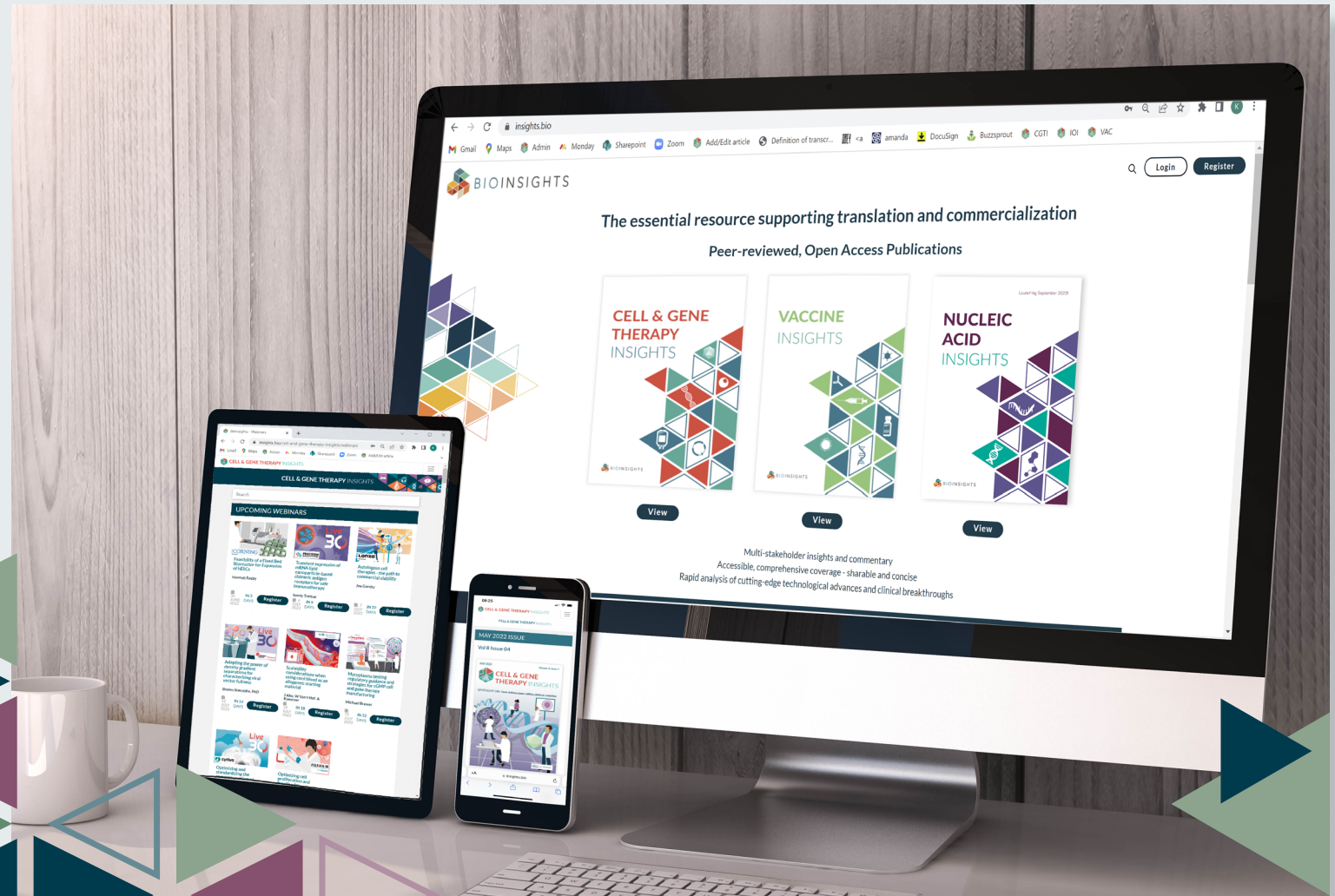


MEDIAKIT 2025



**BIOCONJUGATION
INSIGHTS**



INDEX

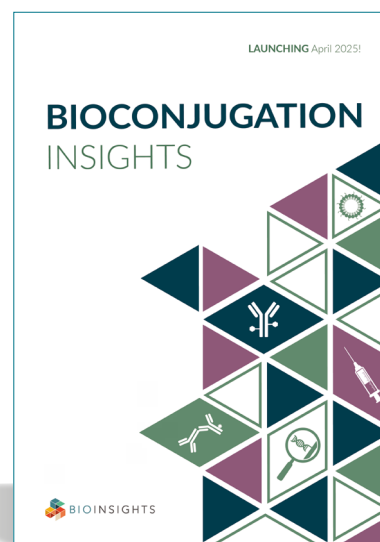
*Bioconjugation Insights—
your content marketing
partner for life sciences*

| | | | |
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ABOUT

Bioconjugation Insights—the first and only dedicated digital content channel designed for the bioconjugation community of experts

Bioconjugation Insights provides a unique platform for the bioconjugation community's experts to explore key current trends,



Core areas for coverage include, but are not limited to: ADCs; antibody-oligonucleotide conjugates (AOCs); bispecific ADCs (BsADCs); conjugated vaccines; diagnostic and imaging tools; enzyme conjugates; nanoparticle conjugates; polymer conjugates (including PEGylation); protein and peptide conjugates (PPCs); radioconjugates; targeted drug delivery; and theranostics.

Bioconjugation Insights comprehensive scope and coverage spans engineering and design, manufacturing and supply chain, preclinical and clinical R&D, regulation, financing, market access, and more.

Bioconjugation Insights is the first and only dedicated digital content channel specifically designed to keep industry and academic professionals up to date with this truly global sector's evolution on a genuinely worldwide scale.

Bioconjugation 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 bioconjugate manufacturing and R&D?

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

Bioconjugation 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 bioconjugate therapies to patients, and those designing, developing, and producing the delivery, linker, and payload technologies.

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

Targeted sectors include:

- ▶ 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 *Bioconjugation Insights* offers an unparalleled opportunity to target this particular audience
- ▶ Prolific academic institutions and research hospitals, in particular those that generate spin-outs
- ▶ Pharmaceutical companies and large biotechs with a major or growing focus on bioconjugation
- ▶ Government-funded organizations (such as NIH) and NGOs
- ▶ Investors and analysts
- ▶ Solution and service providers



BIOTECH



ACADEMIC/
HOSPITAL



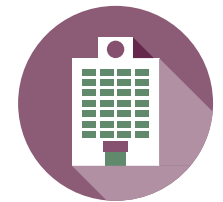
PHARMA/
LARGE BIOTECH



SOLUTION/
SERVICE PROVIDER,
including CROs
and CDMOs



INVESTOR/
ANALYST



GOVERNMENT/
NGO

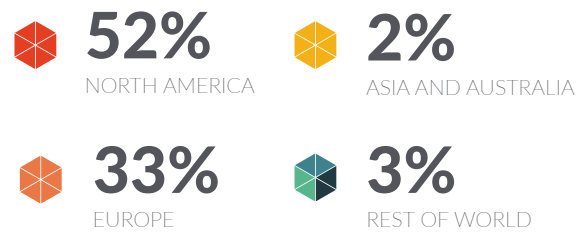
Bioconjugation Insights has a translational focus, featuring content of value to individuals along the R&D pipeline

Data by interest area

Readership includes individuals focused on:

- ▶ Discovery and basic research
- ▶ Preclinical development and translational R&D
- ▶ Clinical research
- ▶ Product development, process development, operations, logistics and manufacture
- ▶ Diagnostics and imaging
- ▶ Regulatory affairs, QA/QC and validation
- ▶ Business development, corporate management and licensing
- ▶ Formulation and delivery platform development
- ▶ Public health and market access

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



SPOTLIGHTS

Monthly Spotlights focus 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...



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.



| APRIL | JUNE | JULY |
|--|---|---|
| Special launch issue | Evolving ADCs: expanding horizons | Targeting precision: bioconjugates in diagnostics and imaging |
| SEPTEMBER | OCTOBER | NOVEMBER |
| New frontiers: how are oligonucleotide, peptide, and other emerging conjugates extending the reach of the field? | Driving improvements in the delivery and stability of next-generation bioconjugates, including oligo, polymer, and enzyme | Overcoming challenges in the ADC manufacturing and R&D ecosystems |



WHO WE WORK WITH



| | |
|----------------------------|--------------------------|
| AGC Biologics | Phenomenex |
| Batavia Biosciences | Qiagen |
| Berkeley Lights | Repligen |
| Bio-Rad | Roche Custom Biotech |
| Bio-Techne | Sartorius |
| Charles River Laboratories | SCIEX |
| Cytiva | Single Use Support |
| Eppendorf | Sony Biotechnology |
| Eurofins | Thermo Fisher Scientific |
| Gyros Protein Technologies | Tosoh |
| Lonza | WuXi |
| Malvern Panalytical | |
| MilliporeSigma | |

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

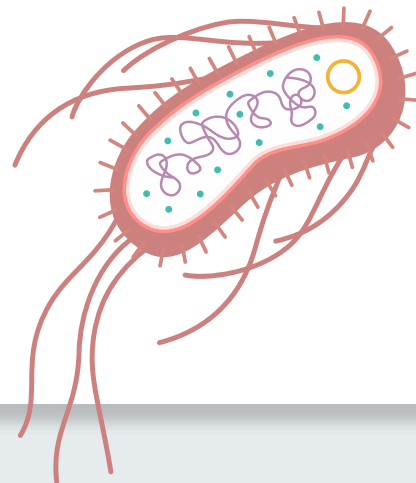
Webinars can stand alone or can be included in a Spotlight, depending on the topic and timing fit

Our 2025 webinar schedule is filling up fast

Contact n.mccall@insights.bio to discuss options and availability

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

- ▶ generate qualified leads from amongst the global bioconjugation 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 a sample of our on-demand webinars [here](#)

Here are some examples of previous webinars for our clients:



Format

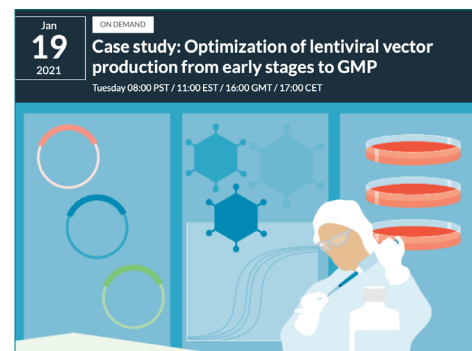
Panel-style webinar with accompanying transcript-based article

Client

Bio-Techne

[VIEW THE WEBINAR HERE](#)

[READ THE ARTICLE HERE](#)



Format

Presentation-style webinar with Q&A

Client

Polyplus-transfection

[VIEW THE WEBINAR HERE](#)



Format

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

Client

Mirus Bio

[VIEW THE WEBINAR HERE](#)

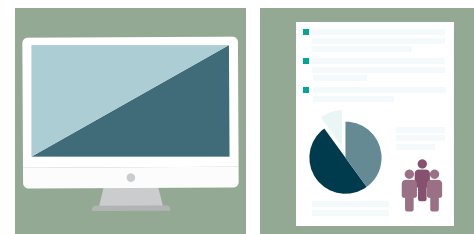


EXPERT ROUNDTABLES

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



ARTICLES

Here are some examples of articles for our clients:



Automated, spinning membrane filtration for preparation of mobilized leukapheresis products for CD34+ cell selection
Cell Gene Therapy Insights 2017; 3(8), 623-637.
10.18609/cgti.2017.059
PUBLISHED 30 OCTOBER 2017
RESEARCH ARTICLE
Alaina Schlinker

CD34⁺ hematopoietic stem and progenitor cells are used to generate hematopoietic stem cell-based gene therapy products and autologous CD34⁺ T cell-based gene therapy products. Depending on the application, the selection, the leukapheresis products for CD34⁺ cell selection, these processing steps are time-consuming and costly. Commercially available instrument processing time compared to a manual process is 4.72 ± 0.41 log T cell reduction for CD34⁺ cell selection and 2.29 log T cell reduction for CD34⁺ cell selection. Automated, spinning membrane filtration for preparation of mobilized leukapheresis products for CD34⁺ cell selection significantly reduces processing time compared to a manual process. When performed manually, the processing time for CD34⁺ cell selection is 4.72 ± 0.41 log T cell reduction for CD34⁺ cell selection and 2.29 log T cell reduction for CD34⁺ cell selection. Automated, spinning membrane filtration for preparation of mobilized leukapheresis products for CD34⁺ cell selection significantly reduces processing time compared to a manual process. When performed manually, the processing time for CD34⁺ cell selection is 4.72 ± 0.41 log T cell reduction for CD34⁺ cell selection and 2.29 log T cell reduction for CD34⁺ cell selection.

Format

A full independently peer reviewed, data-based article

Author

Alaina C Schlinker, Manager, Cell Therapy Application Support, Fresenius Kabi, USA

[READ THE ARTICLE HERE](#)



Critically Evaluating the Benefits of Automation in Commercial-Scale Manufacture
Cell Gene Therapy Insights 2017; 3(8), 695-700.
10.18609/cgti.2017.071
PUBLISHED 30 OCTOBER 2017
INNOVATOR INSIGHT
Nina Bauer

Nina Bauer is a senior consultant in the Regenerative Medicine and Biotechnology Practice at the University of Edinburgh. She holds a PhD in Biotechnology from the University of Edinburgh and is currently working on the development of novel cell-based gene therapy products. She is also a member of the European Society for Gene Therapy and the International Society for Cell and Gene Therapy.

Automation in commercial-scale manufacture offers many benefits, including reduced processing time, increased consistency, and reduced risk of contamination. However, automation also presents challenges, such as increased capital expenditure and the need for specialized personnel. This article critically evaluates the benefits of automation in commercial-scale manufacture and discusses the challenges associated with its implementation. The author, Nina Bauer, is a senior consultant in the Regenerative Medicine and Biotechnology Practice at the University of Edinburgh. She holds a PhD in Biotechnology from the University of Edinburgh and is currently working on the development of novel cell-based gene therapy products. She is also a member of the European Society for Gene Therapy and the International Society for Cell and Gene Therapy.

Format

An independently peer reviewed commentary-style article

Author

Dr Nina Bauer, Associate Director, Commercial Development, Lonza, Switzerland

[READ THE ARTICLE HERE](#)

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

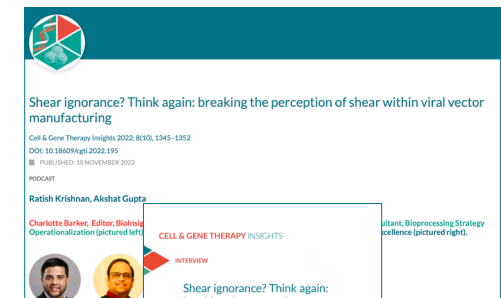
Podcast and written

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
31 MAR 2022
PUBLISHED 2 MARCH 2022
PODCAST

View pod

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 Bacheroud**, QC Scientist, Children's Hospital Meyer, **Oystein Annelien**, Director of Cell Therapy, Thermo Fisher Scientific, and **Xavier de Mollerat du Jiu**, 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. Interview, you can visit our site for more about what you do at the Meyer Children's Hospital!*

241

CELL & GENE THERAPY INSIGHTS

Q *The MycoSEQ product is an interesting molecule because it has been around for a while and is used in many processes. As a former cell therapy producer, how do you think and evaluate these are important for the cell therapy industry? Can you give us some insight into why this is a critical tool for production, safety, and quality? How do you think the industry will evolve in the future? What are the challenges you are facing and how do you think the industry will evolve in the future?*

VB: *The most important innovation for the future is the ability to produce more and more cell therapy products and to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high.*

Q: *Identify you mentioned that you face the challenges of manufacturing, how do you think the industry will evolve in the future?*

VB: *One of the challenges of manufacturing is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high.*

XMJ: *Another challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high. The most important challenge is to ensure that the production process is safe and that the quality is high.*

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HEAR THE PODCASTS AND READ THE ARTICLE HERE

Listen to the full podcast:

Bioinsights Publishing
Key factors to consider for successful cell therapy manufacturing: a case study
Privacy policy

Listen to each individual question and answer:

Bioinsights Publishing
Can you tell us a little bit more about what you do at the Meyer Children's Hospital?
Privacy policy

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

Bioinsights Publishing
What are the challenges you have identified and what are we working on at Thermo Fis...
Privacy policy

Bioinsights Publishing
Can you detail your experience with Iaria Scarfone implementing the MycoSEQ analyt...
Privacy policy

Bioinsights Publishing
Can you detail your experience with Iaria Scarfone implementing the MycoSEQ analyt...
Privacy policy

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

Bioinsights Publishing
Are there any other thoughts that we haven't touched upon?
Privacy policy



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.



FASTFACTS

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

Abstracts

Ryan Coward

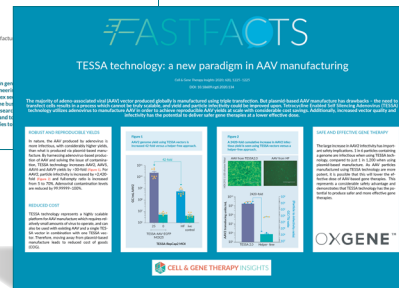
Watch the video or read the poster to learn:

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

About the speaker

Ryan Coward founded Cell & Gene Therapies in 2015, after starting a first class degree in gene biotechnology at the company was to simplify and standardise the process of DNA engineering called 'drag and drop' that allowed researchers to be the first to use it to assemble complete AAVs and use this technology to generate, engineer and package to gain and grow the business. Ryan has worked on the development of the 'drag and drop' platform through to the current state of the art, addressing the challenges of the development of new therapies. This platform is a key enabler for the development of a scalable production process using a combination of proprietary technologies through design, recovery, development and manufacture of a novel biologic.

Client
OXGENE



FASTFACTS

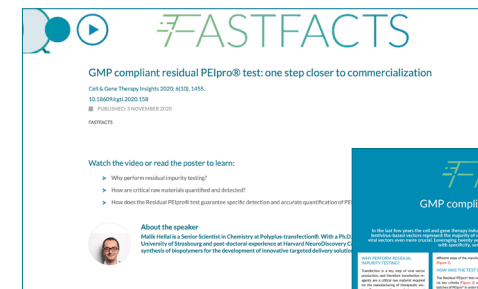
TESSA technology: a new paradigm in AAV manufacturing

The discovery of a novel, non-viral AAV vector production platform using Tetraacycline Enabled Self-Inducing Adenovirus (TESSA) has enabled the development of a scalable production process for AAV. This platform is a key enabler for the development of a scalable production process using a combination of proprietary technologies through design, recovery, development and manufacture of a novel biologic.

KEY TAKEAWAYS

- TESSA technology enables a 10x increase in AAV production yield compared to conventional methods
- TESSA technology enables a 10x increase in AAV production yield compared to conventional methods
- TESSA technology enables a 10x increase in AAV production yield compared to conventional methods

CELL & GENE THERAPY INSIGHTS



FASTFACTS

GMP compliant residual PEI test: one step closer to commercialization

Cell & Gene Therapy Insights 2020, 4(10), 1455
10.18699/cgt.2020.1455
PUBLISHED: 10 NOVEMBER 2020

Abstracts

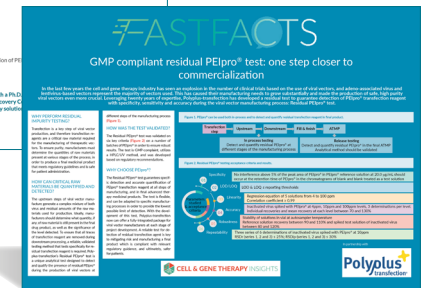
Watch the video or read the poster to learn:

- Why perform residual PEI testing?
- How are cell and gene therapy products tested and detected?
- How does the Residual PEI test guarantee specific and accurate quantification of PEI?

About the speaker

Maria Helena is a Senior Scientist in Chemistry at Polyplus Transfection. With a PhD from the University of Strasbourg and postdoctoral experience at Harvard Neuro-Oncology Center, she is currently leading the development of innovative targeted delivery solutions.

Client
Polyplus-transfection



FASTFACTS

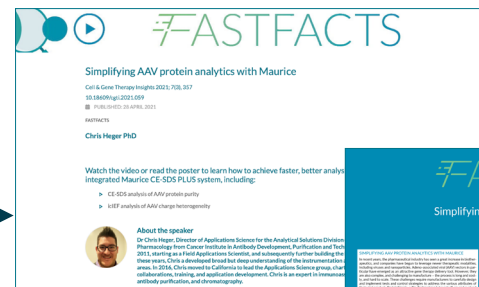
GMP compliant residual PEI test: one step closer to commercialization

In the last few years the cell and gene therapy industry has seen an exponential increase in the number of clinical trials based on the use of cell and gene therapy products. This has led to a significant increase in the demand for GMP compliant residual PEI testing. The Residual PEI test is a key enabler for the development of a scalable production process for cell and gene therapy products.

KEY TAKEAWAYS

- The Residual PEI test is a key enabler for the development of a scalable production process for cell and gene therapy products.
- The Residual PEI test is a key enabler for the development of a scalable production process for cell and gene therapy products.
- The Residual PEI test is a key enabler for the development of a scalable production process for cell and gene therapy products.

Polyplus Transfection



FASTFACTS

Simplifying AAV protein analytics with Maurice

Cell & Gene Therapy Insights 2021, 7(8), 317
10.18699/cgt.2021.317
PUBLISHED: 28 APRIL 2021

Abstracts

Chris Heeger PhD

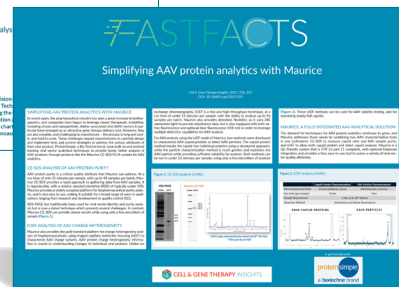
Watch the video or read the poster to learn how to achieve faster, better analysis of integrated Maurice CE-SDS PLUS systems, including:

- 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 instrumental in the development of Maurice CE-SDS PLUS systems, including the Maurice CE-SDS PLUS system, which is a key enabler for the development of a scalable production process for cell and gene therapy products.

Client
Protein Simple



FASTFACTS

Simplifying AAV protein analytics with Maurice

The Maurice CE-SDS PLUS system is a key enabler for the development of a scalable production process for cell and gene therapy products. It provides a simple and efficient way to analyze AAV protein purity and charge heterogeneity.

KEY TAKEAWAYS

- The Maurice CE-SDS PLUS system is a key enabler for the development of a scalable production process for cell and gene therapy products.
- The Maurice CE-SDS PLUS system is a key enabler for the development of a scalable production process for cell and gene therapy products.
- The Maurice CE-SDS PLUS system is a key enabler for the development of a scalable production process for cell and gene therapy products.

PROTEIN SIMPLE



FASTFACTS

Identify and select optimal T cell phenotypes

Cell & Gene Therapy Insights 2021, 7(1), 81
10.18699/cgt.2021.081
PUBLISHED: 22 FEBRUARY 2021

Abstracts

James Lougans

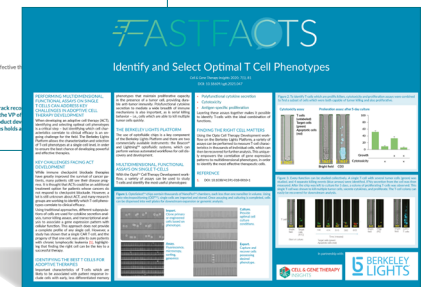
Watch the video or read the poster to learn:

- 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 Lougans has an accomplished track record with a distinguished track record 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 a member of the Board of Directors of the company.

Client
Berkeley Lights



FASTFACTS

Identify and Select Optimal T Cell Phenotypes

The identification and selection of optimal T cell phenotypes is a key challenge in adoptive cell transfer (ACT). This platform is a key enabler for the development of a scalable production process for cell and gene therapy products.

KEY TAKEAWAYS

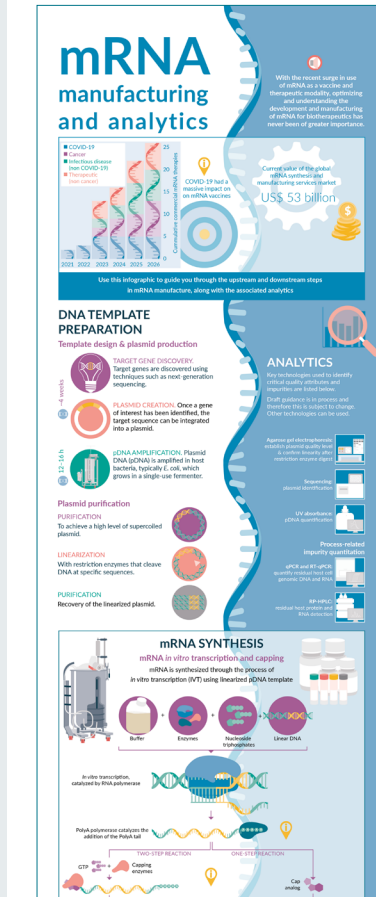
- The identification and selection of optimal T cell phenotypes is a key challenge in adoptive cell transfer (ACT).
- The identification and selection of optimal T cell phenotypes is a key challenge in adoptive cell transfer (ACT).
- The identification and selection of optimal T cell phenotypes is a key challenge in adoptive cell transfer (ACT).

BERKELEY LIGHTS



INFOGRAPHICS

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

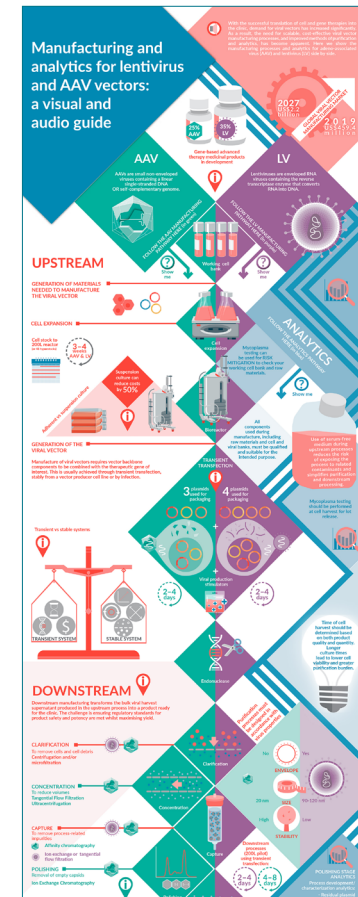


Our team are experts in communicating complex scientific information via visual formats, including infographics (static, voiced, and animated), PPT presentations and illustrations.

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

Format
Interactive, voiced infographic

Client
Thermo Fisher Scientific

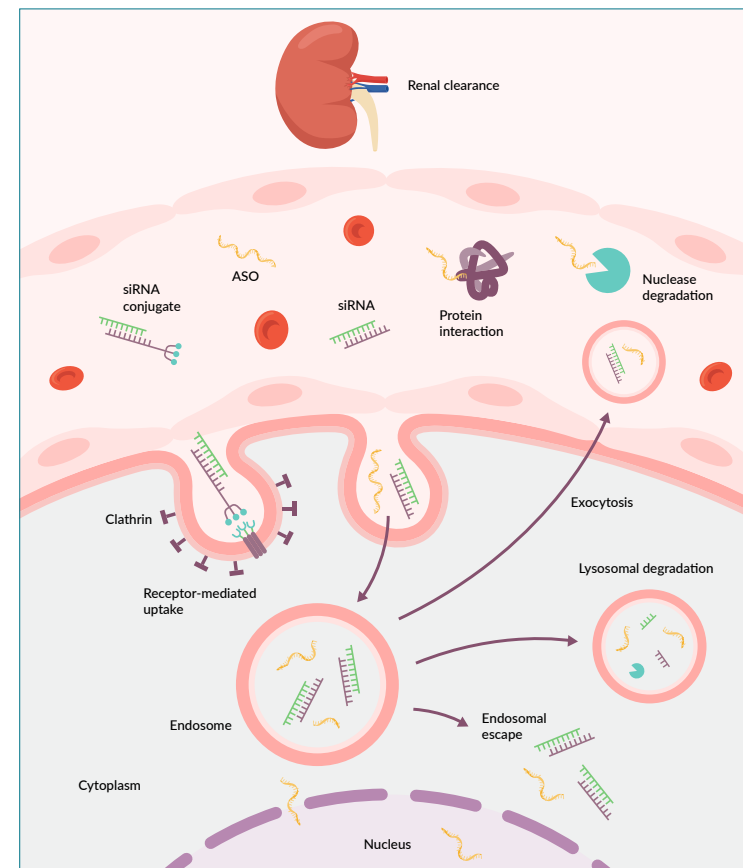
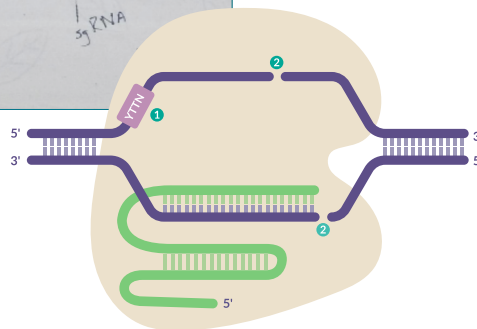
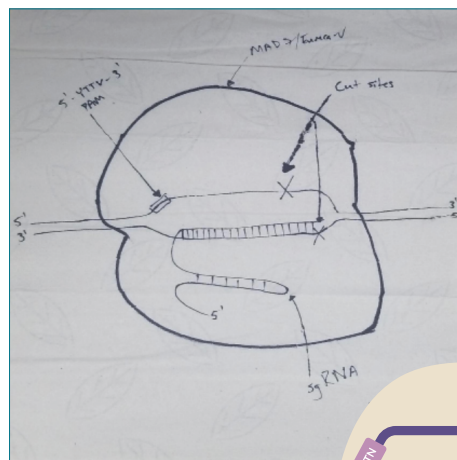


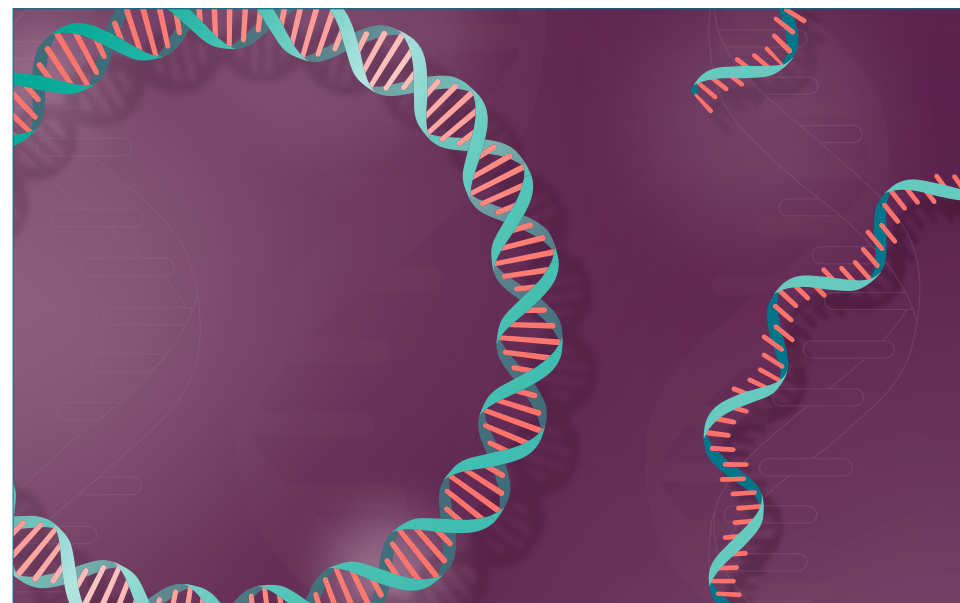
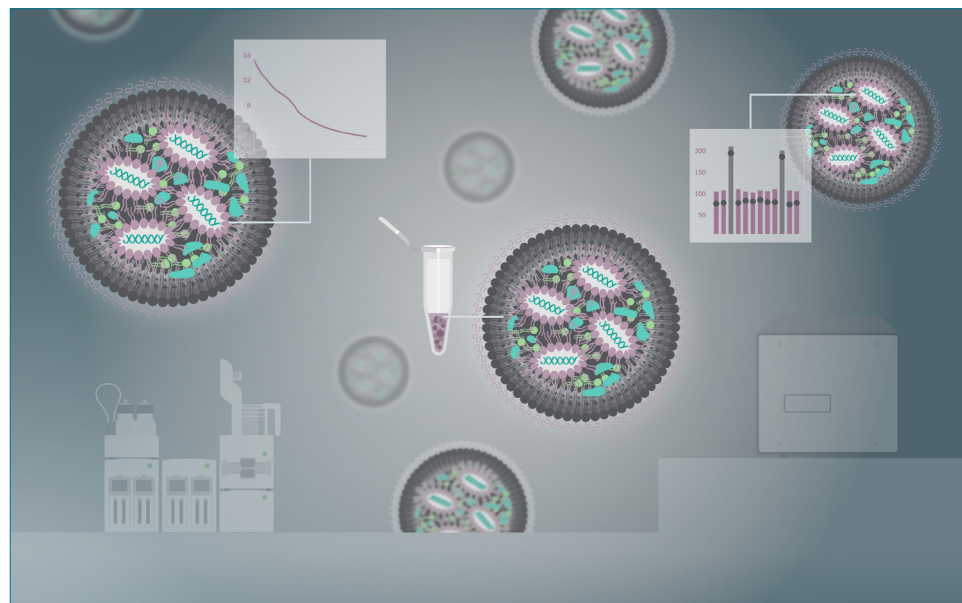
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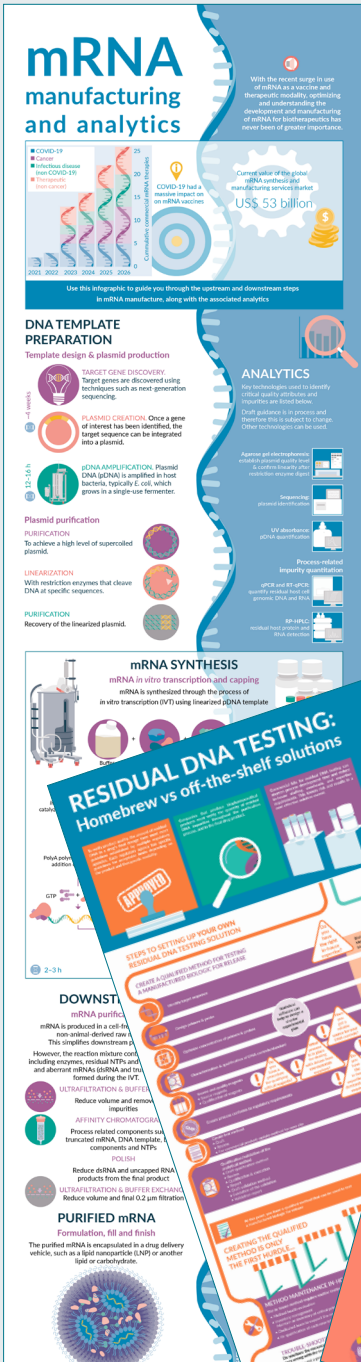
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PREMIUM SERVICES



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 to mRNA synthesis and manufacturing involves a **US\$ 53 billion** investment.

COVID-19 has a massive impact on the mRNA vaccine market.

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

TARGET GENE DISCOVERY: Target genes are discovered using techniques such as next generation sequencing.

PLASMID CREATION: Once a gene of interest has been identified, the target sequence can be integrated into a plasmid.

PLASMID AMPLIFICATION: Plasmid DNA (pDNA) is amplified in host bacteria, typically E. coli, which grows in a single-use fermenter.

ANALYTICS: New techniques used to identify host contamination and impurities are food below. Draft analysis is in process and detection has not been chosen. Other techniques can be used.

Agarose gel electrophoresis enables accurate quality control in culture through the restriction enzyme digest.

Sequencing related detection.

UV absorbance related quantification.

Process-related impurity quantification.

Plasmid purification

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 *in vitro* transcription and capping.

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

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

STEPS TO SETTING UP YOUR OWN RESIDUAL DNA TESTING SOLUTION

DOWNSTREAM

mRNA purification

mRNA is produced in a cell-free non-animal derived raw. This simplifies downstream.

However, the reaction mixture contains including enzymes, residual NTPs and other abnormal mRNAs (dsRNA) and must be removed during the IVT.

ULTRAFILTRATION & BUFFER EXCHANGE

Reduce volume and remove impurities.

AFFINITY CHROMATOGRAPHY

Process related components such as truncated mRNA, DNA template, components and NTPs.

Reduce dsRNA and incorporated RNA products from the final product.

ULTRAFILTRATION & BUFFER EXCHANGE

Reduce volume and final 0.2 um filtration.

PURIFIED mRNA

Formulation, fill and finish

The purified mRNA is encapsulated in a drug delivery vehicle, such as a lipid nanoparticle (LNP) or another 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 requires large-scale production of high-quality plasmid DNA (pDNA) in gene therapy production for cell transfection. However, pDNA is a starting sufficient quantities of pDNA can be a challenge. Therefore, 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, recombinant protein therapies, viral vector manufacturing, and gene modified cell therapies (i.e., CAR-T cells).

CHALLENGES IN THE SUPPLY OF pDNA

- Complex supply chains
- Production and capacity high demand
- Costs of goods high
- Evolving regulatory landscape
- Quality assurance

MANUFACTURING CHALLENGES

pDNA and contaminants are of similar size and charge

Large size of product

High negative charge

pDNA is sensitive to shear stress and nuclease degradation

Intermediate process pools can be highly viscous

High volume of impurities in the starting material (~1% pDNA)

Conventional chromatography resins exhibit low binding other impurities to 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 bio-reactor using the seed train (inoculation/inoculation of the cells, and resultant pDNA)

DOWNSTREAM

During the downstream process, pDNA is extracted from 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 clarification of low or high viscosity.

Extraction of cell-free supernatant

- Shear damage due to centrifugation can reduce the yield.
- Shear damage due to centrifugation can reduce the yield.

ANALYTICS

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

RESIDUAL HOST CELL TESTING

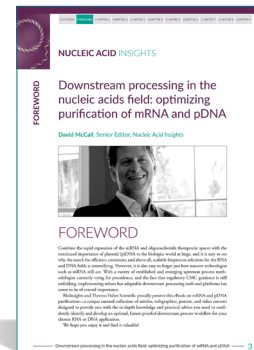
- ELISA
- PCR

Host cell E. coli DNA:

- qPCR

Host cell RNA:

- Agarose gel electrophoresis (AGE)
- RT-qPCR



NUCLEIC ACID INSIGHTS

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

David McCall, Senior Editor, Nucleic Acid Insights

FOREWORD

Content in the rapid response of mRNA and oligonucleotide therapies with the evolution of plasmid pDNA and the challenges with large scale production of pDNA and mRNA. However, the rapid increase of the gene therapy pipeline and genetic vaccination for infectious diseases requires large-scale production of high-quality plasmid DNA (pDNA) in gene therapy production for cell transfection. However, pDNA is a starting sufficient quantities of pDNA can be a challenge. Therefore, manufacturing and analytics processes to produce large quantities of pDNA.

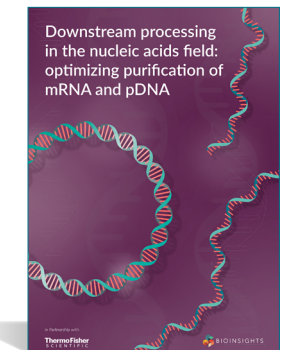
Download processing in the nucleic acids field: optimizing purification of mRNA and pDNA



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

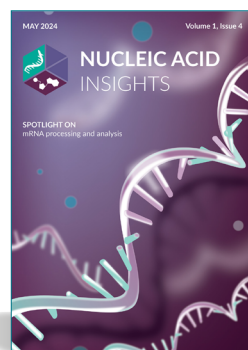
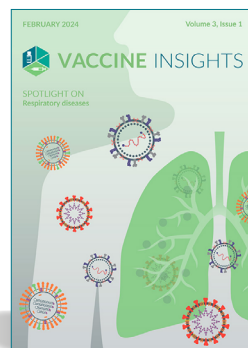
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