



## The Roadmap for Manufacturers



Mike Flood  
Head, Application Entry & Co-ordination Section  
Office of Devices, Blood and Tissues  
TGA



## Outline

- Framework requirements
- Selecting a procedure
- An example procedure
- The Agency's Role
- As applied to Class I devices



## The Participants –

- The Manufacturer
  - has an obligation to show that products conform to safety and performance principles
    - GHTF Essential Principles
  - has an obligation to follow an assessment procedure
    - to ensure the initial and on-going conformity to the Essential Principles
    - includes quality management system requirements
    - includes post-market monitoring, investigation and reporting requirements
    - similar to the EU Conformity Assessment Procedures



## The Participants –

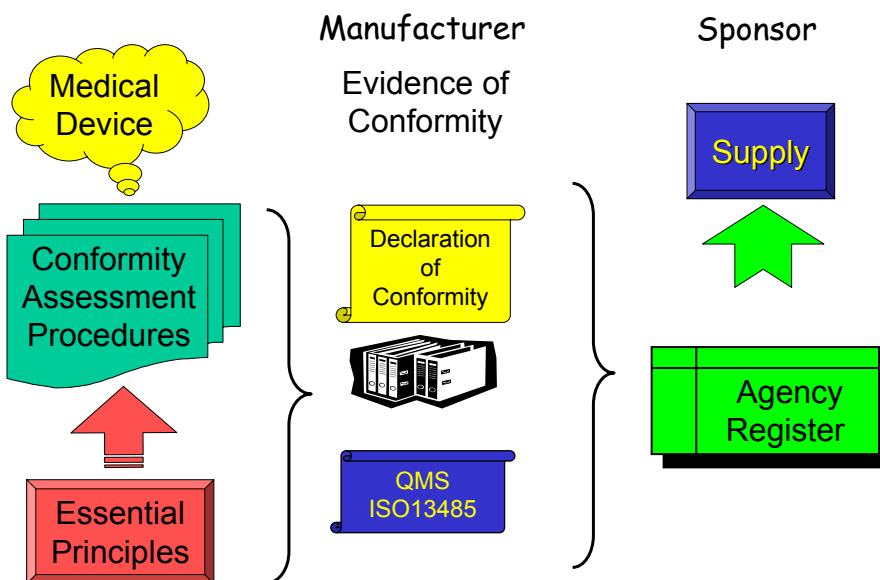
- The Sponsor
  - certifies that a manufacturer has met their obligations
  - ensures information flows to and from the manufacturer
  - accepts the responsibility for the supply of product
  - assists the manufacturer to comply with the obligations on the manufacturer
  - submits the manufacturer's evidence of conformity to the Agency
  - applies for an entry for the manufacturer's product on the Agency Product Licence Register



### The Participants –

- The Regulator
  - the Trans-Tasman Agency
  - performs selected full pre-market assessment
  - performs selected short pre-market assessments
  - performs post-market vigilance and investigation

### The Roadmap





## Conformity Assessment Procedures

- Apply to all medical devices –
  - The manufacturer must show conformity with the Essential Principles (EP)
    - Principles of Safety and Performance
    - Applies to all medical devices – regardless of class
  - The manufacturer must apply a conformity assessment procedure (CAP)
    - Means of demonstrating compliance with the EP's
  - The sponsor must include the medical device on the Agency Product Licence Register



## Conformity Assessment Procedures

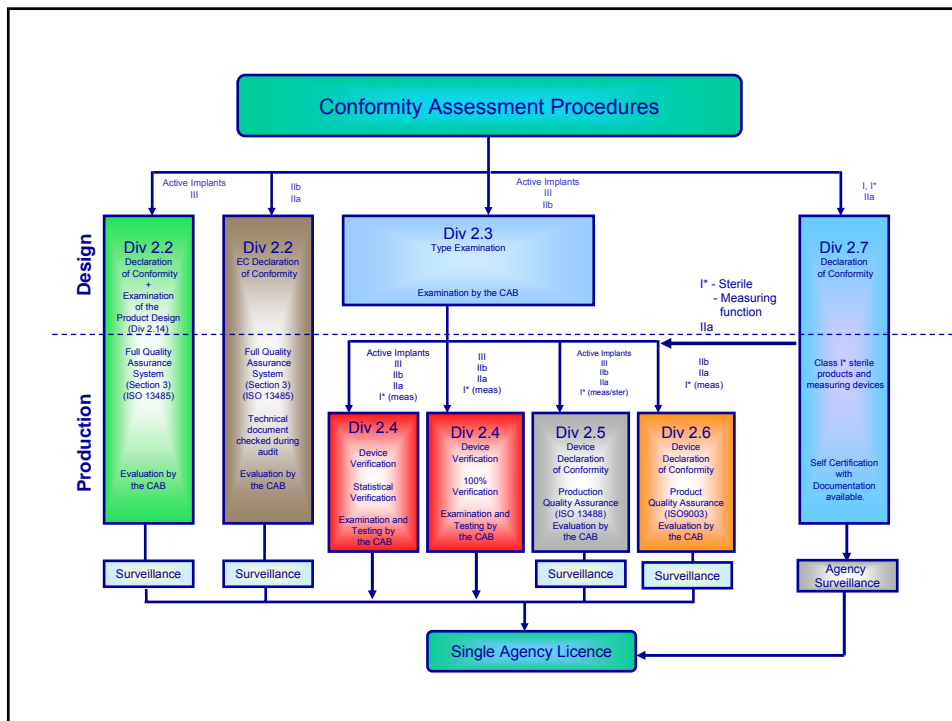
- Obligations relating to:
  - Use of a quality management system
  - Certification of a quality management system
  - Compliance with the essential principles
  - Notification and assessment of changes
  - Declarations of conformity
  - Ongoing surveillance of a QMS
  - Performance monitoring
  - Corrective action
  - Keeping of records



## In the beginning .....

The manufacturer chooses a CAP based on device class

- will determine the Quality Management System (QMS) requirements
  - the type of audit and / or the product assessment process
- Assessment
    - Apply for audit when QMS has been implemented
    - Apply for assessment when technical documentation is complete





## Assessment Process

- After audit, an opportunity provided to correct non-conformities
- Certification
  - Subject to ongoing surveillance
  - It is a condition of certification to notify substantial changes to the Conformity Assessment Body (CAB)



## Conformity Assessment Procedures

- Schedule 2 of the Medical Devices Rule
  - Div 2.1 – Overview (describes flowchart)
  - Div 2.2 - Full Quality Assurance
  - Div 2.3 - Type Examination
  - Div 2.4 - Verification
  - Div 2.5 - Production Quality Assurance
  - Div 2.6 - Product Quality Assurance
  - Div 2.7 – Self Assessment Procedures (Class I devices)
  - Div 2.8 - Devices used for a special purpose (Custom made, customised & Procedure Packs)
  - Div 2.9 - Clinical assessment procedures



## Many Common Elements -

- Risk management
- Clinical evidence
- Quality management systems
- Documentation
- Record keeping
- Post production monitoring
- Declaration of conformity



## Risk Management & Risk Analysis



## Some Definitions

- **Hazard**
  - Potential source of harm
- **Harm**
  - Physical injury or damage to the health of people/property/environment
- **Risk**
  - Combination of the probabilities of the **occurrence** of that hazard and the **severity** of that harm



## More Definitions

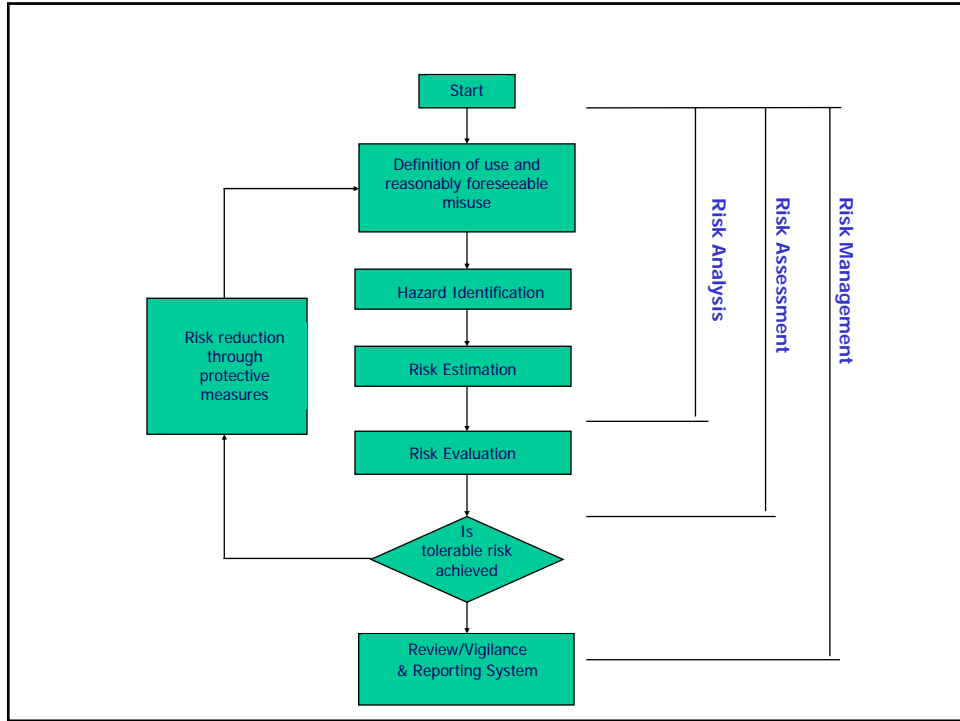
- **Risk Analysis**
  - Use of available information to identify hazards and to estimate risk
- **Risk Evaluation**
  - Judgement, on the basis of risk analysis, of whether a tolerable risk has been achieved
- **Risk Assessment**
  - Overall process of risk analysis and risk evaluation
- **Risk Management**
  - Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risk.



## More Definitions (cont'd)

- **Residual Risk**
  - Risk remaining after protective measures have been taken
  
- **Tolerable Risk**
  - Risk which is accepted in a given context based on the current values of society

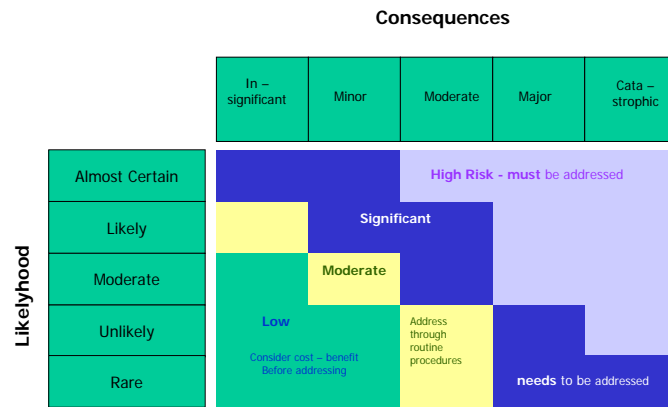




## An Example Risk Analysis



## An Example Risk Analysis



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## An Example Risk Analysis

	Consequences	Likelihood	Immediate Relevance	SUM	Ranking
Contact lens Care Solutions	5	9	2	90	4
Home Use IVD's	8	8	7	448	2
Disinfectants	2	8	8	128	5
Condoms/Gloves/Catheters	8	9	8	576	1
Blood bags/tubing	8	7	7	392	3
Endotoxin testing	5	7	5	175	6
Tampons	4	3	8	96	8
Barrier Contraceptives	7	6	1	42	9
Polyurethane Condoms	7	3	7	147	7
Wound Dressings	4	6	4	192	4

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## Clinical Evaluation Procedures



## Clinical Evaluation Procedures

- Applied **in addition** to the procedures selected on the basis of Class
- Applicable to **all** classes of devices
- Requires clinical evidence to be generated on the basis of a critical evaluation of clinical data
  - evidence of safety and performance in use
  - requires the collation of data from clinical trials, published literature, preclinical testing or traceable historical use
  - requires a competent evaluation of the data to establish the likely performance and safety in general use.



## Clinical Evidence

### Essential Principle 14 – Clinical Evidence of conformity

Every medical device requires clinical evidence, appropriate for the use and classification of the device, that demonstrates the device conforms with the applicable provisions of the essential principles



## Clinical Evidence (cont'd)

### Obtaining clinical data

- (1) The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of **either or both** of the following:
  - (a) **Clinical investigation data** in accordance with .....
  - (b) **A literature review** in accordance with .....
- (2) The manufacturer must ensure the clinical data obtained takes account of any medical device standard or conformity assessment standards that may apply to the device.



## Clinical Evidence (cont'd)

### Clinical investigation data

- (1) For section ....., *clinical investigation data*, in relation to a *kind of medical device*, includes:
- (a) documentation in relation to the design, approval, conduct and results of **each investigation** carried out by the manufacturer of the device in relation to the use of the device in or on a human body; and
  - (b) a record of qualitative or quantitative information obtained through observation, measurement, tests or any other means used to assess the operation of the device; and
  - (c) a **written report by an expert in the relevant field**, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.



## Clinical Evidence (cont'd)

### Literature Review

For section ....., a *literature review*, in relation to a *kind of medical device*, includes:

- (a) a compilation, prepared using a **documented methodology**, of **published literature** and **unpublished** scientific literature, both **favourable and unfavourable**, relating to medical devices of that kind, including the following:
  - i. expert opinion;
  - ii. information about the hazards and associated risks arising from the use of the device for its intended purpose, and the foreseeable misuse of the device;
  - iii. information about the performance of devices of that kind, including a description of the techniques used to examine whether devices of that kind achieve their intended purpose; and
- (b) a **written report by an expert in the relevant field**, being a report that contains a **critical evaluation of the compilation of literature** mentioned in paragraph (a).



## Clinical Evidence (cont'd)

### Evaluation of clinical data

- (1) The manufacturer of a kind of medical device must ensure that the clinical data is **evaluated** by **competent clinical experts**.
- (2) The manufacturer must ensure that clinical evidence **demonstrating** that the device **complies** with the applicable provisions of the **essential principles** is **documented** in writing.



## What is clinical data?

Can comprise:

- clinical trial data;
- reports of clinical experience;
- post-market reports; and
- adverse event database data.

Can also also draw on:

- risk analysis; and
- preclinical testing.

Brochures and testimonials are not forms of clinical data.



## What type of clinical data?

Case-by-case approach.

Requirements will vary according to the nature and clinical application of the technology used in or by the device.

Devices based on new or "unproven" technology and those that extend the intended purpose of an existing technology through a new clinical use, **must** be supported with clinical investigation data. Devices based on an existing technology and intended for an established and accepted use may rely on literature review.



## What is a critical evaluation?

**The data used for the clinical evaluation is not necessarily limited to clinical data.**

This will depend on the proposed use of the device and the history of the technology on which the device is based.

For a device based on well established technology, it may be possible to use well reasoned argument, based on the risk analysis and pre-clinical data **supplemented** by the post-marketing history of the device technology to satisfy the need for clinical evidence.

Most established Class I medical devices would be covered by this scenario.



## What is a critical evaluation?

Evaluation of the clinical data to determine if it is sufficient to demonstrate compliance with the relevant essential principles.

Should indicate how the applicable requirements of the essential principles for the clinical evaluation of the device have been met.

It must critically appraise the quality, completeness and clinical significance of clinical investigation data and/or literature-based data that are pivotal to establishing the performance and safety of the device.

Must be undertaken by a competent clinical expert in the field relevant to the intended use of the device.



## What is NOT clinical data

The following do not constitute clinical evidence:

- brochures;
- clinical study reports (unevaluated);
- literature compilations (unevaluated);
- summaries of the medical device's characteristics; and
- testimonials.



## Who is a “competent clinical expert”?

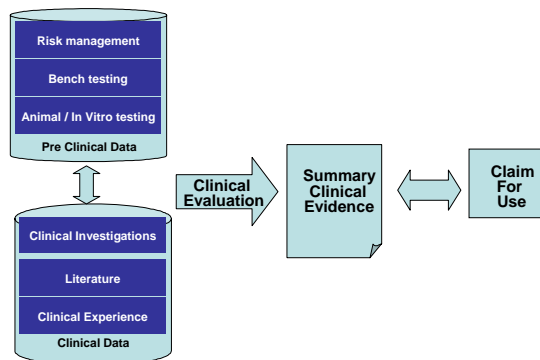
Must have qualifications and experience in the field relevant to the intended use of the device.

Does not always have to be medically qualified.

**Must sign and date the critical evaluation!!!**



## GHTF Ad-hoc Clinical Working Group - Clinical Evidence





## Full Quality Management System (QMS)



## Full Quality Management System (QMS)

- Usually requires:
  - Assessment of the quality management system for design, production, packaging, labelling and final inspection of the kind of device.
    - Usually based on an ISO13485 audit
  - For Class III and AIMD, conduct an examination of the design dossier.
  - Conduct surveillance audits.
  - Ensure that the Declaration of Conformity is in place and correct.
  - Assess the impact of any changes notified by the manufacturer.



## Full Quality Management System (Cont'd)

- The manufacturer is to
  - Implement a full quality management system including design control, production, packaging, labelling and final inspection
  - Make a Declaration of Conformity
  - Arrange for assessment and certification by the Agency
  - If a device is Class III or AIMD, arrange for a design examination and certification of the product by the Agency
  - Allow the Agency to conduct surveillance audits
  - Notify significant changes to the system or the product to the Agency
  - Establish and keep up to date a post-market monitoring, reporting and corrective action system



## Full Quality Management System (Cont'd)

- Objective
  - To demonstrate correct application of, and compliance with
    - the classification rules,
    - the essential principles, and
    - these conformity assessment procedures,

at each stage, from the design of the device until its final inspection before being supplied

Note - Regulatory requirements must be part of the specified requirements of the quality system



## Documentation

- Manufacturer's quality objectives
- Organisation and responsibilities
- Methods of monitoring the system
- Methods of monitoring the design process
  - Verification and validation
- Device description and design specifications
- Documentation of compliance with Essential Principles
- Evidence of Risk management activities in design and production
  - Risk management file – risk analysis
  - AS ISO 14971:2003 Clause 3.6



## Documentation (cont'd)

- Identification of
  - standards used, **or**
  - description of tests and criteria used to determine compliance with the EP's
- For systems, evidence the combination meets requirements
- Statement if
  - the device contains
    - a medicine
    - tissues, cells or substances of animal, microbial or recombinant origin
  - evidence of the tests performed on the device combination to establish both meet the relevant requirements
- Clinical evidence



## Documentation (cont'd)

- Information to be provided with the device
  - Labelling
  - Instructions for use
  - Re-processing instructions (if appropriate)



## Documentation (cont'd)

- Purchasing controls
- Production materials specifications, incoming test procedures and records
- Manufacturing Processes and procedures
- In-process and final inspection tests and procedures
- Post-production phase monitoring, and
- Correction actions



## Records



## Records

- QMS records
  - Device Master File (product specific)
  - Device History Record (device/batch specific)
- Documented evidence of compliance with the Essential Principles
- Details of changes to the system or the product



## Records

- Declaration of Conformity
- Details of the post production phase monitoring
- Any certificates, reports or correspondence issued by the subcontractors or the Agency



## Records

- Keep for at least 5 years after the manufacture of the last device to which the records relate
  - ISO 13485 requires two years or the lifetime of the device.
  - Distribution records for Class III, AIMDs and Implantable Class IIb's must be kept for 10 years
- Must make available to the Agency on request
- within 20 working days of the request



## Design Examination

- Class III or AIMD only
- Submit information on the design, the production processes and the intended performance including the documentation described above for examination by the Agency.
- If making a change to the design must consult with the Agency to determine if further assessment of the change is required.
- Documentation will be work products of a Quality Management System where the Essential Principles are an objective.



## Full Quality Management System - Changes

- Contact the Agency to discuss
  - Upgrading QMS to include design control
  - Arranging for processes or components to be out-sourced
  - If a condition on certification requires notification of changes
  - Adding new product ranges
  - Change to the design of a Class III or AIMD
  - Most changes should be dealt with by the QMS
- May need further certification by the Agency



## Surveillance Audits

- Conformity Assessment Certification Surveillance
  - certification only remains valid when periodically inspected
  - re-inspection is known as a surveillance audit
  - a program of scheduled surveillance audits is established for all manufacturers



## Surveillance Audits (cont'd)

- Where the Agency has issued a Conformity Assessment Certification
  - Routine, short notice and unannounced surveillance will be undertaken to ensure the manufacturer is continuing to apply the approved quality system
  - Audit cycle will be approximately 12-18 months.



## Declaration of Conformity

- Statement:
  - that the manufacturer has followed the relevant procedure; and
  - declares that the product complies with the relevant essential principles
- Format defined in the Rule
- May be prepared for a range or category of devices
- Must identify the range and the lot, batch or serial numbers that it covers else will be assumed to cover all products



## Declaration of Conformity (cont'd)

- Required for an application for entry into the Agency Product Licence Register
  - Must include the Global Medical Device Nomenclature codes (GMDN)
  - Must include the Unique Product Identifier for the products
- ... a small diversion ...



## 'Kind of Medical Device'

- A device is the same kind of device as another device, if it has the same
  - Manufacturer
  - Sponsor
  - Classification
  - **GMDN Code**
- For a Product Licence Register entry for Class IIIs and AIMDs
  - must also have the same **Unique Product Identifier (UPI)**
- For the manufacturers Declaration of Conformity
  - must state the **GMDN** and the **Unique Product Identifier (UPI)**
  - **regardless of Class**



## Unique Product Identifier

- Part 1, Rule ..... - Kinds of medical devices — other common characteristics
  - ... in relation to a Class III medical device, or Class AIMD medical device, a characteristic is the **unique product identifier** given to the device by its manufacturer **to identify the device and any variants**
  - **variant** means a medical device
    - the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device); or
    - any other variation approved by the Managing Director for the purposes of this definition, provided the variation does not change the intended purpose of the device.



## Post-Production phase monitoring

- Common element of all the Conformity Assessment Procedures
- to systematically review experience gained, post-production; and
- to implement appropriate means to apply any necessary corrective action in relation to the design or production.



## Post-Production phase monitoring (cont'd)

- Conformity Assessment Procedures require ...
  - a written undertaking from the manufacturer to notify the Agency of information received in the post-market phase related to problems with the device
  - documentation of the system for
    - reviewing experience gained in the post-production phase; and
    - the process for corrective action
  - that the Agency be notified of substantial changes:
    - to the quality management system; or
    - to the devices to which the system is to be applied



## Post-Production phase monitoring (cont'd)

- Manufacturer's are required to
  - Systematically review experiences gained after the device is supplied
    - be pro-active!
  - Information can come from many sources ...
    - expert user groups
    - customer surveys
    - customer complaints and warranty claims
    - service and repair information
    - literature reviews
    - user feedback, other than complaints
    - registers for device tracking and registration
    - user response during training programs



## Post-Production phase monitoring (cont'd)

- Manufacturer's are required to (cont'd)
  - implement corrective action if necessary in response to information received
  
  - notify the sponsor (and/or the Agency) of adverse events and near events



## Post-Production phase monitoring (cont'd)

The Agency must be informed of an event ....

- which has led, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in the state of health
  - any malfunction or deterioration in the characteristics or performance;
  - any inadequacy in the design, production, labelling, instructions for use, advertising material; or
  - any use in accordance with, or contrary to, the intended use;



## Post-Production phase monitoring (cont'd)

- Manufacturer must also inform the Agency of any ...
  - information relating to
    - any technical or medical reason for
      - a malfunction; or
      - deteriorationthat has led the manufacturer to take steps to recover devices that have been distributed
  - that is, any proposed recall action
    - overseas recall action if it has occurred prior to recall in the Trans Tasman market



## Post-Production phase monitoring (cont'd)

- And .....
  - information that indicates that the device does not comply with the Essential Principles
  - information that indicates that a certificate (other than one issued by the Agency) has been restricted, suspended, revoked or is no longer in effect
    - certificates may relate to compliance with the EPs or
    - application of the CAPs



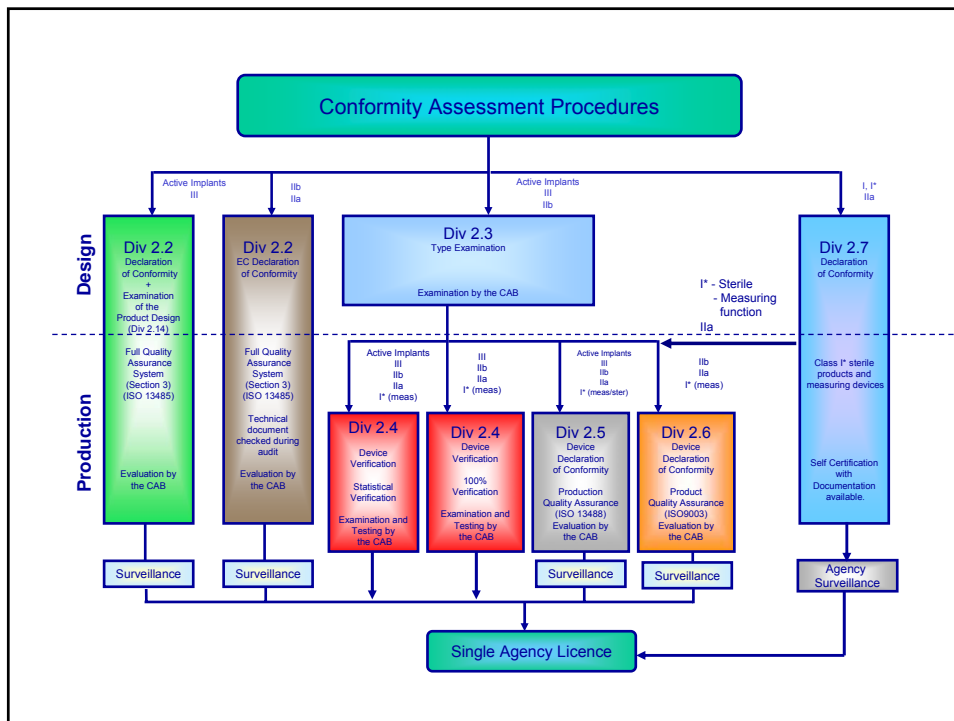
## Post-Production phase monitoring (cont'd)

- Prescribed timeframes
  - information related to an occurrence that represents a serious threat to public health
    - 48 hours after becoming aware of the event
  - information about an occurrence that led to death or serious deterioration in the health of a patient or user
    - 10 days after becoming aware of the event
  - “near miss” - might have led to death or serious deterioration in the health of a patient or user
    - 30 days after becoming aware of the event



## Post-market Monitoring Summary

- Manufacturers must
  - maintain a system to actively seek information from the marketplace
  - take corrective action when necessary
  - inform the Agency of substantial changes to the device or the QMS as a result of such action
  - report to the Agency (or sponsor) when
    - an adverse event has occurred, and
    - the device is associated with the event, and
    - the event has led to death or serious injury, or might have led to a death or serious injury.





In summary -



Schedule 2, Division 2.2, Rule 2.14– Design Examination

Technical  
Documentation

Design Dossier:

- ▶ Description of device
- ▶ Intended purpose
- ▶ Declaration of Conformity
- ▶ Details of medicinal substances and/or materials of non-viable animal origin
- ▶ Evidence of compliance with **Essential Principles** including:
  - Design specifications including standards and procedures
  - Details of verification processes (bench testing)
  - Other procedures (eg: manufacturing methods, reviews of complaint history or manufacturer's experience with device)
  - Risk analysis
  - Labelling & Instructions for Use
  - Clinical evidence

Quality System  
Requirements

None



**Schedule 2, Division 2.2 – Full Quality Assurance**

**Technical Documentation**

Technical File:

- ▶ Description of device
- ▶ Intended purpose
- ▶ Declaration of Conformity
- ▶ Evidence of compliance with **Essential Principles** including:
  - Design specifications including standards and procedures
  - Details of verification processes (bench testing)
  - Other procedures (eg: manufacturing methods, reviews of complaint history or manufacturer's experience with device)
  - Risk analysis
  - Labelling & Instructions for Use
  - Clinical evidence

**Quality System Requirements**

For design, production, packaging, labelling and final inspection  
**All clauses** of ISO 13485:2003



**Schedule 2, Division 2.3– Type Examination**

**Technical Documentation**

Technical Documentation:

- ▶ Description of device
- ▶ Intended purpose
- ▶ Specifications, drawings and circuit diagrams
- ▶ Details of medicinal substances and/or materials of non-viable origin
- ▶ Evidence of compliance with **Essential Principles** including:
  - Description of manufacturing methods (including sterilisation)
  - Standards, procedures and specifications
  - Specification of materials
  - Risk analysis
  - Labelling & Instructions for Use
  - Bench testing
  - Clinical evidence

**Quality System Requirements**

Schedule 2, Division 2.4, 2.5 or 2.6



Schedule 2, Division 2.4 – Device Verification

<p>Technical Documentation</p>	<ul style="list-style-type: none"> <li>▶ Either:             <ul style="list-style-type: none"> <li>– Technical documentation required for Division 2.3 – Type Examination; or</li> <li>– Technical documentation required for Division 2.7 – Declaration of Conformity (not requiring assessment by the Agency)</li> </ul> </li> <li>▶ Evidence that manufactured device complies with ‘type’</li> <li>▶ Description of manufacturing methods including inspection &amp; testing</li> </ul>
<p>Quality System Requirements</p>	<p>None</p>



Schedule 2, Division 2.5 – Production Quality Assurance

<p>Technical Documentation</p>	<ul style="list-style-type: none"> <li>▶ Either:             <ul style="list-style-type: none"> <li>– Technical documentation required for Division 2.3 – Type Examination; or</li> <li>– Technical documentation required for Division 2.7 – Declaration of Conformity (not requiring assessment by the Agency)</li> </ul> </li> <li>▶ Declaration of Conformity (for class AIMDs, III and IIb devices only)</li> </ul>
<p>Quality System Requirements</p>	<p>For production &amp; final inspection (no design control) ISO 13485:2003 <b>except clause 7.3 Design and Development</b></p>



Schedule 2, Division 2.6 – Product Quality Assurance

<p>Technical Documentation</p>	<ul style="list-style-type: none"> <li>▶ Either:             <ul style="list-style-type: none"> <li>– Technical documentation required for Division 2.3 – Type Examination; or</li> <li>– Technical documentation required for Division 2.7 – Declaration of Conformity (not requiring assessment by the Secretary)</li> </ul> </li> <li>▶ Declaration of Conformity (for Class IIb devices only)</li> </ul>
<p>Quality System Requirements</p>	<p>For final inspection &amp; testing of device (no production or design control)</p> <p>ISO 13485:2003 <b>except clauses:</b></p> <ul style="list-style-type: none"> <li>– 7.3 <i>Design and Development</i></li> <li>– 7.5.2 <i>Validation of processes for production and service provision</i></li> </ul>



Schedule 2, Division 2.7 – Declaration of Conformity (Self assessment procedures)

<p>Technical Documentation</p>	<p>Technical File</p> <ul style="list-style-type: none"> <li>▶ Description of device</li> <li>▶ Intended purpose of device</li> <li>▶ Specifications, drawings and circuit diagrams</li> <li>▶ Description of sterilisation method (if applicable)</li> <li>▶ Declaration of Conformity (for Class IIa, I, I* (meas/ster) devices only)</li> <li>▶ Compliance with <b>Essential Principles</b> including:             <ul style="list-style-type: none"> <li>– Standards, procedures and specifications</li> <li>– Specification of materials</li> <li>– Risk analysis</li> <li>– Labelling &amp; Instructions for Use</li> <li>– Bench testing</li> <li>– Clinical evidence</li> </ul> </li> </ul>
<p>Quality System Requirements</p>	<p>None</p>



## The Agency's Role



## Conformity Assessment

- The Agency is to be satisfied that
  - an appropriate conformity assessment procedure has been followed;
  - the essential principles have been demonstrated for the device.



## Conformity Assessment Certification

- Specific manufacturers
  - All New Zealand and Australian manufacturers, and some specific devices are required to have a Conformity Assessment Certificate (except Class I devices)
    - if the selected procedure requires assessment by the Managing Director
    - if the regulations require a certificate for a Agency Product Licence Register entry
    - evidence that regulatory requirements have been assessed



## Conformity Assessment Certification

- Specific devices
  - medical devices that contain tissues of animal origin that have been rendered non-viable
    - (other than those that are intended to come into contact with intact skin only);
  - medical devices that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body;



## Conformity Assessment Certification

- Specific devices (cont'd)
  - medical devices incorporating **stable derivatives of human blood or human plasma** that are liable to act on the human body in a way that is ancillary to the device;
  - medical devices that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, **might be considered to be a medicine** that is intended to act on a patient in a way that is ancillary to the device.



## Conformity Assessment Certification

- The Agency is to consider **some or all** of the evidence of conformity to the Essential Principles and Conformity Assessment Procedures
  - either through a full or abridged initial assessment
  - business rules used to determine if assessment can be shortened on the basis of information known to the Agency
  - the Agency must be satisfied that requirements have been met



I'm getting there, but .....  
now translate that for class I devices !!



### When is it a Class I medical device

- must fit the definition of a medical device
- must be classified in accordance with the Classification Rules
  - non-invasive
  - invasive through a body orifice and for transient use (less than 60 minutes)
  - for short term use (1 hour to - 30 days) in the oral cavity
  - reusable surgical instrument
  - active medical device
- **UNLESS ANOTHER RULE APPLIES!!!!**



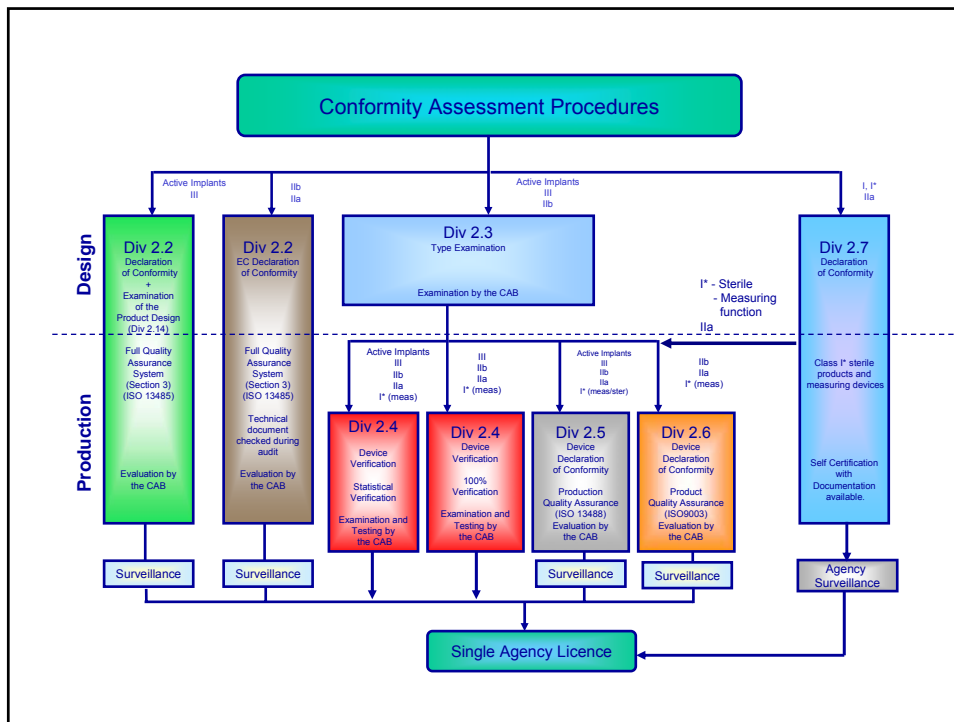
## Class I medical devices

- must meet the Essential Principles
- manufacturers must follow the appropriate conformity assessment process
- must have appropriate technical file documentation
- manufacturers must have a Declaration of Conformity
- must have post market corrective action and vigilance procedures in place
- **HOWEVER, no involvement by the Agency required**
- sponsors must apply for a licence which will enter the product on the Agency Product Licence Register
- sponsors must make the required certification.



## The Rule - Class I devices

- Schedule 2, Part 2, Division 2.1 of the Medical Devices Rule set out the requirements for application of the conformity assessment procedures
- Schedule 2, Part 2, Division 2.7 specifies the conformity assessment procedures relevant to Class I medical devices
- **Minimum** procedure that must be applied is the declaration of conformity - self-assessment



## The Rule - Class I devices

- Division 2.7 **cannot** be used alone for Class I devices that are supplied as sterile or that have a measuring function.
- For these devices, Division 2.7 \*\* must be used in conjunction with one of the other CAPs, and the Agency must be involved in the assessment of the application of the CAPs.

\*\* Production Quality Assurance associated with sterilisation of verification of the measuring function of the device



## Class I sterile or measuring ....

- Sterile
  - Production QMS
  - Validation in accordance with Conformity Assessment standards for sterilisation
    - EN or ISO standard appropriate to method of sterilisation
  - Division 2.7 DOC
  
- Measuring
  - Production QMS
  - Product QMS – final test & release
  - Product verification – batch verification or 100% verification
  - Division 2.7 DOC



## Division 2.7 – Self Assessment Procedures

- 2.45 - Overview
- 2.46 - References to kinds of medical devices
- 2.47 - Implementation
- 2.48 - Required technical documentation
- 2.49 - Post-marketing system
- 2.50 - Declaration of conformity
- 2.51 - Records



## Implementation

- requires the manufacturer to prepare technical documentation in a form that allows the Agency to assess compliance with the EPs, classification rules and the application of the CAP.
- Details information that must be held, in writing, in relation to the details of the company and the devices manufactured.
- Requires a written undertaking to notify the Agency of adverse events, problems or recall of the devices.

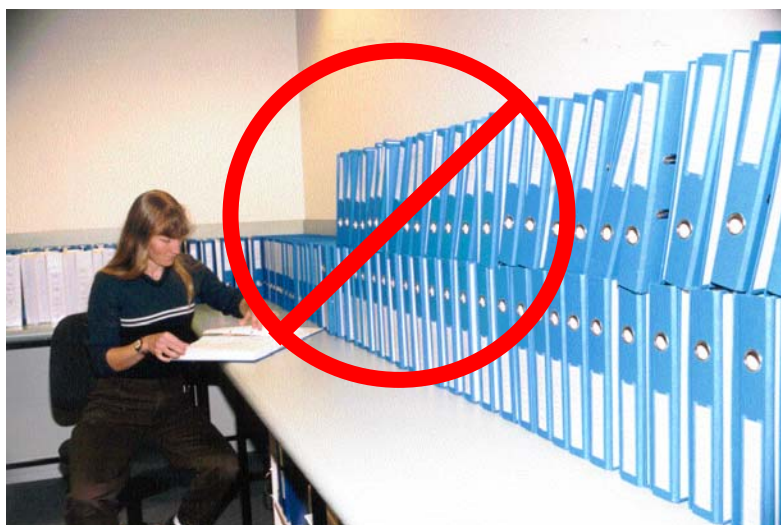
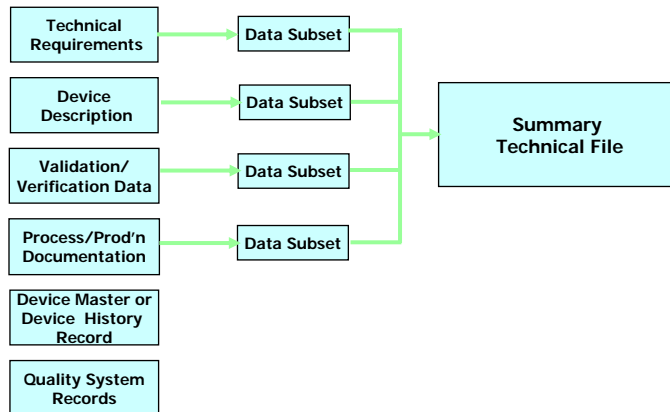


## Documentation Elements

- Elements of a Quality System & Quality Manual
- Device specific elements
  - Design inputs
    - specs, risk analysis, drawings, .....
  - Design outputs – validation, test data, reports ....
  - Manufacturing Documentation
    - Specs, procedures, in-process testing, release spec's .....
    - Systems/procedure pack specific declarations if appropriate
  - Clinical Evidence
  - Labelling, Instructions for use
  - Post-production monitoring
  - Declaration of Conformity



## Technical Documentation





Now let's really dive into it !!

Time for Questions .....

