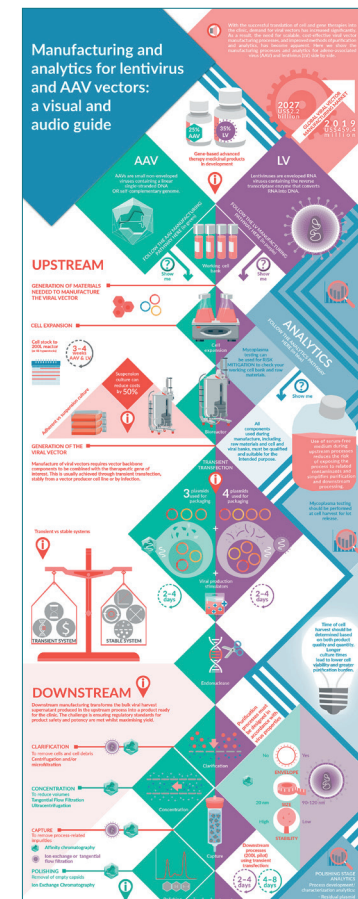
Our team are experts in communicating complex scientific information via visual formats, including infographics (static, voiced, and animated), PPT presentations and illustrations.

They work closely with your team to define contents and style, and the resulting content can be published in *Nucleic Acid Insights* or simply provided to you for your own use.



Format
Interactive, voiced infographic

Client
Thermo Fisher Scientific

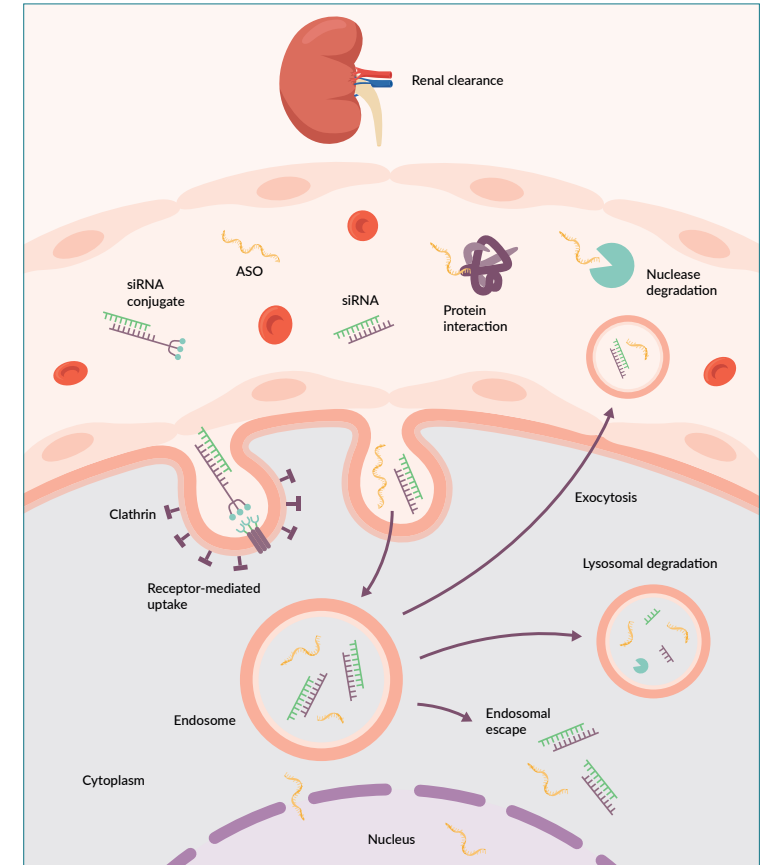
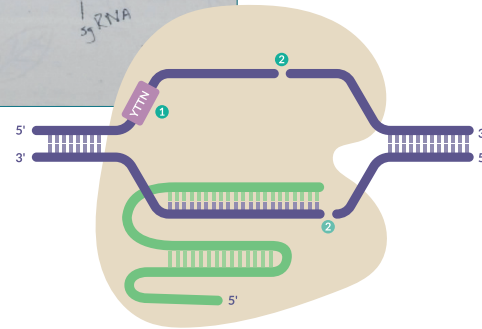
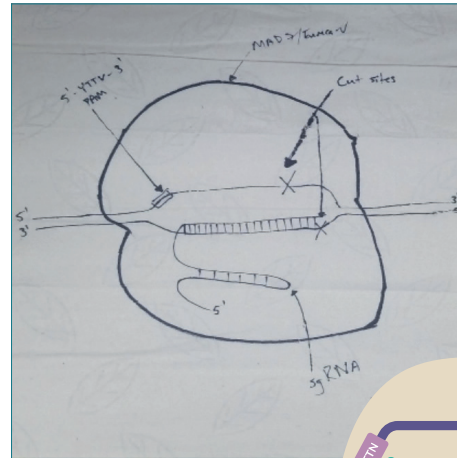


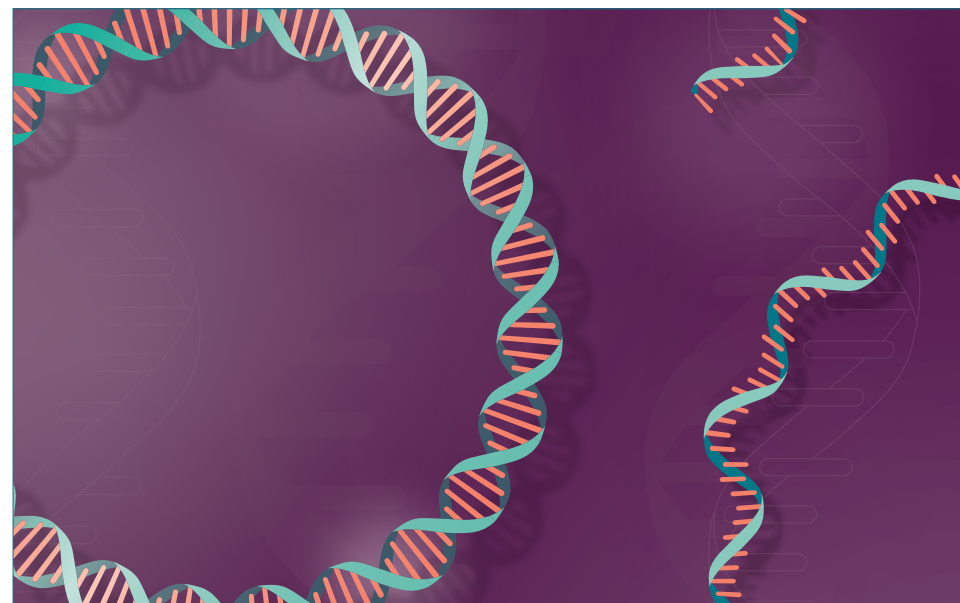
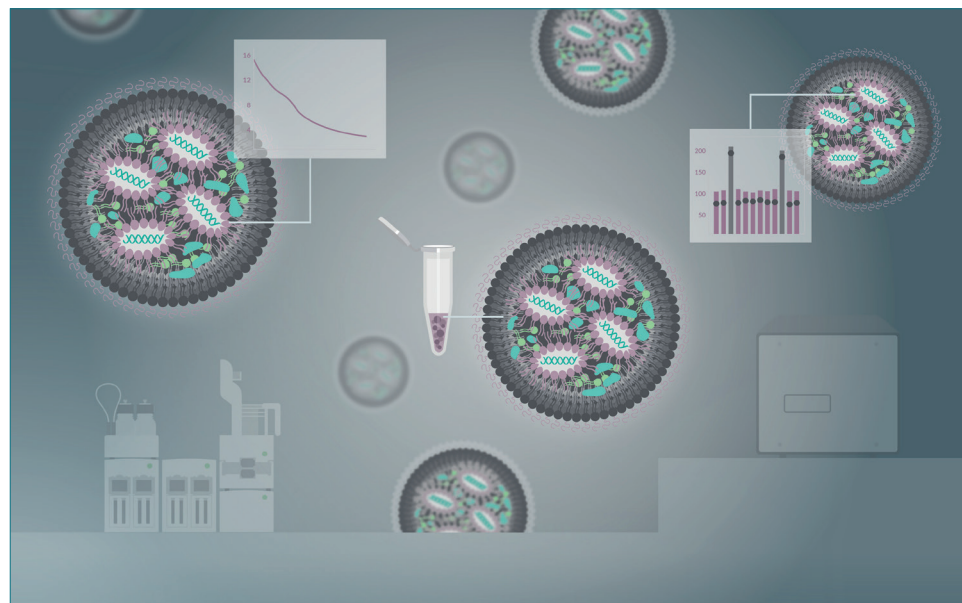
Format
Interactive, voiced infographic

Client
Thermo Fisher Scientific

SCIENTIFIC ILLUSTRATIONS

We work from your sketch or concept to create schematics or illustrations of your products or services





e-BLASTS

Our 2025 schedule is open for bookings

Contact jamie.cox@insights.bio to discuss options and availability

We offer a strictly limited number of third-party e-blasts to our registered users.

PREMIUM SERVICES

mRNA manufacturing and analytics

With the recent surge in use of mRNA as a vaccine and therapeutic modality, optimizing and understanding the development and manufacturing of mRNA for biopharmaceuticals has never been of greater importance.

Conversion of the gene into mRNA synthesis and manufacturing technologies. COVID-19 has a massive impact on the mRNA vaccine market. US\$ 53 billion.

Use this infographic to guide you through the upstream and downstream steps in mRNA manufacture, along with the associated analytics.

DNA TEMPLATE PREPARATION
Template design & plasmid production

ANALYTICS
New technologies used to identify those quality attributes and attributes are listed below. Draft analysis is in process and detection has not been done. Other technologies can be used.

PLASMID PURIFICATION
To achieve a high level of supercoiled plasmid.

LINEARIZATION
With restriction enzymes that cleave DNA at specific sequences.

PURIFICATION
Recovery of the linearized plasmid.

mRNA SYNTHESIS
mRNA is synthesized through the process of in vitro transcription (IVT) using linearized pDNA template.

RESIDUAL DNA TESTING: Homebrew vs off-the-shelf solutions

DOWNSTREAM
mRNA purification. mRNA is produced in a cell-free non-animal derived raw. However, the reaction mixture contains including enzymes, residual NTPs and other components and NTPs.

PURIFIED mRNA
Formulations, fill and finish. The purified mRNA is encapsulated in a drug delivery vehicle, such as a lipid nanoparticle (LNP) or other lipid or carbohydrate.

We offer a number of premium options, both for content creation and for market research. These include:

- ▶ bringing together KOL panels to discuss the topics of your choice, publishing the output as an ebook, video, and written roundtable, or other suitable content format;
- ▶ designing infographics, which can be animated and/or voiced, ideal for communicating complex technical or scientific information in an easily digestible format;
- ▶ inviting industry or academic subject matter experts to join your live webinars to add their opinions to the discussion;
- ▶ building and deploying surveys amongst our users, providing detailed reports on the responses; and
- ▶ bringing together focus groups to discuss your products/services, or topics of interest to you.

Plasmid DNA Manufacturing and Analytics

The rapid increase of the gene therapy pipeline and genetic vaccination for infectious diseases require large-scale production of high-quality plasmid DNA (pDNA) in gene therapy production facilities. However, it is essential to establish robust manufacturing and analytics processes to produce large quantities of pDNA.

APPLICATIONS OF pDNA
pDNA is used as a starting material in the manufacture of many advanced therapies. It can also be used as a therapeutic itself in DNA vaccines & therapies, template for mRNA manufacture, and viral vector manufacturing.

CHALLENGES IN THE SUPPLY OF pDNA
• Complex supply chains
• Production and capacity
• High demand
• Costs of goods
• Evolving regulatory landscape
• Quality assurance

MANUFACTURING CHALLENGES
Large size of product
High negative charge
pDNA is sensitive to shear stress and nuclease degradation
High volume of impurities in the starting material (~1% pDNA)
Conventional chromatography resins exhibit low binding other impurities in the lysate
High purity is required

pDNA MANUFACTURE

PLASMID SYNTHESIS
• Sequence determination for gene of choice
• Gene creation
• Gene insertion into cloning vector

UPSTREAM
During the upstream process, pDNA is produced in host cells. E. coli is typically used as the host as they proliferate rapidly and synthesize.
• Scale expansion & production
• Fermentation of the host vector using the seed train (fermentation (inoculation of the cells, and residual pDNA)

DOWNSTREAM
During the downstream process, pDNA is extracted from the host cells and purified from the host cell proteins, DNA and other impurities in the lysate.
• Cell harvest
Cells are concentrated and the fermentation broth is removed.
• Separation of cells can be achieved using centrifugation or microfiltration/tangential flow filtration.
• Chromatography is more cost effective for extraction of pDNA from host cells.

ANALYTICS
pDNA is subject to stringent requirements for purity, efficacy, and quality grades, depending on the intended use. The information in this infographic relates to the manufacture of GMP-grade plasmid.

ANALYTICS TESTING
Residual host cell protein
• ELISA
• PCR
Host cell E. coli DNA:
• qPCR
Host cell RNA:
• Agarose gel electrophoresis (AGE)
• RT-qPCR

MARKET VALUE
Global plasmid DNA manufacturing market value 2022: \$400-700 million

NUCLEIC ACID INSIGHTS

Downstream processing in the nucleic acids field: optimizing purification of mRNA and pDNA

David McCall, Senior Editor, Nucleic Acid Insights

FOREWORD

Over the rapid response of an mRNA and oligonucleotide therapeutic space with the evolution of plasmid pDNA and the challenges with large scale production of pDNA and the high demand, it is essential to establish robust manufacturing and analytics processes to produce large quantities of pDNA.

With the rapid increase of the gene therapy pipeline and genetic vaccination for infectious diseases require large-scale production of high-quality plasmid DNA (pDNA) in gene therapy production facilities. However, it is essential to establish robust manufacturing and analytics processes to produce large quantities of pDNA.

We hope you find it valuable.

CONTENTS

Downstream processing in the nucleic acids field: optimizing purification of mRNA and pDNA

Foreword	1
Part 1, pDNA	4
• DNA vaccines and therapies	5
• Template for mRNA manufacture	17
• Challenges in the supply of pDNA	21
• DNA synthesis	25
• Upstream	27
• Downstream	31
• Analytics	35
Part 2, mRNA	53
• mRNA synthesis	55
• Purification	59
• Analytics	63

Downstream processing in the nucleic acids field: optimizing purification of mRNA and pDNA

ThermoFisher Scientific | BIOINSIGHTS

OUR OTHER PUBLICATIONS

In addition to *Nucleic Acid Insights*, BioInsights also publishes *Cell & Gene Therapy Insights* and *Vaccine Insights*

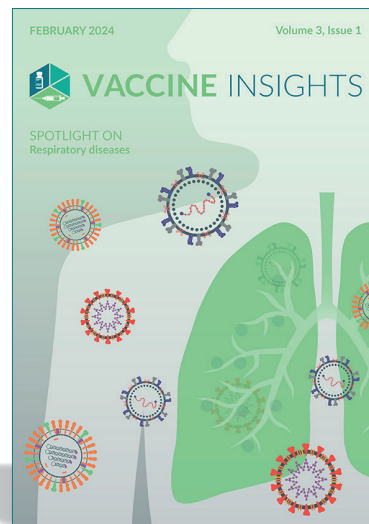
If you would like to distribute content to more than one of the cell and gene therapy, nucleic acid, and vaccine communities, we can promote it across multiple journals and market it to more than one set of users



CELL & GENE THERAPY INSIGHTS

Launched in 2014, *Cell & Gene Therapy Insights* is our inaugural online, open access, peer-reviewed journal with a translational focus.

Cell & Gene Therapy Insights addresses the important challenges and advances in the field of cell and gene therapy, publishing original research, reviews, commentary articles, clinical trial reports, and much more.



VACCINE INSIGHTS

Launched in 2022, *Vaccine Insights* is a peer-reviewed, open-access journal providing insights into development and manufacture of prophylactic and therapeutic vaccines. The journal brings together leading experts from pharma, biotech, academia and other key stakeholders to address critical issues and put the latest developments into context. Guided by an expert advisory board, the journal covers the most important advances in vaccine development and manufacture across all disease areas.