



**RESPONSE FROM  
THE AUSTRALIAN INSTITUTE OF MEDICAL SCIENTISTS  
TO THE PROPOSED STANDARDS AND CODE OF GMP FOR HUMAN BLOOD  
AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR  
THERAPIES**

**INTRODUCTION**

The Australian Institute of Medical Scientists (AIMS) thanks the Therapeutic Goods Administration for the opportunity to respond to these proposed standards.

AIMS is the professional organisation representing Medical Scientists from all disciplines of pathology and associated industries, from all states of Australia and from overseas.

AIMS members are medical scientists working in private and public pathology laboratories, hospitals and universities. Medical scientists conduct tests on blood and body tissues to assist doctors in the diagnosis, treatment and prevention of disease.

AIMS wishes to comment on only the *Draft Australian Code of GMP Human Blood and Blood Components, Human Tissue and Human Cellular Therapies* and *Therapeutic Goods Order No. XX standards for the minimising infectious disease transmission via human blood and blood components, human tissues and human cellular therapies*.

**RESPONSE**

**Draft Australian Code of GMP Human Blood and Blood Components, Human Tissue and Human Cellular Therapies.**

As outlined in the introduction this is a revision of the Code and is designed to be a living document; comments on this code are invited at anytime to accommodate changes in technology and to clarify any uncertainties that may arise during the life of this document. In general this is a clear and concise, well structured document and easy to read.

**Section 1 Quality Management**

104 dot point 8 the code states:

(The system of Quality Assurance appropriate for the manufacture of products should ensure that): .....satisfactory arrangements exist to ensure, as far as possible, that the therapeutic products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life;

This would imply that any lab or hospital, handling any of these products is also subject to this code. Is this the intention?

## **Section 2 Personnel and training.**

While the document states that all personnel should be competent there is no mention of maintaining that competency or of continuing professional development (CPD).

AIMS supports the proposal that the quality and production nominees should be different persons, neither responsible to the other and that the responsibilities of both are outlined.

### **Sub sections 2.201 and 2.205**

AIMS considers that it is important that appropriately qualified medical scientists be engaged in these crucial areas.

## **Section 9**

It is stated that "quality control is not confined to laboratory operations but should be involved in all decisions which may concern the quality of the product." Everyone who has any part in the process from donor to recipient has a role to play in ensuring their quality control processes comply. This statement can also apply to the decisions made by the end users as to the suitability of the product. Perhaps some statement is required as to the end-users deferring to the manufacturer before discarding or choosing to use a product that they believe has been compromised.

**905** *"Screening tests for donor suitability should be carried out by competent laboratories"*

There is no requirement that these laboratories should be accredited by a suitable authority and to what standard. The section does state that where required by legislation the laboratory should be licensed. AIMS recommends that the word "should" be replaced by "must".

## **Section 10 Computers.**

As computerised systems are now a major part of many operating systems they too need to have written protocols and procedures and be subject to regular checks, records maintained and updates documented. This section is very well thought out and written

Jan Noble  
Chief Executive  
Australian Institute of Medical Scientists (AIMS)  
PO Box 1911  
Milton Q 4064  
Australia  
Phone: 61 7 3876 2988  
Mob: 0419 655 937  
Facsimile: 61 7 3876 2999  
[www.aims.org.au](http://www.aims.org.au)

12 February 2010