

大阪大学工学研究科附属フューチャーイノベーションセンターテクノアリーナ

最先端研究拠点部門「内山遺伝子治療用ベクター革新的製造拠点」

インキュベーション部門「遺伝子治療用ベクター製造に関する研究開発と人材育成」

2026 特別講演会 ～Antibody Engineering and AAV CMC Strategy～

抗体医薬と AAV 遺伝子治療の最前線をテーマに、特別講演を開催します。JN Biosciences の Naoya Tsurushita 博士には、抗体工学の発展を振り返り、ADC・二重特異性抗体の特徴と将来展望をご紹介します。Sangamo Therapeutics の Anthony Chikere 博士には、AAV 遺伝子治療の製造・品質管理と規制対応を支える実践的な CMC 戦略をご講演いただきます。皆様のご参加をお待ちしております。

日時：2026 年 10 月 1 日（木）13:30～15:00

場所：大阪大学大学院工学研究科生物工学専攻サントリーメモリアルホール

吹田キャンパス工学研究科 C3 棟 5 階、<https://www.eng.osaka-u.ac.jp/ja/access/>

人数確認のため下記 URL または QR コードから登録をお願いします。

<https://forms.gle/UMtfJEFiLYfo3gvWA>

問い合わせ先：大阪大学大学院工学研究科 内山 進、suchi@bio.eng.osaka-u.ac.jp



Lecture Title: Dreams of Antibody Engineers: ADC, bispecific antibodies, and beyond

Speaker: Naoya Tsurushita, Ph.D., Managing Partner, JN Biosciences LLC

Abstract: An IgG antibody is a multifunctional protein that plays a critical role in the immune defense system. It binds tightly and specifically to an antigen, triggers cytotoxicity by its effector functions, and exhibits a long half-life in the circulation. Immediately after the introduction of the hybridoma technology in 1975, monoclonal antibodies (mAbs) captured eyes as a potential new category of human therapeutics. In 1982, a murine anti-idiotypic mAb was reported to have achieved complete remission of a B-cell lymphocytic lymphoma patient. The fever with mAbs, however, soon got chilled due to high immunogenicity of mouse antibodies in humans. To solve this problem, antibody engineers came up with ideas to generate less immunogenic chimeric mAbs and then little immunogenic humanized mAbs, opening a door for their therapeutic use in humans. The first chimeric and humanized antibodies were approved for marketing by the U.S. FDA in 1994 and 1997, respectively.

Innovations by antibody engineers continued further beyond eliminating immunogenicity, including affinity maturation, modification of effector functions, and elongation of serum half-life. Moreover, two important classes of modality, i.e. antibody drug conjugate (ADC) and bispecific antibody (BsAb), were generated, tested, and improved over the time to meet the requirement for therapeutic use.

The first ADC and BsAb were approved by the FDA in 2000 and 2014, respectively, but it took many additional years until their real value became appreciated in the medical field.

The near-term goals of antibody engineers include multispecific T cell (or other immune cell) engagers, delivery to the brain, targeting intracellular antigens, and so forth. After such challenges, is there anything left for antibody engineers? The answer is clearly no. If you are engaged deeply in antibody engineering, you will certainly come up with new ideas regardless of whether they are practical. Dreams of antibody engineers are endless. Current headache of antibody developers is perhaps that there are too many choices of ADC, BsAb and other modalities of engineered antibodies. It has become so difficult to select the optimal one that meets each one's specific goal and situation. In this presentation, I will quickly review the history of antibody engineering and provide pros and cons of ADC, BsAb and other modalities from the viewpoint of an antibody engineer. I would also like to spend some time to provide my view of the future of antibody engineering.

Biography: Co-Founder and Managing Partner, JN Biosciences LLC Dr. Naoya Tsurushita is Co-Founder and Managing Partner of JN Biosciences LLC, where he applies extensive expertise in antibody engineering to the discovery and development of therapeutic antibodies. Before co-founding JN Biosciences, he spent fourteen years at Protein Design Labs, Inc., progressing to Director of Protein Engineering. His work there encompassed monoclonal antibody humanization, Fc and effector-function engineering, optimization of affinity and specificity, extension of antibody and Fc-fusion protein half-life, and development of mammalian surface-expression technologies. Earlier in his career, he served as an Assistant Professor at Kyoto University's Institute for Virus Research and completed postdoctoral training at Stanford University Medical Center and the University of California, Berkeley. Dr. Tsurushita earned his Ph.D. in Molecular Biology from Kyoto University and is an inventor on numerous U.S. patents related to therapeutic antibodies.



Lecture Title: Innovating Within Control: A CMC Strategy for Regulatory Readiness for AAV based therapies

Speaker: Anthony Chikere, Ph.D., Senior Director, Sangamo Therapeutics, Inc.

Abstract: AAV-based gene therapies require a careful balance between innovation and regulatory compliance. This presentation highlights a pragmatic CMC strategy for achieving regulatory readiness by integrating robust control strategies, risk-based product and process characterization, and phase-appropriate analytical development. Key considerations for managing process changes, demonstrating comparability, and maintaining product quality throughout development will be discussed. Real-world examples will illustrate how organizations can advance manufacturing and analytical innovations while ensuring compliance, accelerating development, and supporting successful regulatory submissions.

Biography: Senior Director, Vector Process Development & MSAT, Sangamo Therapeutics. Anthony Chikere, Ph.D., is an experienced biopharmaceutical professional with expertise in process development and manufacturing of biologics and viral vectors for gene therapy. He has held key roles at Johnson & Johnson, BioMarin, Grifols, and Bayer, with responsibilities spanning process development, MSAT, process validation, technology transfer, and commercial manufacturing support for protein biologics. At Sangamo Therapeutics, he leads vector process development and MSAT activities, with a particular focus on AAV process development, scale-up, process characterization, and manufacturing technologies. He brings extensive practical experience in developing robust and scalable manufacturing processes for gene therapy products.