

Метод анализа потенциальных от-
казов FMEA позволяет понять, каким
опасностям для продукции необходи-

мо уделить особое внимание при ква-
лификации туннеля в каждом конкрет-
ном случае. ■

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Potential Failure Analysis During Production Equipment Qualification

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key words

depyrogenation, qualification,
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In the given article we have considered the application of the FMEA method in the process of equipment qualification in the pharmaceutical industry. The advantages and disadvantages of the failure mode and effects analysis have been analyzed by the example of the qualification of a depyrogenation tunnel.

The relevance of the article is because the FMEA method is promising for use in the pharmaceutical industry and requires a comprehensive analysis for improving standardization documents of the Russian Federation.

The main task of equipment qualification is risk management to ensure high quality of medicines. We pay special attention to this issue, recommending that all potential threats analyzed in the article be taken into account when drawing up the qualification protocol. Examples of dangers, their consequences, as well as the necessary measures to eliminate them are given in our work.

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