# Consultation on the Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapies

**Submission by**
**Medical Technology Association of Australia**

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## About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability.

The medical technology industry in Australia has an annual turnover of $6.0 billion (2007/2008), earns an export income of $1.3 billion (2007/2008) and employs in excess of 17,500 people. Local manufacturing produces earnings of $2.6 billion. The medical technology industry invested $160 million in research and development in Australia in 2007/2008[1].

MTAA estimates that $1.6 billion is spent on medical technologies in the private hospital system in Australia with a further $2.8 billion spent in the public health system[2].

There are 9,492 products listed on the Prostheses List at February 2009, of which 87% are listed by member companies of MTAA. There are a total of 25,993 (non-dental) medical devices listed on the Australian Register of Therapeutic Goods (ARTG) (at September 2008) by 1,710 sponsors.

## Comments on the proposed draft Australian Code of Good Manufacturing Practice

MTAA supports the development and application of appropriate international standards to the design, development and use of medical technology and therapeutic products. The use of standards has been a long accepted feature of regulatory requirements in numerous jurisdictions for many years. With the increasing internationalisation of the therapeutic goods industry it has also been accepted that differences between the regulatory requirements of jurisdictions around the world should be reduced. Imposing unique national requirements, unless those requirements can be properly justified on safety grounds, for example, can have the effect of limiting the availability and hence the usefulness of therapeutic goods.

The proposal to introduce a unique Australian code of GMP for human blood and blood products, human tissues and human cellular therapies has the potential to limit its adoption and implementation, especially by overseas based companies. It also will create limitations for the industry as a whole due to the relatively small number of people who are likely to be trained in the auditing skills required to certify the standard. It would be a far more practical approach to base the requirements for an appropriate standard for use in Australia on an established international standard with the addition of an annex to cover the requirements specific to human blood and blood products, human tissues and human cellular therapies.

For example, the international standard ISO 14385:2003 Medical devices - Quality management systems - Requirements for Regulatory Purposes, which was based on

[1] MTAA estimate based on Australian Bureau of Statistics Report 81040DO012_200607
[2] This figure does not include major medical equipment in the public health system

the international standards for general quality management systems has been established and accepted as an appropriate and effective standard for the design, development and manufacture of medical technology around the world. The standard makes provision for the use of other specific standards or requirements which may be relevant for particular aspects of the medical technology, but as far as the design, development and manufacture of the technology, the general over arching standard is ISO 14385:2003. This standard is appropriate for the manufacture of a vast range of medical technologies. The use of an internationally recognised standard also means that there should be many similarly qualified auditors in many countries. The other advantage of the concept is that during any audit specialist auditors trained for specific technologies can audit any specialised requirements leaving the general requirements to be assessed by the generalist auditors. This reflects the applicability of horizontal and vertical standards to any assessment of the manufacture of therapeutic goods.

MTAA considers that the same approach could be adopted for human blood and blood products, human tissues and human cellular therapies.

Apart from Section 8 of the proposed draft Australian code of GMP for human blood and blood products, human tissues and human cellular therapies, the proposed draft code establishes some of the quality management system requirements already required in ISO 14385:2003. MTAA also considers that as ISO 14385:2003 goes further than the draft code, the international standard coupled with an annex detailing the requirements of Section 8 in the current draft code could be a better solution to adopt for the blood products industry. ISO 14385:2003 considers more of the organisational requirements necessary to manufacture medical technology than the proposed draft code. These organisational requirements would also be pertinent to the blood products sector. While not detailing all the requirements and considering that exact comparisons may not be possible due to the broad coverage of issues in ISO 14385:2003, the following table comparing the contents of the draft code of GMP and ISO 14385:2003 illustrates this point.

| ISO 14385:2003 | Proposed draft Code of GMP for Blood and Blood Products |
|---|---|
| Quality Management System | Quality Management |
| General Requirements | |
| Documentation Requirements | Documentation |
| Management Responsibility | |
| Management Commitment | |
| Customer Focus | |
| Quality Policy | |
| Planning | |
| Responsibility, Authority and Communication | |
| Management Review | |
| Resource Management | |
| Provision of resources | Computer Systems |
| Human Resources | Personnel and Training |
| Infrastructure | Premises and Equipment |
| Work Environment | |
| Product Realisation | Quality Control |
| Planning of Product Realisation | |
| Customer related processes | Complaints and Recalls |
| Design and Development | |
| Purchasing | Subcontracting |
| Production and service provision | Control of Material |
| Control of monitoring and measuring devices | |
| Measurement, Analysis and Improvement | |
| Monitoring and Measurement | |
| Control of Non-Conforming Product | |
| Analysis of Data | |
| Improvement | |