# Sponsor Information & Training Day

Tuesday 9 September 2014
Hyatt Hotel, Canberra

Session A2 - Medical Devices

# Changes (I)

# Devices that have undergone TGA Conformity Assessment

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# Introduction

- You have your TGA CA certificates
- You have a current ARTG entry
- The manufacturer decides to make a change to device design and/or a manufacturing related change….
- This session will take you through which changes need to be notified to TGA

# What is the legislative basis for notifying the TGA of changes?

# Legislative basis – change notification

## Section 41EJ subsection (3) – Therapeutic Goods Act 1989

- The manufacturer of a medical device will notify the TGA, in writing, of any plan for substantial changes to the:
  - quality management systems
  - product range
  - product design
- Guidance coming soon

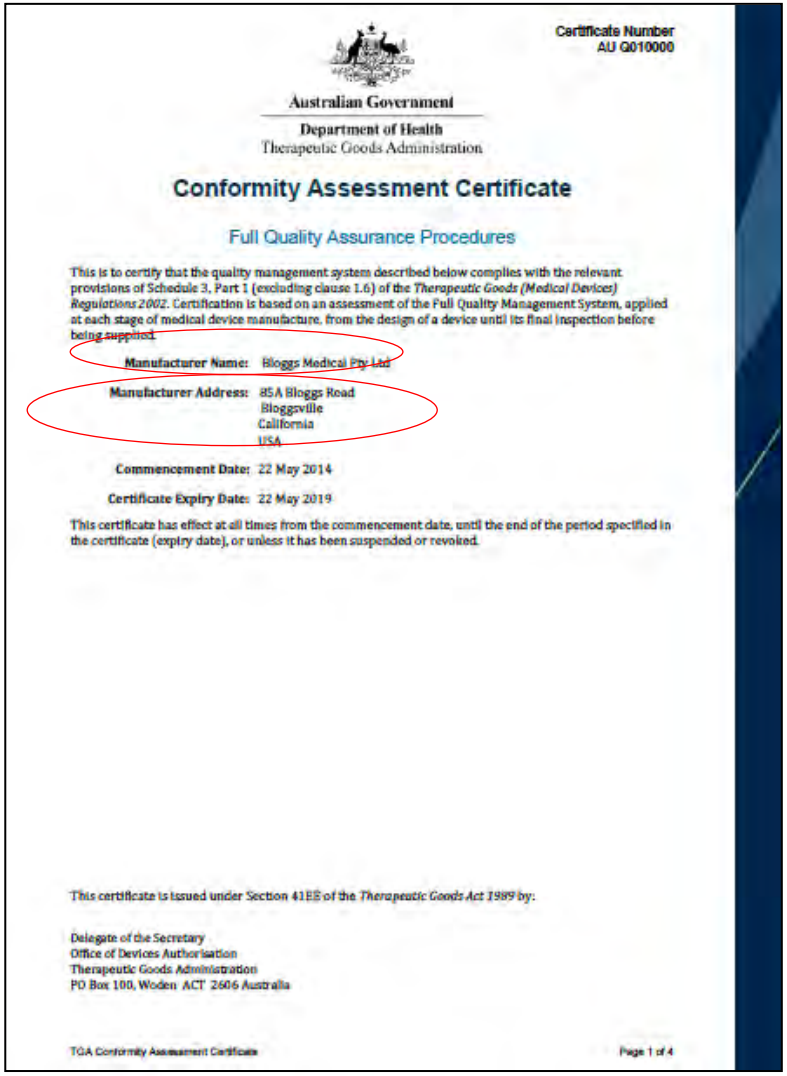
# So which changes are significant?

# Definition of substantial change

- The TG legislation does not contain a definition for “substantial changes”
- It is not practicable to specify what types of changes are or are not “substantial”
- Recommended that manufacturers have a system for categorising changes as substantial or not.

# How does a manufacturer determine what should be notified?

# Certificate Fields



Certificate Number
AU Q010000

Australian Government
Department of Health
Therapeutic Goods Administration

## Conformity Assessment Certificate

### Full Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

**Manufacturer Name:** Bloggs Medical Pty Ltd

**Manufacturer Address:** 85A Bloggs Road
Bloggsville
California
USA

**Commencement Date:** 22 May 2014

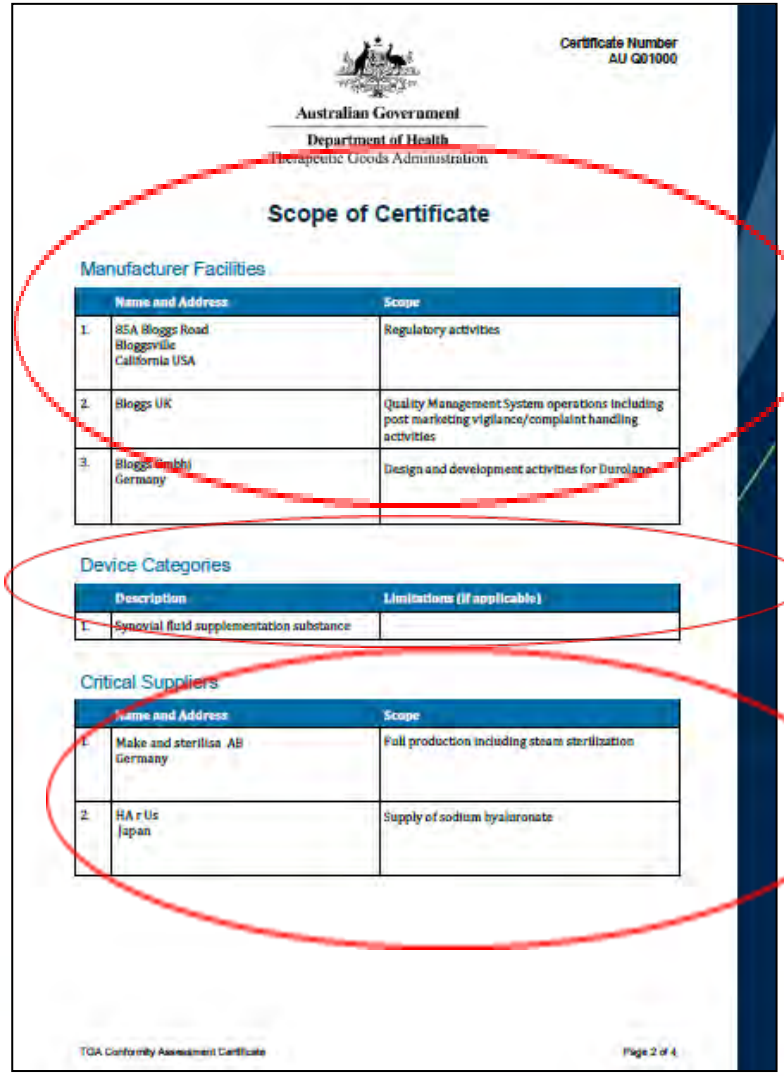
**Certificate Expiry Date:** 22 May 2019

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

Delegate of the Secretary
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

TGA Conformity Assessment Certificate Page 1 of 4



Certificate Number
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Therapeutic Goods Administration

## Scope of Certificate

### Manufacturer Facilities

| | Name and Address | Scope |
|---|---|---|
| 1. | 85A Bloggs Road<br>Bloggsville<br>California USA | Regulatory activities |
| 2. | Bloggs UK | Quality Management System operations including post marketing vigilance/complaint handling activities |
| 3. | Bloggs GmbH<br>Germany | Design and development activities for Duroland |

### Device Categories

| | Description | Limitations (if applicable) |
|---|---|---|
| 1. | Synovial fluid supplementation substance | |

### Critical Suppliers

| | Name and Address | Scope |
|---|---|---|
| 1. | Make and sterilisa AB<br>Germany | Full production including steam sterilization |
| 2. | HA r Us<br>Japan | Supply of sodium hyaluronate |

TGA Conformity Assessment Certificate Page 2 of 4

# Have a change assessment process

- Manufacturer may have a change assessment process to work out if a change is significant and notifiable to TGA or other regulatory authorities.
- The process may ask a series of questions such as : Does the change introduce new hazards/risks?
- Does the change alter the intended use and/or compliance with the EPs?
- Does the change affect clinical performance?
- Does the change require the device to undergo further validation?
- Does the change mean the device will be used on different users?

# How can a Sponsor ensure that the TGA is notified of changes?

# Manufacturer/Sponsor Quality Agreements

This an example clause for the Sponsor to determine if the change needs to be notified to TGA:

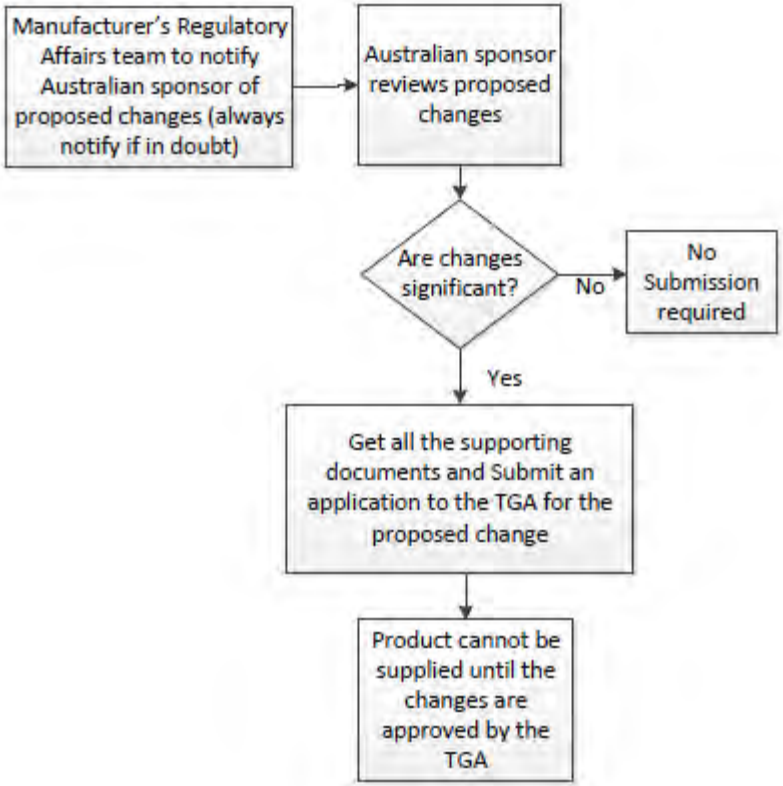
The manufacturer agrees to provide written notice the changes listed below to the Products as detailed in the scope of this agreement as soon as reasonably possible.

- Change(s) to the intent to supply any or all of the Products
- Change(s) to the part number, description or significant labelling information of the Products - Significant labelling information is considered to be change to the text information excluding formatting
- Change(s) to the intended use of the Products
- Change(s) to design of the Products or Services that affect the form, fit or function, particularly dimensional changes.

# Manufacture/Sponsor Quality Agreement
(continued)

- Change(s) to the material(s) used in the Products.
- Change(s) in the Australian/European regulatory certification of the Products if applicable.
- Change of manufacturing site where the Products are made
- Change(s) to Supplier/Manufacturing Quality Management System Certification
- Change(s) to Supplier ownership or contact details
- Shelf-life

# Global change notification SOP



# Example Product Change Notification response from the manufacturer

**PART B – REGULATORY REQUIREMENTS** (PCN Number: [redacted])
*Response from Geography: please answer **all four questions** & sign document.*

Your response is required by: *(dd/mm/yyyy)* 25/07/2014

**1. What country(ies) are you responding for?**

[List countries here]

**2. Will change(s) to product or process require *submission or registration* in any countries under your responsibility?** ☐ **Yes** ☐ **No**

***If No*** (no submission or registration), include a documented rationale/reason for the decision(s):

***If Yes*** (submission required):
a) Which countries require a submission or registration?

b) What approval time is expected (weeks/months) post filing per country (if applicable)?

c) Identify supportive information required per country (if any):

**3. Will change(s) to product or process require *notification* in any countries under your responsibility?** ☐ **Yes** ☐ **No**

***If No*** (no notification), include a documented rationale/reason for the decision(s):

***If Yes*** (notification required):
a) Which countries require notification?

b) Identify supportive information required per country (if any):

**4. Can the change be implemented immediately without restrictions (e.g. import, sales etc)?** ☐ **Yes** ☐ **No**

***If No*** (restrictions do apply),
a) Which countries have restrictions?

b) Identify the restrictions and associated timelines per country:

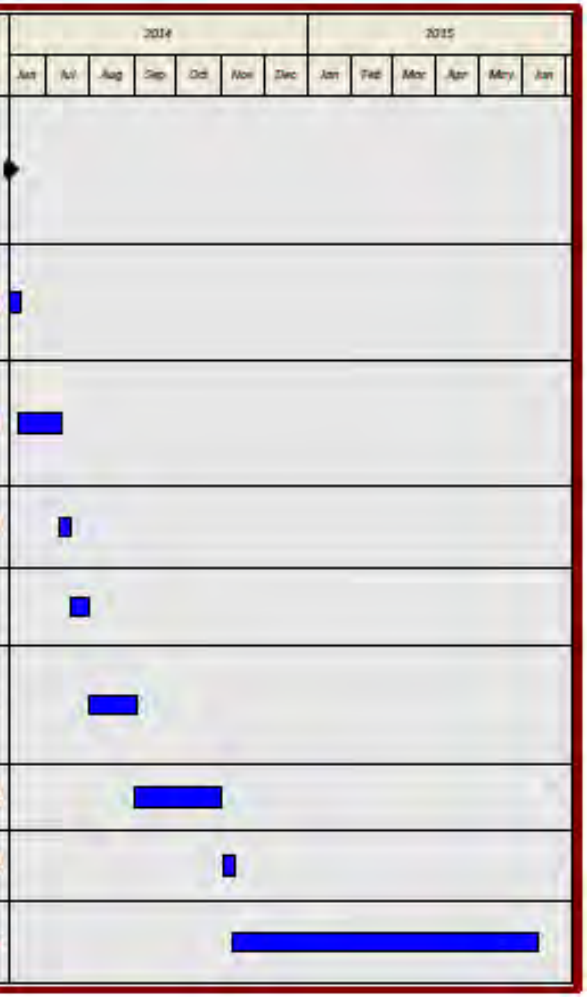
| **Completed by:** | **Date:** *(dd/mm/yyyy)* |
|---|---|

*Note*: This record must be traceable to the specific individual making the above decisions. Please scan the signed form to PDF or use an electronic signature. Attach the signed PDF file to your reply email. The geography is encouraged to maintain a copy for their records.

# How do you plan for changes?

# Have a plan

| ID | Task Name | Start | Finish |
|---|---|---|---|
| 1 | Sponsor made aware of the proposed change of change to shelf life from X years to Y years | 5/06/2014 | 5/06/2014 |
| 2 | Sponsor to confirm if this is a significant change and since in this case it is, go ahead with the next steps | 5/06/2014 | 12/06/2014 |
| 3 | Obtain supporting documents for submission such as test reports (drug stability reports if applicable, ageing / shelf life and product performance reports etc) | 12/06/2014 | 11/07/2014 |
| 4 | Put in the TGA eBS application | 11/07/2014 | 18/07/2014 |
| 5 | TGA will issue a request for information using the S41JA format | 18/07/2014 | 31/07/2014 |
| 6 | Provide the TGA with the supporting documents – A cover letter explaining the change is always useful, please ensure to put in the application for "abridgement" at this point of time. | 31/07/2014 | 2/09/2014 |
| 7 | TGA performs initial assessment and issues invoice | 2/09/2014 | 31/10/2014 |
| 8 | Sponsor to pay the invoice (please note that the application will not progress until invoice is paid) | 3/11/2014 | 10/11/2014 |
| 9 | TGA review / approval – depending on the queries the timeline may vary | 10/11/2014 | 10/06/2015 |

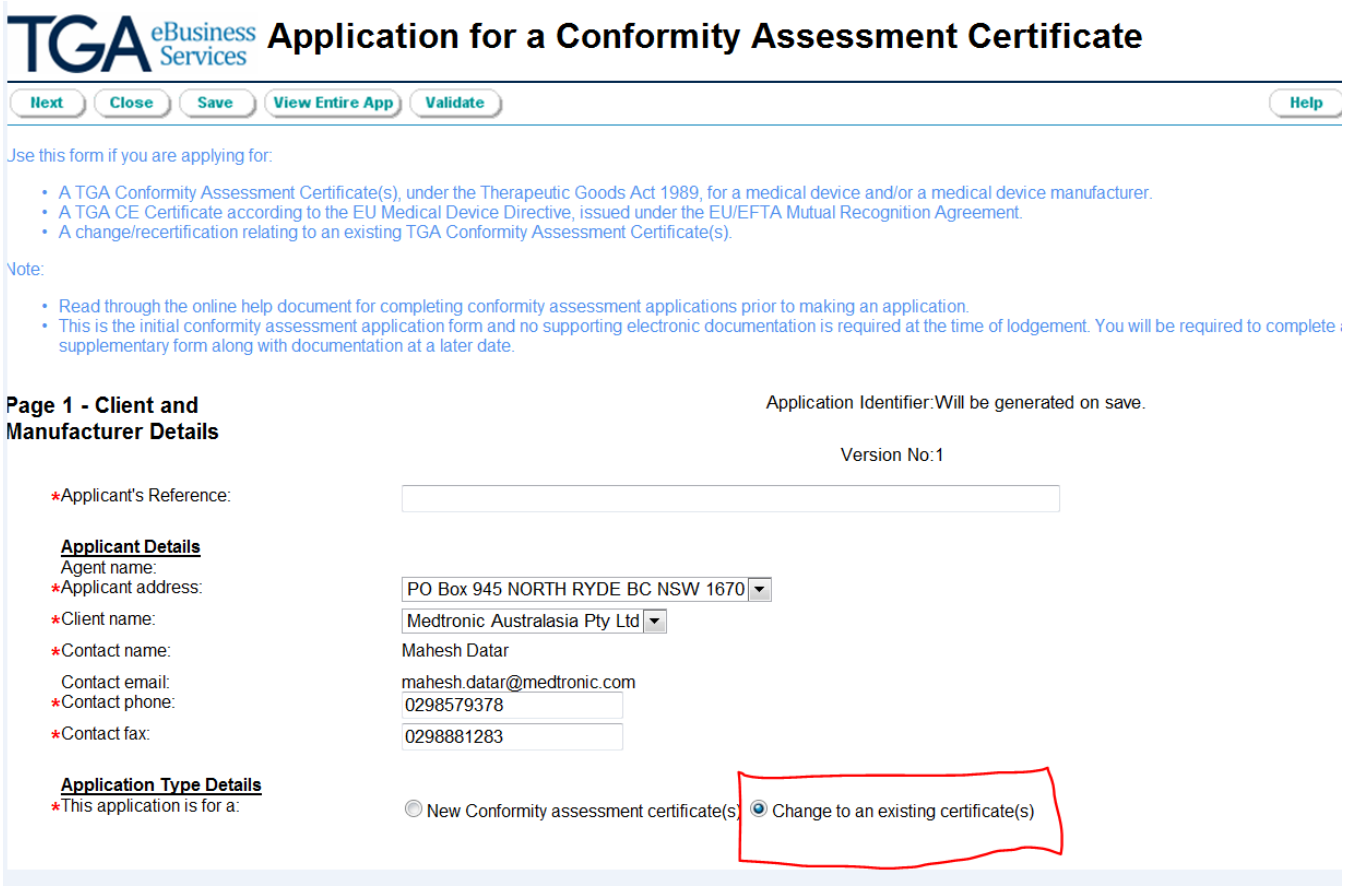


# Timing of when to let TGA know about the change

- Please allow adequate time for the TGA to consider and complete the assessment of the proposed changes. The assessment may require an onsite inspection which will have to be incorporated into the TGA inspection schedule.
- Before products are distributed for sale in Australia

# Common significant changes – what to do

# How to submit a change



TGA eBusiness Services **Application for a Conformity Assessment Certificate**

Next | Close | Save | View Entire App | Validate | Help

Use this form if you are applying for:

- A TGA Conformity Assessment Certificate(s), under the Therapeutic Goods Act 1989, for a medical device and/or a medical device manufacturer.
- A TGA CE Certificate according to the EU Medical Device Directive, issued under the EU/EFTA Mutual Recognition Agreement.
- A change/recertification relating to an existing TGA Conformity Assessment Certificate(s).

Note:

- Read through the online help document for completing conformity assessment applications prior to making an application.
- This is the initial conformity assessment application form and no supporting electronic documentation is required at the time of lodgement. You will be required to complete a supplementary form along with documentation at a later date.

**Page 1 - Client and Manufacturer Details**

Application Identifier:Will be generated on save.

Version No:1

*Applicant's Reference:

**Applicant Details**

Agent name:

*Applicant address: PO Box 945 NORTH RYDE BC NSW 1670

*Client name: Medtronic Australasia Pty Ltd

*Contact name: Mahesh Datar

Contact email: mahesh.datar@medtronic.com

*Contact phone: 0298579378

*Contact fax: 0298881283

**Application Type Details**

*This application is for a: New Conformity assessment certificate(s) | Change to an existing certificate(s)

http://www.tga.gov.au/industry/manuf-forms-conformity-assessment-certificates.htm

# Change of Legal Manufacturer HQ address

Examples of supporting documentation

- Updated CE cert
- Notified body letter
- Legal entity declaration
- Council letter

# Manufacturing facility/Site change

- Communicate and submit  as soon as you are aware
- Provide a plan e.g. GANNT chart, Visual Stream Map, Master Validation Plan,  explanation of changes and products affected.

Examples of evidence to be provided to TGA:

- Evidence to demonstrate on going compliance to the EPs, Master validation plan/report (IQ/OQ/PQ), regulatory body audit report, updated certificates, validation protocols and reports for special processes e.g. Cleanroom qualification, packaging qualification, and sterilisation.

# Change to design

Example changes: additional sizes,  changes to material, indications and shelf-life.

- Evidence to demonstrate on going compliance to the EPs
- Updated Essential Principles Checklist
- Design Verification and Validation protocols and reports including biocompatibility if  the material has change, standards applications.
- Risk analysis
- Clinical Evidence – e.g. population may have changed.
- Shelf-life:  functional stability  as well as sterility.

# Changes to Critical Suppliers

- Evidence to demonstrate on going compliance to the EPs
- Explain what they are supplying e.g. Drug,  tissue, sterilisation facility.
- Procedures for supplier qualification and reports
- Demonstrate compliance  to ISO 13485 e.g. Supplier qualification records, audit schedule and audit reports.
- Any supplier certification e.g. ISO /GMP
- In-coming inspection procedures and records

# Common Mistakes

- The applicant not being aware of changes occurring at the manufacturing site
- Not being clear on the change or the extent of a change
  - Often informed of manufacturing changes, however, several design changes have been implemented.

# Considerations once the change has been assessed and approved

- What about pre-change products still in circulation, can continue to be used?
- What happens if there is another change when one change is submitted?
- What do I need to do with the new CA certs?
- Will there be another manufacturing site audit?

# Thanks for listening
# Questions?

# Brought to you by:

AusBiotech
AusMedtech
MEDICAL DEVICES & DIAGNOSTICS

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