Registration of Medical Devices

AHRDMA,VASM, ARCS Melbourne June 2017

From the *Therapeutic Goods Act 1989*...

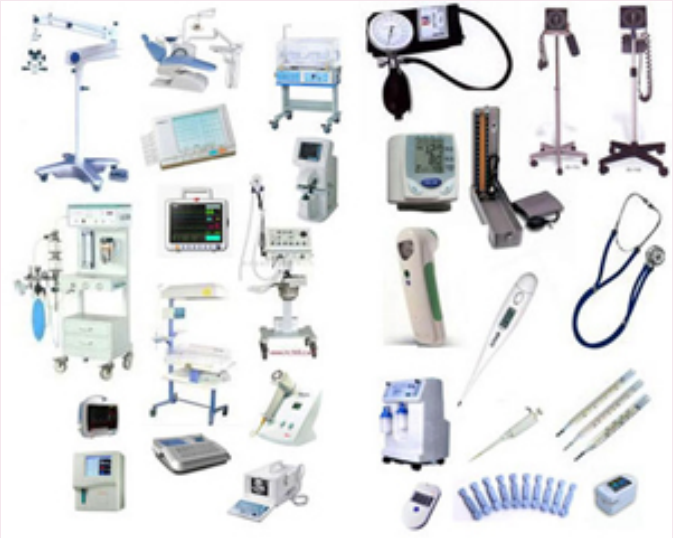
41BD What is a medical device

1. A medical device is:
    a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
        i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
        ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
        iii. investigation, replacement or modification of the anatomy or of a physiological process;
        iv. control of conception;

    and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

    b. an accessory to such an instrument, apparatus, appliance, material or other article.

What are Medical Devices



Medical devices:

- are used on humans
- have therapeutic benefits
- do NOT have a pharmacological, immunological or metabolic action
- generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body
- includes in vitro diagnostic devices since 2007

Major Differences between Drugs and Devices

Drugs

- Long product Life Cycle
- Based on chemistry and pharmacology
- Safety and Efficacy
- Clinical Trials
- Local and Systemic Side effects
- Drug interactions
- Development based on large populations

Devices

- Short product Life Cycle
- Based on engineering
- Safety and Performance
- Clinical Evaluation – on patient and user
- Side effects, effect on user, near miss
- Device malfunction
- Development based on limited population

Regulation of Medical Devices

- Medical Devices have been regulated since late 1970s
- Regulated under the Act and Regs from 1991 as therapeutic devices
- New Legislation Oct 2002
  - Harmonised to GHTF recommendations
  - Incorporated MRA with EU
- Review in 2016

CE

How does a Medical Device get registered

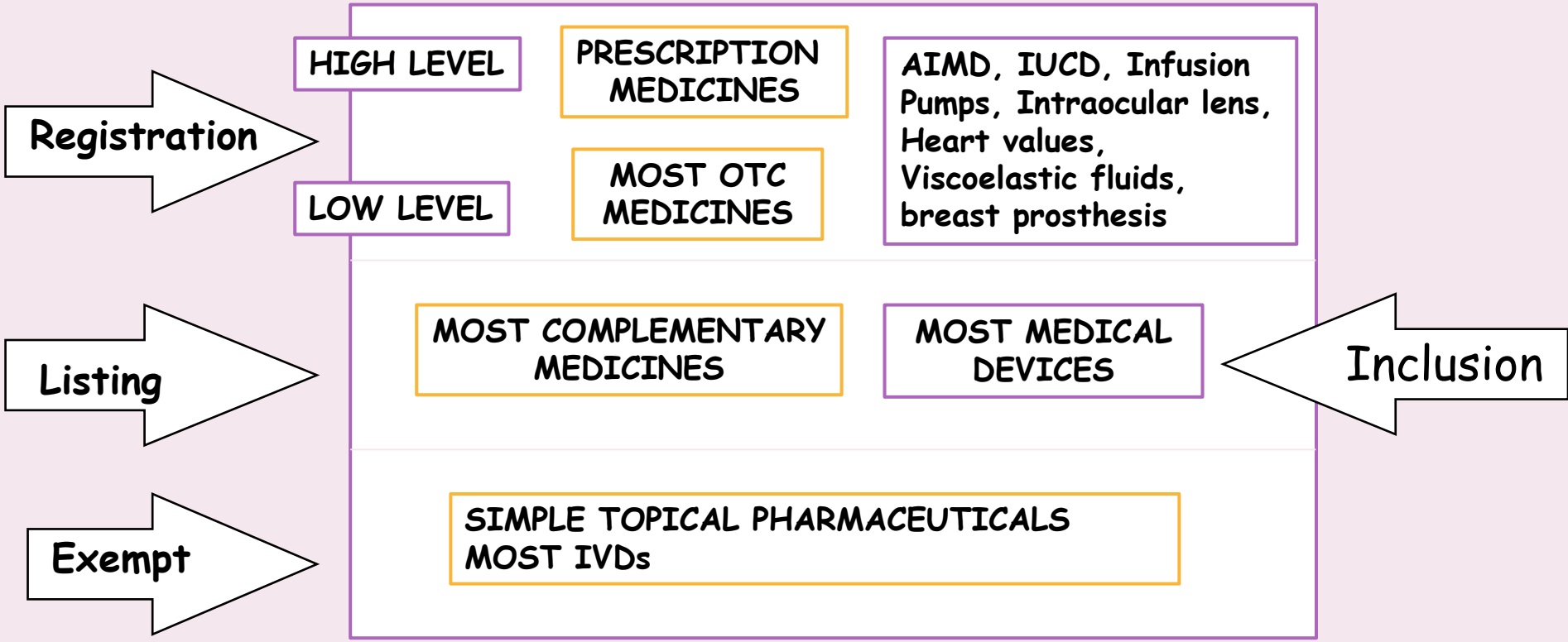
An Australian sponsor makes an application to TGA to include the device on the ARTG so that it can be supplied in Australia

The applicant must have information available to demonstrate the quality, safety, and performance of the device

The product must undergo an evaluation (conformity assessment) procedure to comply with the Essential Principles

May be done in Australia (TGA) or in Europe (NB)

Approval for Supply
Entry on Australian Register of Therapeutic Goods



www.ebs.tga.gov.au

Regulatory Philosophy

- Regulates sponsor activity covering importation, manufacture, export and supply
- Risk based approach – level of control is commensurate with product risk
- Greater emphasis on post-market surveillance
- Separates manufacturer from sponsor
- Manufacturer declares compliance to Australian requirements
- Sponsor expected to have a direct relationship to manufacturer

Regulatory Process in Australia

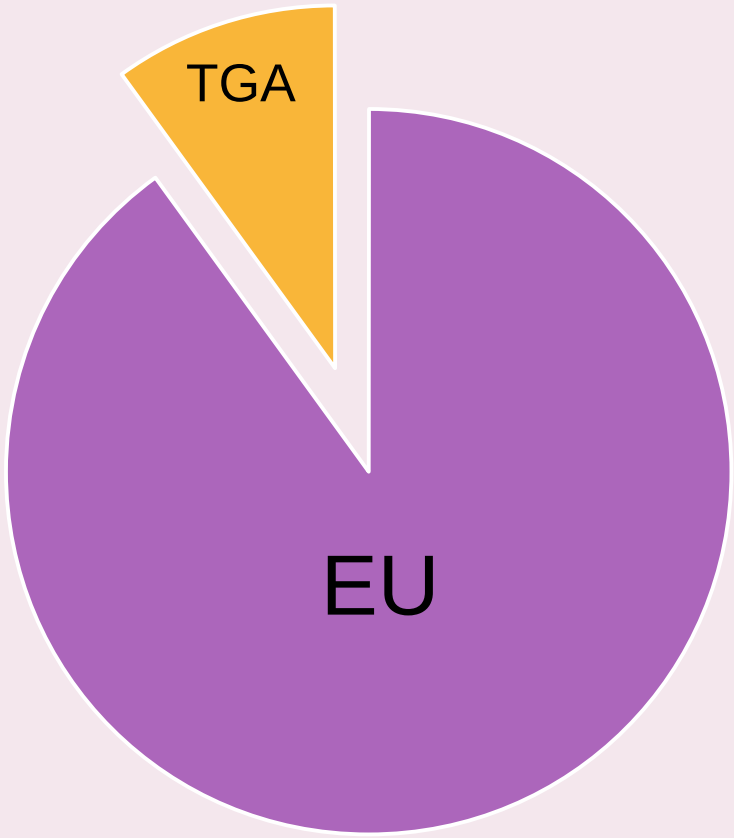
Choice of procedure

- Full assessment in Australia
  - Same as assessment by European Notified Body
  - Takes no regard to overseas approval
    - Apply for conformity assessment
    - Apply for inclusion of product on register
- Abridged Assessment in Australia
  - Recognises approval in Europe
  - Documentation of conformity to Australian requirements
    - Notify Manufacturer - provide CE certificate
    - Apply for inclusion of product on register

Medical Devices in Australia

- Majority of devices are supplied in Australia under EC certification

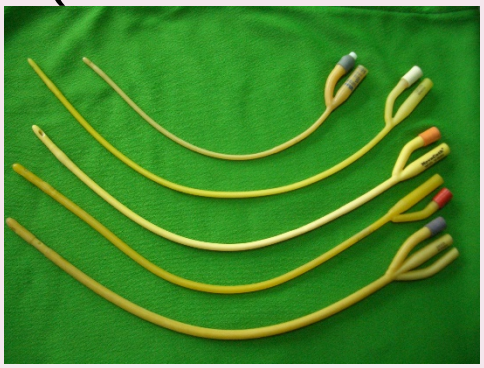
- Some high risk devices must be evaluated by TGA for conformity assessment:
  - Product containing animal, microbial or recombinant material
  - Products containing blood or blood products



Grouping of products

A medical device is considered to be of the “same kind” (ie can be grouped) as another medical device if they have to same:

- Sponsor, and
- Manufacturer, and
- Medical device classification; and
- Device nomenclature system code (GMDN), and
- (same intended purpose)



Classification of Medical Devices

- A classification system based on the inherent risks of types of products.
- Determined by the manufacturer based on:
  - The intended purpose of the product
  - A set of classification rules
- Set out in Schedule 2 of Regulations

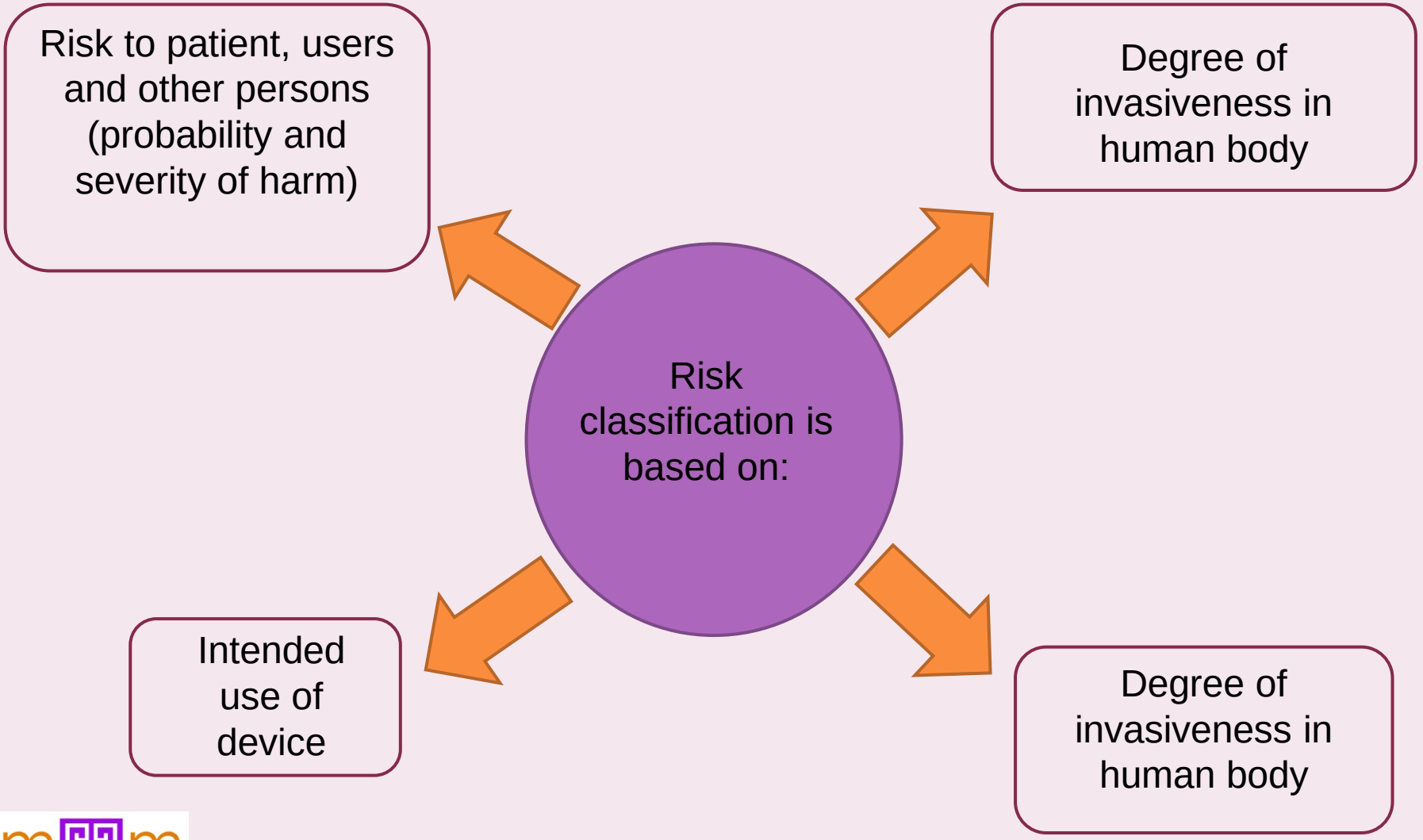
Classification of Medical Devices

High risk

- AIMD Active Implantable Medical Device — Implantable pacemakers
- Class III — Biological heart valve, absorbable sutures
- Class IIb — Insulin pens, metal screws
- Class IIa — SU Sterile surgical instruments, syringes, needles, IV cannulas
- Class Is - sterile — Sterile adhesive dressing
- Class Im - measuring function — Thermometer, scales
- Class I — RU surgical instruments Non invasive and not covered by another rule

Low risk

Classification - Risk Based Approach



How does Classification Relate to Conformity Assessment ?

- The classification determines the conformity assessment procedures which can be used by the manufacturer
- High risk products need more stringent conformity assessment
- Low risk products (Class I) self assessed

Conformity Assessment – Procedures

Part 1
Full
Quality Assurance

Design &
Development

Production Validation

Final Inspection

Part 4
Production
Quality Assurance

Production Validation

Final Inspection

Part 5
Product
Quality Assurance

Final Inspection

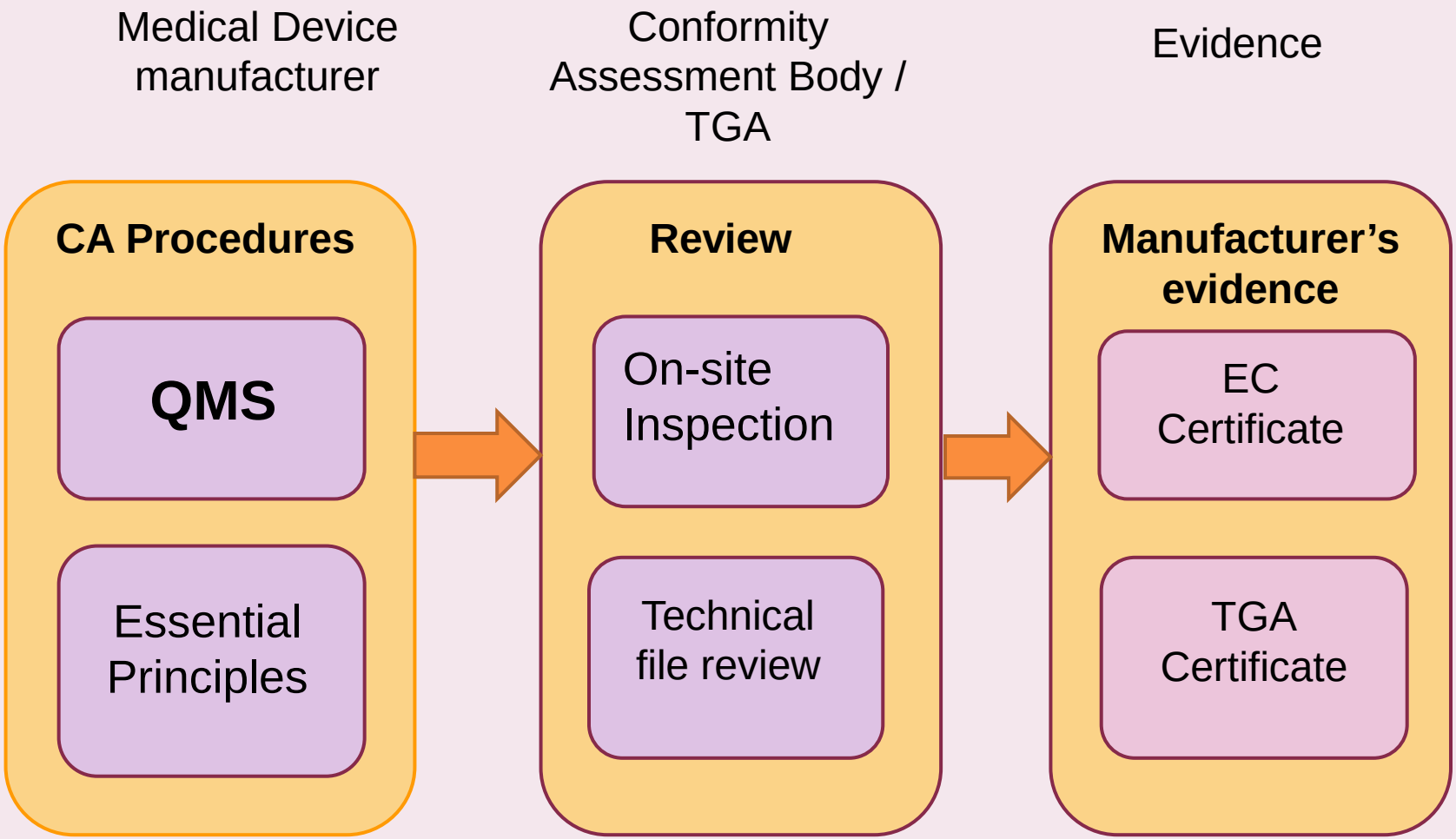
Conformity Assessment - Elements

The Conformity Assessment Procedures require the following elements:

Quality Management System	QMS in compliance with ISO 13484 (except Class 1)
Technical Documentation	Technical documentation for design of the device Evidence of compliance with Essential Principles
Declaration of conformity	Declaration that the device complies with the regulatory requirements
Post market surveillance	Surveillance of product performance in the market

TGA 2015

Conformity Assessment basics



TGA 2015

Essential Principles

General Principles

1. Use not to compromise health and safety
2. Design and construction to conform with safety principles
3. Must perform the way the manufacturer intended
4. Must be designed and manufactured for long-term safety
5. Must not be adversely affected by transport or storage
6. Benefits must outweigh undesirable effects

Clinical Evidence

EP 14

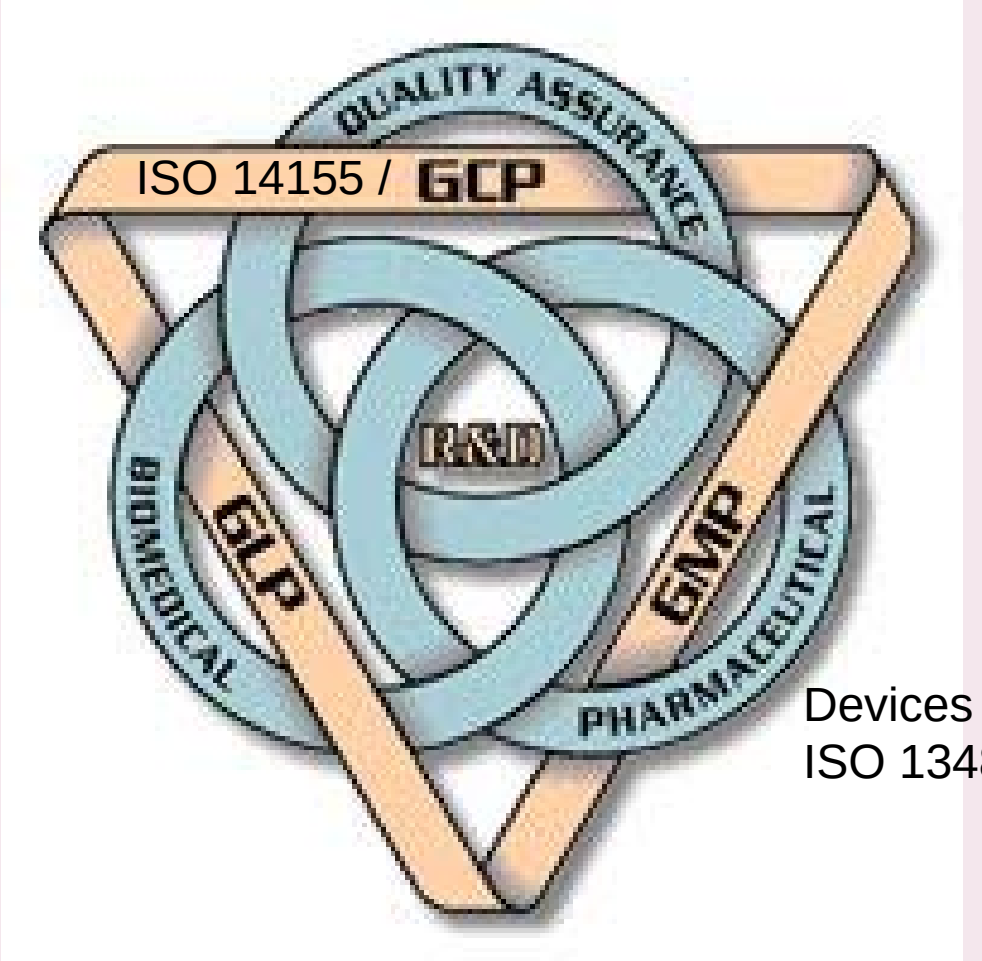
"Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles"

Clinical evidence may be obtained from:

- Clinical investigation data, or
- Literature review

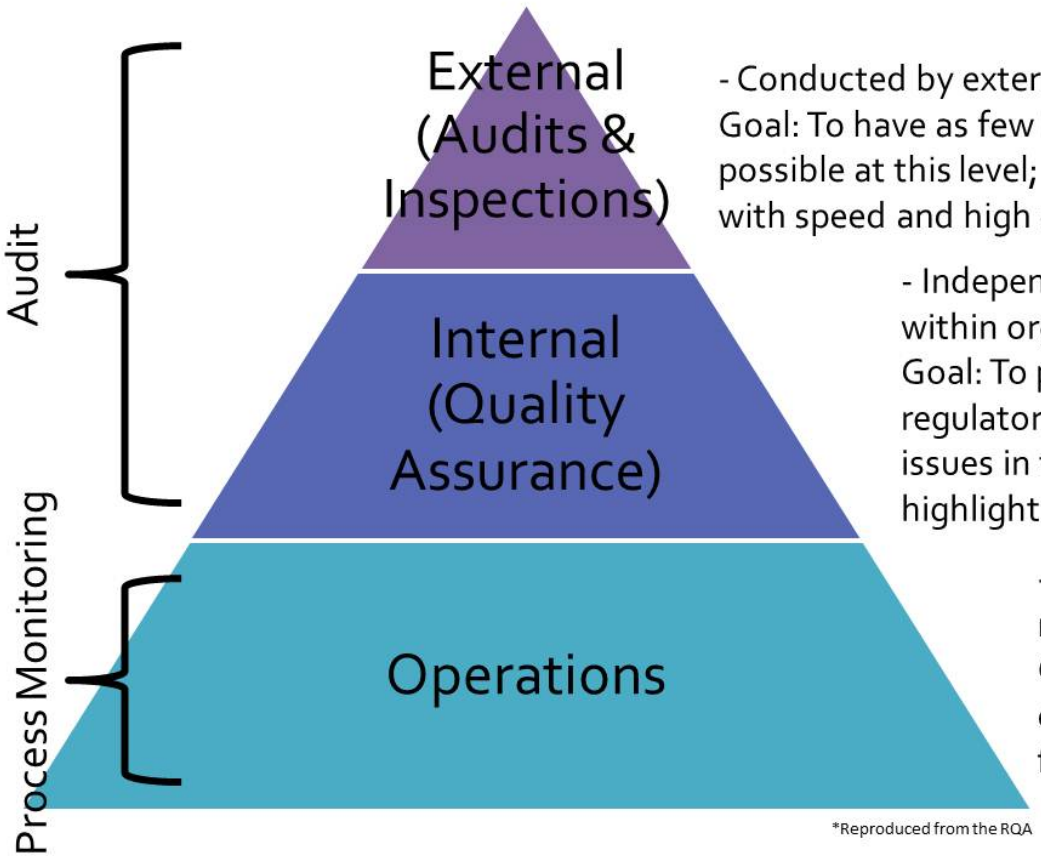
Clinical evidence must be critically evaluated by competent clinical experts in the relevant field. (Report + CV of expert)

QMS



Devices -
ISO 13485

Quality Management



- Conducted by external parties
Goal: To have as few issues as possible at this level; fix issues with speed and high quality

- Independent audits of key risk areas within organization
Goal: To prevent external auditor and regulatory observations; uncover issues in following procedure and highlight risks

- Quality Control Checks as part of normal processes
Goal: Use information to continuously improve and prevent future issues in audits