

МИКРОБИОЛОГИЧЕСКИЙ МОНИТОРИНГ ПОМЕЩЕНИЙ ЛАБОРАТОРИИ МИКРОБИОЛОГИИ. АНАЛИЗ РИСКОВ

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Резюме: В статье показаны возможные влияния окружающих факторов на качество анализов, выполняемых в лаборатории микробиологии Испытательного центра экспертизы качества ЛС и необходимость проведения микробиологического мониторинга чистых зон и помещений в период их эксплуатации. Для оценки степени опасности каждого источника рассматриваются факторы риска и категории критичности, на основе которых делается вывод о частоте проведения текущего мониторинга в лаборатории. Оцениваются основные риски, влияющие на результаты микробиологического исследования, описываются методы управления указанными рисками. Представлены также материалы по оптимизации процесса микробиологического мониторинга всех помещений лаборатории, в том числе не относящихся к чистой зоне.

Ключевые слова: экспертиза качества лекарственных средств, микробиологический мониторинг, факторы риска.

ENVIRONMENTAL MONITORING OF MICROBIOLOGY LABORATORY PREMISES. RISK ANALYSIS

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Abstract: The article shows possible influence of environmental factors in the quality of analyses performed in the Laboratory of microbiology of the Testing Centre for Evaluation of Medicinal Products Quality and the need for microbiological monitoring of clean areas and premises during the whole period of operational use. In order to assess the danger level of each source, the consideration of risk factors and criticality categories, which appear to be the basis for defining the frequency of routine monitoring in the laboratory is performed. Major risks affecting the results of microbiological studies are being assessed and the methods for managing these risks are described. It provides the data on optimizing the process of microbiological monitoring of the laboratory premises, including non-clean area.

Key words: drug quality evaluation, microbiological monitoring, risk factors.

В соответствии с современными требованиями [1] при выполнении асептических процессов на производстве или при контроле качества необходимо постоянно проводить микробиологический мониторинг, включающий исследование воздуха и чистоту рабочих поверхностей. Наряду с этим, в соответствии с МУК 4.2.734-99 [2] и утвержденными стандартными операционными процедурами (СОП), микробиологический мониторинг окружающей лабораторной среды охватывает: оценку качества воды очищенной; тестирование эффективности дезинфектантов; подтверждение качества стерилизации. Текущий мониторинг чистых помещений и чистых зон проводится в период их эксплуатации. Точки отбора проб выбираются на основе анализа рисков и результатов, полученных при классификации чистых помещений. Исследования, связанные с мониторингом, выполняются с такой частотой и при таком объеме отбираемых проб, чтобы можно было зафиксировать изменения уровня контаминации [1].

В соответствии с указанными положениями в лаборатории микробиологии Испытательного центра экспертизы качества ЛС (ИЦЭК/ЛС) проводится ми-

кробиологический мониторинг, в программу которого включают следующее:

- определение ответственных исполнителей и контролирующего лица;
- выбор адекватных методов анализа в соответствии с процедурой микробиологического мониторинга, описанной в рабочей инструкции;
- использование только откалиброванного оборудования и приборов, прошедших метрологическую аттестацию;
- установление допустимых пределов, уровней тревоги и действия;
- регистрацию полученных результатов в утвержденных протоколах, а в случае превышения установленных верхних пределов, проведение расследования и выполнение корректирующих мероприятий.

Целью настоящей работы является определение влияния окружающих факторов на качество анализов, выполняемых в лаборатории микробиологии, для постоянной гарантии стабильности асептических условий, выявления начальных отклонений и выработки корректирующих действий до возникновения ситуации, приводящих к появлению ложных результатов.

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