
**On 30 November and 1 December 2021, *European Pharmaceutical Review* hosted its first ever event – The Future of QA/QC for Complex Biologics Online Summit. Bringing together more than 600 attendees, 15 expert speakers and Thermo Fisher Scientific and Merck as sponsors, the summit gave industry experts the chance to advance their QA/QC skills to ensure they can meet the challenges of advanced therapy medicinal products and other emerging biologic therapies.**

WITH NEARLY 100 cell and gene therapies launched in markets worldwide and hundreds more under development, as well as novel vaccine technologies paving our way out of the COVID-19 pandemic, it has never been more essential for QA/QC professionals to rise to the challenge of complex biological therapies.

As biologics increase in complexity, gain precision, become personalised and more widely adopted globally, patient safety and product quality are only growing in importance.

At this event, experts from across the biopharmaceutical industry gave the audience the skills and information they need to release high quality biological therapies ranging from vaccines to antibodies and cell & gene therapies, while enhancing efficiency, productivity and cost-effectiveness.

> **Presenting my research at this event and listening to the experts in biopharma was a great experience. I want to express my sincere appreciation for a well-planned and well-executed event. Grateful to the organisers for making it an effortless and smooth experience for the speakers and attendees. Looking forward to attending more events by *European Pharmaceutical Review* in the future.**
>
> Sakshi Gautam, Graduate Student, Texas Tech University

## Combatting contamination

Ensuring any pharmaceutical product is free of contaminants is a major concern for the industry, especially as recalls can result in huge losses and reputational damage. This webinar brought together Dr Andrew Feilden of Hall Analytical Laboratories Ltd and Dr Tim Sandle of Bio Products Laboratory Ltd to explore the regulations and strategies to ensure the control of extractables & leachables and microbes, common contaminants found in biological therapies.

## Characterisation of mRNA therapeutics using automated LC-MS workflows

Large RNA molecules such as messenger RNA (mRNA) have emerged as important therapeutics. However, the methods currently available to analyse them are limited, leaving a significant demand for new and improved analytical methods. This symposium, sponsored by Thermo Fisher Scientific, saw The University of Sheffield's Professor Mark Dickman describe the development of a novel workflow leveraging partial RNase digestions, ion pair reverse phase liquid chromatography and mass spectrometry to characterise mRNA therapeutics.

## Ensuring quality: viral vectors for vaccines and cell & gene therapies

Viral vectors are a key component of numerous biological therapies, including vaccines and cell & gene therapies. As the applications of vectors grows, so too does the range of technologies and techniques ensuring they are safe, potent and pure. This webinar brought together experts from the National Institute for Bioprocessing Research and Training (NIBRT) and session sponsor Merck to discuss methods to characterise AAV capsids and review the application of the monocyte activation test (MAT) to detect pyrogens during cell & gene therapy production.

> **It was a pleasure to speak at this event. It was very well organised, with a focus on encouraging networking and promoting discussion. There were some excellent talks on key areas including oligonucleotide therapeutics and gene therapy.**
>
> Vicky Smith, Principal Scientist, Centre for Process Innovation

## QA/QC for cell & gene therapies – adapting for the challenges of ATMPs

As the applications and number of advanced therapy medicinal products (ATMPs) on the market continues to grow, so too does the importance of ensuring they meet quality standards. In this webinar, Nadine Ritter, President and Analytical Advisor at Global Biotech Experts, LLC, discussed chemistry, manufacturing and control (CMC) principles for ATMPs, providing guidance and a wealth of resources to enable manufacturers to fulfil regulatory requirements for CMC.

> **Thank you to *European Pharmaceutical Review* for giving me the opportunity to educate and inform the attendees on some of the aspects around extractables and leachables for biologicals.**
>
> Dr Andrew Feilden, European E&L Strategic Director, Hall Analytical Laboratories Ltd

## Biologics QA/QC and Pharma 4.0

Digitalisation and automation are permeating every aspect of life, including biopharmaceutical quality control. In this webinar, experts from McKinsey and Company, as well as session sponsor Merck, explored how digitalisation and automation could transform the quality control of biologics. While Matthias Ringel and Norman Carra of McKinsey explained how they envision Smart Quality may evolve, Merck's Anke Hossfeld described how implementing robotics and digital tools can transform QC workflows, using bioburden testing as an example.

## Enhancing oligonucleotide quality

Large RNA molecules are not the only nucleotide-based therapies emerging on the market, several smaller oligonucleotides such as small interfering RNAs (siRNAs) and antisense oligonucleotides have also been approved for a range of conditions. This webinar brought together Mike Webb of MikeWebbPharma Ltd and Biogen's Jing Yang to discuss analytical control strategies for smaller oligonucleotide therapeutics. The session examined the major challenges presented by oligonucleotide QC, as well as the technologies Biogen is using and developing for the QC of its oligonucleotide therapies.

## QC characterisation of synthetic oligonucleotide therapeutics

Continuing in the theme of the webinar above, this symposium saw Dr Ken Cook of Thermo Fisher Scientific, one of our event sponsors, reveal how to simplify the analysis of synthetic RNA therapeutics. Dr Cook also discussed how recent advances in the direct sequencing and intact mass analysis of oligonucleotides enable researchers to gather greater insight.

## Quality considerations for mRNA vaccines

mRNA vaccines have been a vital part of the COVID-19 pandemic response, but they are novel – having only just been approved for use for the first time. In this case study session, Dr Vicky Smith of the UK's Centre for Process Innovation (CPI) discussed the critical quality attributes of mRNA vaccines, as well as the use of capillary electrophoresis in assessing the integrity and purity of mRNA drug substance.

> **This event was well organised with an excellent IT platform which provided ease of presentation and interaction. The sessions were organised and smoothly facilitated. The talks were of high quality and aimed at the challenge of getting new medicines supply chains operating smoothly with excellent scientific solutions to challenging problems.**
>
> Mike Webb PhD, Founder and CEO, MikeWebbPharma Ltd

## QA/QC for antibodies and ADCS – where we are and where to next?

Antibodies and antibody-drug conjugates (ADCs) are critical technologies enabling diseases such as cancer and autoimmunity to be treated in a targeted way. This webinar brought together Sakshi Gautam from Texas Tech University and Deepa Raghu of Merck, this session's sponsor, to review the challenges in characterising and assessing the quality of antibodies and ADCs. The speakers explored the development of a mesoporous graphitised carbon (MGC) chromatography column for the analysis of glycosylation in antibodies and discussed how surface plasmon resonance (SPR) can be applied to analyse binding kinetics.

## Speakers and sponsors – thank you

*European Pharmaceutical Review* would like to thank our valued speakers for sharing their experience, resources and research, plus all of our sponsors and exhibitors for their support.

## ON-DEMAND

Don't worry if you missed any of the sessions from The Future of QA/QC for Complex Biologics Online Summit – the event platform is still available to access on-demand for the next 12 months, just visit **www.pharmaceutical.events** to register, or scan the QR code:

Symposium Sponsors:

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