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Evaluation of post-production handling procedures of monoclonal antibodies throughout Europe

Background

Over the last two decades, monoclonal antibodies (mAbs) have revolutionized the treatment of many diseases and have become the fastest developing class of protein therapeutics. Monoclonal antibodies are protein drugs that are susceptible to different forms of stress. Once the monoclonal antibody is produced and shipped by the manufacturer, there is potentially little control over the many factors that may affect the structural integrity and quality of these monoclonal antibodies. Since post-production handling is essential and no strict procedures are available yet, it is very important to investigate which practices in postproduction handling are widely used and where the potential problems may lie.

Rationale

Only few studies have been conducted to provide insight into the post-production handling of monoclonal antibodies. Alas, there is a general lack of appropriate procedures for post-production handling of monoclonal antibodies. Moreover, little is known about the actual handling of procedures in daily practice in hospitals or outpatient clinics. Therefore, the need to perform studies in order to gain an overview of the potential risks that are associated with post-production (mis)handling of monoclonal antibodies are of crucial importance. To investigate this problem, a specific research question has been prepared: What are the post-production practices of monoclonal antibodies throughout Europe?

Methods

In order to answer this question, the following method has been determined: a web-based survey about post-production handling of monoclonal antibodies will be conducted. This questionnaire will be sent to >3000 pharmacists throughout Europe by the Membershipservice of ESOP and will consist of a maximum of 17 questions, which can be completed within 10 minutes. The survey tool google forms will be used to build the questionnaire. Furthermore, data analysis will be performed using the statistical programs SPSS and Excel. Examination of the data will include descriptive statistics and in the interpretation, the handling devices and procedures will be compared to known hazards from the literature with regards to compatibility of materials, the occurrence of mechanical shock, light exposure and temperature fluctuations.

Conclusion

Now is an opportune time to investigate the post-production handling of monoclonal antibodies. This will complete the last part of the protein product supply chain. We will be the first investigators, who investigate this topic. Hereby, we hope to reduce the knowledge gap so that we can make a good scientific contribution that can eventually lead to an international publication.