LGC CLINICAL DIAGNOSTICS

Science for a Safer World

Educational Workshop

ISO 15189 standard: 2022 version

Context and objectives:
The revision of the ISO 15189 (2012) standard was decided to take into account the evolution of the concept of conformity assessment following the example of the ISO 9001 (2015) and ISO 17025 (2017) standards and the results of a survey showing the need for a less prescriptive standard.

Method:
The project was conducted in accordance with ISO rules by the working group in charge of quality and competence in medical laboratories (GT1).

Results:
The version currently being approved (FDIS - Final Draft International Standard stage), will no doubt be published before the end of 2022. The main changes relate to the structure of the document, the development of the concepts of impartiality, confidentiality and requirements vis-à-vis patients, taking into account the risks and opportunities for improvement relating to the field of activity of the laboratory and the integration of the requirements relating to Delocalized Biology Examinations (EBMD) of the ISO 22870 standard.

Conclusion:
Risk-based thinking makes it possible to reduce prescriptive requirements and replace them with requirements focused on improving the control and performance of laboratory activities for better efficiency in taking into account patient load and user satisfaction.

Presented by

Dr. Anne Vassault,

ISO expert
Technical Committee TC 212

Thursday, December 1 | 11:30am

Palais Des Congrès De Paris
Room S07

1-2 DÉCEMBRE 2022 | PALAIS DES CONGRÈS DE PARIS FRANCE

JIB 65e ÉDITION JOURNÉES DE L'INNOVATION EN BIOLOGIE

LIMITED PLACES AVAILABLE

Sponsored By

TECHNOPATH
CLINICAL DIAGNOSTICS