TGA consultation on draft Australian code of Good Manufacturing Practice for Human blood and blood Components, Human Tissues and Human Cellular Therapies (Dec 2009)

Comment and Questions

TGO Reference	Comment and/or Question
Clause 905	Does this mean that the laboratory doing the testing should be TGA licensed, as the TGA are the regulatory authority for therapeutic products?
Clause 915	Note: typographical/grammatical error at end of the last sentence of 1st paragraph ie. “can such products <u>are</u> released”. Should probably read ie. “can such products <u>be</u> released”.
Clause 915	Is this referring to the system for “exceptional release” where it is a requirement for TGA notification and/or authority to release? If so can TGA clarify how this mechanism is expected to function and what timeframe for response is expected if release is urgent due to medical need for a unique patient?

Submitted by XXXXXX

Date: 5/02/2010