

## QVance AB publishes particulates article in collaboration with ISCT

QVance AB, Huddinge, Sweden has today announced its co-founder and CSO at parent company, NextCell Pharma AB, Dr Lindsay Davies, has published an article in the journal *Cytotherapy*. Dr Davies is a member of the International Society of Cell and Gene Therapy (ISCT) where she is the European Regional Secretary and a member of the Manufacturing Materials Safety and Technology Working Group (MMST).

The article, entitled “Particulates in CGT Guidance Survey Results - Cell and Gene Therapy Industry Knowledge Awareness”, is the result of the MMST’s extensive work to globally survey cell and gene therapy (CGT) industry professionals to establish awareness of particulates in CGT products. The conclusion from the research conducted was that common regulatory guidance across global legislation for CGT products is employed, however gaps remain in with respect to cell therapy and medical device management, and when products are used in combination. The Working Group calls for a unification of guidance across jurisdictions, with a need for clarification in risk management strategies and advanced therapy product classifications.

Dr Davies commented, “The work undertaken with the ISCT and MMST Working Group are instrumental in influencing policy decision makers. There is a need for advanced therapy representatives from industry and academia to come together with regulatory bodies to support the evolution of regulatory guidelines and legislation for CGTs.” She adds, “In a fast moving and dynamic field such as CGTs we need to work together to ensure the transition of new drug products in a safe and effective way to patients. This is the founding ethos of QVance, taking the knowledge that our team have learnt working in the CGT therapy development community into designing quality control programmes that are effective and practical for the individual drug product.”

The full article can be accessed ahead of print at: [Cytotherapy Particulates in CGT Guidance Survey Results](#)

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**Certified Adviser**

**FNCA Sweden AB is assigned as Certified Adviser.**

**About QVance AB**

**QVance is a quality analytics service provider for advanced therapies. The company's vision is to be a one-stop analytics service supporting customers throughout development and drug product lifecycle.**