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GMP requirements for Canadian blood & blood establishments

The Blood and Blood Establishments generally require following very strict GMP regulations in order to protect their blood products recipients from being contaminated with various potential blood borne diseases. In Canada, blood regulations are administered by the Health Products and Food Branch, Health Canada. These regulations recently changed and new regulations that came into the effect just in October 2014, contain requirements for human safety and the safety of blood products with respect to the different activities in all blood and blood components establishments like: Processing (donor suitability assessment, collection, testing, and blood component preparation); transforming (washing, pooling and irradiating); labeling; storing; record keeping; importing; distributing; and error, accident and adverse reaction investigation and reporting. As these set of regulations are still new, it seems there are still some rooms for their improvement. In this presentation, the key elements of the new sets of regulations will be reviewed and discussed and they will be compared with the previous sets of GMP regulations. Also, some suggestions will be provided as to how we can improve the new Canadian Blood Regulations.

Biography

Reza Shojaei has over 18 years of experience in quality management and establishing of medical diagnostic systems, blood and plasma screening laboratories and source plasma collection centers. He started working in Canadian Plasma Resources in 2009 where he designed a unique and Canadian oriented Quality Systems Management for the source plasma collection centers in Canada. Currently he is responsible to ensure that every individual human plasma unit, collected by way of an established automated aphaeresis process, and released for sale from a corporation-controlled facility, meets current quality and safety requirements of both Canadian Plasma Resources and Health Canada.

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