SPECIFICITY OF MANUFACTURING PROCESS VALIDATION FOR DIAGNOSTIC SEROLOGICAL DEVICES

"Biotechnologia Acta" V. 11, No 1, 2018
https://doi.org/10.15407/biotech11.01.025
P. 25-38, Bibliography 60, English
Universal Decimal Classification: 57.083.3 + 616-71 + 543.9

SPECIFICITY OF MANUFACTURING PROCESS VALIDATION FOR DIAGNOSTIC SEROLOGICAL DEVICES

O. Yu. Galkin 1,2, A. G. Komar 3, M. O. Pys'menna 1

1 National Technical University of Ukraine “Igor Sikorsky Kyiv Polytechnic Institute”, Ukraine
The aim of this research was to analyze recent scientific literature, as well as national and international legislature on manufacturing process validation of biopharmaceutical production, in particular devices for serological diagnostics. Technology validation in the field of medical devices for serological diagnostics is most influenced by the Technical Regulation for Medical Devices for in vitro Diagnostics State Standards of Ukraine – SSU EN ISO 13485:2015 “Medical devices. Quality management system. Requirements for regulation”, SSU EN ISO 14971:2015 “Medical devices. Instructions for risk management”, Instruction ST-N of the Ministry of Healthcare of Ukraine 42-4.0:2014 “Medications. Suitable industrial practice”, State Pharmacopoeia of Ukraine and Instruction ICH Q9 on risk management. Current recommendations for validations of drugs manufacturing process, including biotechnological manufacturing, can not be directly applied to medical devices for in vitro diagnostics. It was shown that the specifics of application and raw materials require individual validation parameters and process validations for serological diagnostics devices. Critical parameters to consider in validation plans were provided for every typical stage of production of in vitro diagnostics devices on the example of immunoassay kits, such as obtaining protein antigens, including recombinant ones, preparations of mono- and polyclonal antibodies, immunoenzyme conjugates and immunosorbents, chemical reagents etc. The bottlenecks of technologies for in vitro diagnostics devices were analyzed from the bioethical and biosafety points of view.

**Key words:** in vitro diagnostics, serological methods, validation, risks, quality management.

© Palladin Institute of Biochemistry of National Academy of Sciences of Ukraine, 2018

{spoiler title=References}


7. Shestopal O. A., Pidpruzhnykov Yu. V. Development of approaches to the validation of the
SPECIFICITY OF MANUFACTURING PROCESS VALIDATION FOR DIAGNOSTIC SEROLOGICAL DEVICES

O. Yu. Galkin, A. G. Komar, M. O. Pys'menna


diagnostic medical devices.

Official Journal of the European Communities
. 1998, L. 331 (41), 1.

. 2015, 87 p.


. 2015, 104 p. (In English).


. 2015, T. 1. (In Ukrainian).


   https://doi.org/10.15407/ubj89.01.022

22. Galkin A. Yu., Dugan A. M. Elaboration of immunoenzymatic test-kit for total human IgE assay and investigation of its analytical properties. 
   https://doi.org/10.11648/j.iji.20130101.11


“Khimicheskie tekhnologii, biotekhnologii, geoekologii”

Scientific community of students of the XXI century: Abstracts of the II Student International Correspondence Scientific and Practical Conference
. Novosibirsk, Russia, 16 April 2012.

38. Galkin O. Yu., Grygorenko A. A. Bioethics in Ukraine: from theory to practice.
Normativelegal and educational-scientific aspects. Naukovi visti NTUU “KPI”

Biochem. Eng. J
. 2015, 93 (0), 260–273
https://doi.org/10.1016/j.bej.2014.10.013

2015, 99 (17), 7009–7024.
https://doi.org/10.1007/s00253-015-6743-6

{/spoiler}