

ISO 13019 : 2018(Ed.1)

Tissue-engineered medical products — Quantification of sulfated glycosaminoglycans (sGAG) for evaluation of chondrogenesis

< Overview >

ISO 13019:2018(Ed.1) is a standard for the quantification of sulfated glycosaminoglycans (sGAG) for the evaluation of chondrogenesis (cartilage regeneration). This standard was developed based on a Japanese proposal. Support was provided for the standard's development process through the PMDA's Academia Dispatch Program.

< Technical Committee >

ISO/TC 150/SC7/WG3

< Main Points >

- The standard for the quantification of sulfated glycosaminoglycans for the evaluation of cartilage regeneration was developed based on a Japanese proposal, which was derived from the results of an inter-laboratory study conducted in Japan in 2012.
- Japan contributed as the Working Group Convener and Project Leader.

< Publication History >

- A New Proposal (NP) was proposed and approved/registered in January 2015.
- The Committee Draft (CD) was registered June 2016.
- The Draft International Standard (DIS) was registered, and the DIS vote was held from August to October in June 2017.
- The Final Draft International Standard (FDIS) was registered, and the FDIS vote was held from March to April in February 2018.
- ISO 13019:2018(Ed.1) was published in June 2018.

< PMDA Involvement >

Attendance at international conferences and domestic committees; and the Academia Dispatch Program.