Bureau Veritas

ISO 18385

ISO 18385:2016 - Minimising the risk of human DNA contamination in products used to collect, store and analyse biological matter for forensic purposes. Complying with the requirements of ISO 18385:2016 can help you demonstrate that you have the processes in place to minimise the potential of human DNA contamination in the products you produce.

What is ISO 18385?

ISO 18385 was developed in response to the increasing sensitivity of forensic DNA profiling and the unintentional contamination of consumables used during the Forensic DNA process by the manufacturers.

The potential for DNA contamination can never be totally eliminated but this standard specifies requirements for the production of consumables and reagents used in the collection, storage and analyses of biological material for forensic purposes.

ISO 18385
BUREAU VERITAS
Certification

Who is ISO 18385 for?

ISO 18385 can be applied in any organisation which manufactures consumables and reagents including those used for evidence collection (sampling kits), such as swabs, containers, and packaging, and also products used in the analysis of DNA samples, such as tubes and other plasticware, disposable laboratory coats, gloves, and other consumables. ISO 18385:2016 applies to the production of consumables and reagents which do not require cleaning for continued use.

What are the benefits of ISO 18385?

- Provides the structure around which an organisation can take a comprehensive risk-based view on implementing controls
- Human DNA contamination of consumables has potential catastrophic consequences*

Phantom of Heilbronn

*A female serial killer named "Phantom of Heilbronn" was linked to 40 crimes. Six of these crimes were murders. In 2009, it was discovered that the female was not a master criminal. Inadvertently, her DNA contaminated consumables used in the process of DNA profiling across Europe. ISO 18385 assists manufacturers address this issue.

https://www.iso.org/news/2016/07/Ref2094.html

Why certify to ISO 18385?

- Demonstrate to your customers your commitment to DNA contamination minimisation
- Enhance your reputation and differentiate from the competition
- Identify opportunities for improvement to drive process improvements
- Embed contamination minimisation systems in the culture of the organisation

How do I demonstrate compliance to ISO 18385?

The Bureau Veritas approach to demonstrate compliance follows a clear defined process.

- Definition of compliance assessment scope
- Audit is performed in 2 stages:
  - Stage 1 – readiness review performed to verify that the organisation is ready to progress to the next stage of the assessment
  - Stage 2 – evaluation of implementation, including the effectiveness, of the management system of the organisation
- A certificate, valid for 3 years, is issued upon satisfactory results of the stage 2 audit
- Annual surveillance audits verify that the management system continues to fulfil the requirements of the standard and monitor the continual improvement
- Re-assessment after 3 years to confirm the continued conformance and effectiveness of the management system as a whole

Why choose Bureau Veritas?

NETWORK

6,500 skilled auditors operating in more than 100 countries offer a unique combination of international and local expertise providing consistent services wherever our clients are.

EXPERTISE

Our auditors have extensive knowledge of specific industry sectors, local regulations, markets and language that enables them to provide solutions adapted to your needs.

RECOGNITION

The Bureau Veritas Certification mark is a globally recognised symbol for excellence, sustainability and reliability.

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