The quality and safety of transfusion products – a study on critical aspects of quality and important factors in quality control

Products made from blood (transfusion products and blood derivatives) represent a special group of therapeutic preparations that have specific properties (danger of allergic reactions, transfer of infections etc.).

The aim of this study was to show critical points of the process of producing safe, first-rate transfusion preparations at the level reflecting the progress in medicine and technology. Secondary aim was to analyze whether inspections of the State Institute for Drug Control, strict requirements and implementation of EU legislative have influence on the quality of work in blood establishments (BEs) and whether there are some relations between selected BEs with similar characteristics (the size and type of facility) and quality of work as this is presently a heated topic in discussions about restructuralization of transfusion service.

The author analyzed her own experience gained during 129 inspections from the view of Good Manufacturing Practice (GMP) in BEs in the Czech Republic and abroad.

The survey of results

The most frequent and most important shortcomings (key and critical points) in production of transfusion products are parameters described in the chapter **Documentation, Workers and Facilities and Equipment** (of total number 25,9% /17,7/17,7 % were shortcomings).

The lowest number of shortcomings was in **Reclamation and Recall, Quality Assurance and Information Systems** (0,4/1,8/2,2%), nevertheless, a relatively high number of critical shortcomings may unfavourably influence the result that was found in Information Systems (13,6% of total number of all shortcomings).

The occurence of the most important, i.e. critical shortcomings significantly decreased (of 9 to 1). It is the positive influence of implementation of strict demands of European directives in the system of quality control in our BEs.

The system of controls introduced and practiced during the follow-up period proved to be effective and led to statistically significant drop in shortcomings, especially the critical ones (of 0,26 to 0,05/ 1 inspection).

The presumption that larger BEs show a lower number of shortcomings either in total or in critical shortcomings than smaller BEs *was not verified.* In percentual evaluation difference in numbers was in favour of large BEs (23% versus 45%), however, did not reach statistical significance. There was no difference in shortcomings reccurence between complete BEs and BEs with the production range „collection of blood".

The analysis of the difference in the total number of shortcomings in BEs at repeated controls showed the drop in individual categories according to their importance, especially, a marked drop (elimination) of critical shortcomings (of 8 at the 1st control to 0 at the 2nd control, i.e. after 2 years).

Conclusion: The evaluated period of time is relatively short, but results indicated trends to improving the quality of work in BEs following implementation of strict EU rules in several fields as is analyzed and documented in the study. For further positive development it is necessary to focus our attention on key and critical points in production of transfusion products.