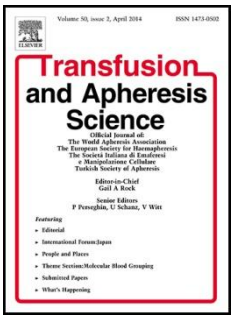
Accepted Manuscript



Title: Quality, safety and sustained therapeutic efficacy of blood-derived serum eye drops to treat dry eye syndrome: r&d road map for future progress

Author: Jerard Seghatchian, Aurora Espinosa, Thierry Burnouf

PII: S1473-0502(16)00025-2
DOI: http://dx.doi.org/doi: 10.1016/j.transci.2016.01.023
Reference: TRASCI 1966

To appear in: *Transfusion and Apheresis Science*

Please cite this article as: Jerard Seghatchian, Aurora Espinosa, Thierry Burnouf, Quality, safety and sustained therapeutic efficacy of blood-derived serum eye drops to treat dry eye syndrome: r&d road map for future progress, *Transfusion and Apheresis Science* (2016), http://dx.doi.org/doi: 10.1016/j.transci.2016.01.023.

Quality, safety and sustained therapeutic efficacy of blood-derived serum eye drops to treat dry eye syndrome: R&D road map for future progress

Jerard Seghatchian[a], Aurora Espinosa[b], Thierry Burnouf[c]

[a] International Consultancy in Blood Components Quality/Safety, Audit/Inspection and DDR Strategies, London, UK
[b] Department of Immunology and Transfusion Medicine, St. Olav's University Hospital, Trondheim, Norway
[c] Graduate Institute of Biomedical Materials and Tissue Engineering, College of Biomedical Engineering, Taipei Medical University, Taipei, Taiwan

Correspondence: jseghatchian@btopenworld.com

Keywords: quality/ safety standard of SED; Sustained therapeutic efficacy of SED; Dry eye syndromes

With the better understanding that serum and platelet lysates contain high concentrations of growth factors [1] and presumably large numbers of blood cell-derived microvesicles [2, 3] and others biological response modifiers, attention in some transfusion services is focused towards developing and validating standardised production, storage, and distribution methods of blood derived serum, for an effective and convenient therapy of patients with dry eyes and related syndroms [4, 5].

In the recent theme articles on serum eye drop (SED) published in TRASCI [6-10], various groups have already highlighted critical safety/quality standards of SED including the procurement of safe donors and continual improvement of processes. This is in line with the regulatory requirements for blood products [11] and the fact that whole blood and blood components have recently been included in the WHO model list of essential medicines [12] and should be prepared following the principles of good manufacturing practices. Some new information will soon be available [13] on sustained patients outcomes in Australia following SED therapy. Clearly, consistently producing high quality SED products and demonstrating safe storage and application in patients is the basis for improving sustained effective clinical outcomes.