



XI INTERNATIONAL EXHIBITION
PHARMATECHEXPO
EQUIPMENT AND TECHNOLOGIES FOR THE PHARMACEUTICAL INDUSTRY



II INTERNATIONAL PHARMACEUTICAL CONGRESS

October 19–21 | 2021



KYIV
EXPO
PLAZA

EC KyivExpoPlaza, Ukraine, Kiev region
village Berezivka, Amsterdamska street, 1

**Seminar “Medical devices in the nomenclature
of pharmaceutical manufacturers.
Conformity assessment of IN-VITRO diagnostic medical devices”**

Date and time:	October 20, 14.30-17.30
Venue:	Hall № 7, KyivExpoPlaza, Amsterdamska str. 1, Zhytomyr Highway M-06, Berezivka Village, Kyiv region, Ukraine
Organizer:	Ukrainian Scientific Institute of Certification
Speaker:	Nikolay Matlaev , The lead auditor on certification of quality management systems and conformity assessment with technical regulations of the Ukrainian Scientific Institute of Certification

PROGRAM*

Devices at the border of definitions:

- medical devices supplied with the medicinal product;
 - medical devices as a means of drug delivery;
 - devices, an integral part of which is a medicinal product;
 - devices for IVD, RUO (research use only) and general laboratory equipment.
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Conformity assessment through self-declaration

Conformity assessment performed by conformity assessment body:

- Choosing the best procedure for your business;
 - Application and documentation;
 - Step-by-step description of the conformity assessment procedure through an audit of the manufacturing facilities;
 - Special procedure for III class devices, which incorporate medicines;
 - Requirements for instruction for use and labeling.
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Conformity assessment of medical devices through the recognition of EU certificates:

- the legislative basis of the recognition procedure and the necessary conditions;
 - list of required documents;
 - step-by-step implementation of the conformity assessment by recognition of EU certificate;
 - the validity period of the certificate issued by recognition and other restrictions.
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Declaration of conformity

Conducting of surveillance audits for issued certificates

**changes and additions are possible in the program*