ASEAN-US Technical Assistance and Training Facility

Medical Device Regulation

A Training Syllabus for ASEAN
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Introduction

The ten member economies are committed to the introduction of a common regulatory framework for the regulation of medical devices by 2015.

That framework will be based on the regulatory model developed by the Global Harmonisation Task Force (GHTF) over the 17 years.

Based on the regulatory model implemented in Europe in 1993, the GHTF framework has now been adopted as the basis for regulation in four of the five founding economies of the GHTF, and is in various stages of adoption in many other economies around the world.

Co-ordination of this process is being facilitated by the Medical Devices Products Working Group (MDPWG), created in August 2004 under the auspices of the ASEAN Consultative Committee for Standards and Quality (ACCSQ).

The MDPWG is one of 12 working groups of the ACCSQ. The MDPWG is charged with developing the ASEAN Medical Device Directive (AMDD), with the aim of publishing a draft of the document by 2012 and having the regulatory intent of the Directive introduced into national law of the member economies by 2015. The regulatory framework introduced by the Directive will be based on the principles for medical device regulation developed by the Global Harmonisation Task Force, and already in place in Australia, Canada, Europe and Japan.

History

Successful introduction and implementation of the Directive will require Regulatory Agencies of each of the ASEAN member countries to have a thorough understanding of both the underlying philosophies of the GHTF framework, and basic building blocks which, when integrated, provide a robust and adaptable framework aimed at ensuring citizens of each of the ASEAN member countries have timely access to safe and effective medical devices.

Training workshops

The MDPWG has met 13 times since its formation, and prior to each of those meetings, has generally hosted a two day training workshop for industry and regulatory officials from participating economies.
These workshops have been facilitated by the MDPWG, with the support of the ASEAN-US Technical Assistance and Training Facility.

To date, trainers for the workshops have consisted primarily of volunteers from within ASEAN member economies, supported by invited speakers from both the industry and regulatory agencies of the GHTF members. These workshops have generally been wide ranging in their topics, with various elements of the GHTF frameworks explored, but because of the heavy reliance on, but limited availability of, invited international speakers from various countries, it has been difficult to develop, or adopt a co-ordinated approach to training within the region.

**More recent experience**

In late 2010, in the lead up to the 11th MDPWG meeting in Manila, a focused two day workshop was held with a single theme, aimed at enhancing understanding of medical device classification, and the ‘downstream’ implications through the regulatory process, of classification. Attendance at this workshop was limited to officers from regulatory agencies.

With 18 attendees from 6 countries, the workshop was facilitated by Mr Noordin Azhari of the ASEAN-US TATF and presented by Mr Michael Flood in association with Nathan Associates Inc. Mr Flood is an international expert on the regulation of medical devices having worked in the field of medical devices for over thirty years, the last seventeen with the Therapeutic Goods Administration in Australia, and was a member of GHTF study groups, both pre and post market, for over 12 years.

The workshop was presented in an interactive format, with presentations on a number of topics, outlining –

- The definition of a medical device – understanding what is, and what is not, a medical device based on that definition
- An outline of the fundamental differences between pharmaceuticals and medical devices, and understanding why the regulatory principles are different for each market sector, including a discussion of ‘combination products’ (ie medical devices containing a medicinal element, or vice versa)
- A walk through of the GHTF Classification ‘Rules’, with an explanation of their rationale, and discussion and exhibition of various example devices
- Hands on training by way of homework and interactive discussions over a series of example devices and device related literature
This training was supplemented with additional presentations aimed at explaining the ‘downstream’ impact the classification of a medical device has on subsequent regulatory processes prior to product, including –

- Linking of classification to use of appropriate conformity assessment procedure by the device manufacturer
- Linking of classification to depth and content of the Common Submission Technical Dossier, developed by the manufacturer of the device
- The role of Conformity Assessment Bodies and National Regulators in premarket conformity assessment
- Considerations in registration of manufacturers, importers and distributors, and listing of medical devices on National Registers

This workshop was the first of two requested by the ASEAN Member States, specifically to address the classification rules for medical devices, as developed by GHTF and incorporated into the ASEAN Medical Device Directive.

The second workshop, following the same format, was held in late June 2011 in Kuala Lumpur and focused primarily on the needs of industry members and their staff in understanding the GHTF classification rules.

Although initially intended to be limited to 50 participants, with strong interest demonstrated once advertised, over 100 participants from eight countries attended the two days.

Feedback from the attendees at both workshops calls strongly for further workshops, on this and other topics to assist them in better understanding the principles of the GHTF regulatory framework. Many topics for future workshops were requested, and the following is provided as an exemplar, but not comprehensive, list of requested topics –

- Cases studies of examples and experience of other countries in the region in establishing regulatory frameworks
- More case study examples of classification, particularly of ‘combination products’
- ISO 13485 and Quality management systems
- Common Submission Technical Dossier (CSDT) and its contents
- Risk analysis
- Product verification and validation
- Clinical evidence – both the generation of by the manufacturer, and the assessment of by the regulatory agency
• Terminologies and definitions relevant to the area of medical device regulation
• Detailed workshops on conformity assessment procedures and the CSDT
• Elements of regulation for In-vitro Diagnostic Devices
• Establishment of a Register
• Postmarket activities such as complaint handling, recall activities, etc

A full list of suggested topics from participants at the workshops can be found at Attachment 1.

It is evident from feedback from participants at both workshops, that there is a pressing need to provide comprehensive training to regulatory agencies in the lead up to full implementation of the AMDD by 2015.

**A strategic and structured approach to training**

Prior to the 11th meeting, held in Siem Reap in April of 2011, informal discussion was held regarding the development of a more formal and structured training program, delivered in the years leading up to formal introduction of regulations in each member country.

At that meeting, a draft list of proposed topics was presented, along with an invitation for members and attendees to put forward further topics or identified needs for consideration in the development of such a program.

This syllabus captures topics and needs identified to date. It is presented in a ‘modular’ form, giving the ability to add further topics as they are identified.

It is structured around the GHTF Regulatory Model document published in April 2011. This document demonstrates the linkages between the individual documents produced by the five Study Groups of GHTF since their inception and aims to demonstrate the regulatory model as applied to the product life cycle of a medical device as displayed in figure 1.
It is a fundamental principle of the GHTF framework that medical devices are designed and manufactured within a Quality Management System (with the exception of class A medical devices). An appropriate QMS has been described by SG 3 of the GHTF as one compliant with the requirements of \textit{ISO 13485:2003 – Medical Devices – Quality management systems – Requirements for regulatory purposes}. Also described by SG 3 is an appropriate risk management framework as one in compliance with the \textit{ISO 14971:2007 – Medical Devices – Application of risk management to medical devices}.

Documents produced to date by SG 3 include –

- \textit{Quality Management System - Medical Devices - Guidance on corrective action and preventive action and related QMS processes}
- \textit{Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers}
- \textit{Implementation of Risk Management Principles and Activities Within a Quality Management System}
- \textit{Quality Management Systems - Process Validation Guidance}

In order to ensure consistency of audit practices guidance on audit planning and reporting is provided in documents produced by SG 4.

Documents produced to date by SG 4 include –

\textit{Medical Device Regulation – A Training Syllabus for ASEAN – V1_0}
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 4: Multiple Site Auditing
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 5: Audits of Manufacturer Control of Suppliers
• Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements - Supplement 2)

The focus of SG1 activities and published documents is on the process of product realization (product design through to product manufacturing, premarket regulatory compliance and market entry). Guidance of clinical the establishment, documentation and review of clinical efficacy is provided by SG 5.

Documents produced to date by SG 1 include –

**Product Realisation**

• Information Document Concerning the Definition of the Term “Medical Device”
• Essential Principles of Safety & Performance of Medical Devices
• Role of Standards in the Assessment of Medical Devices
• Labelling for Medical Devices
• Principles of Medical Devices Classification
• Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
• Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
• Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices
• Principles of Conformity Assessment for Medical Devices
• Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

**Placing on the market**
• Definition of the Terms Manufacturer, Authorised Representative, Distributor and Importer
• Registration of Manufacturers and other Parties and Listing of Medical Devices

Documents produced to date by SG5 include –

• Clinical Evidence – Key Definitions and Concepts
• Clinical Evaluation
• Clinical Investigations
• Reportable Events During Pre-Market Clinical Investigations
• Post Market Clinical Follow-Up Studies

Ensuring product safety, however goes beyond just ensuring a safe medical device is placed on the market. Manufacturers, regulators and authorised representatives must have processes and procedures in place to allow monitoring of product performance while a medical device is on the market and remains in clinical use. There must also be mechanisms for collecting information relating to adverse events which may be associated with the use of a medical device, and ensuring this information is forwarded to the manufacturer and the regulatory authority. SG2 has published guidance in these matters.

Documents produced to date by SG2 include –

• Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices’
• Medical Devices Post Market Surveillance: Content of Field Safety Notices
• Review of Current Requirements on Postmarket Surveillance
• Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

Training beyond the GHTF model

Extending beyond the GHTF model in some jurisdictions, is the use of external bodies, referred to as Conformity Assessment Bodies (CABs) whose role is to undertake the assessment of the manufacturer’s application of a relevant conformity assessment procedure to their Quality Management System and associated medical devices.
Some jurisdictions may choose to undertake such assessments themselves, others may choose to engage a CAB or CABs, to undertake these assessments on their behalf. Others may adopt a possible ‘half-way option’ in which the QMS of the manufacturer is assessed by a CAB, with the device being assessed by the regulatory agency.

These considerations indicate the need for the training curricula to extend beyond the basics of the GHTF model, to incorporate elements to assist the regulatory authority to –

- Examine of the options to allow determination of the best model to suit their circumstance
- Delineate responsibilities between the RA and the CAB(s)
- Assess the suitability of a CAB to act on their behalf
- Assess and monitor the activities of the CAB(s)

It should also be noted that, although the GHTF model is extensive, it is not complete, and there are many elements a Regulatory Authority must consider in implementing their regulatory framework. Although not exhaustive, an exemplar list of topics includes –

- Promotion and advertising of products
- Import/export procedures
- Ethics committee oversight of clinical investigations
- Maintenance, selection, and/or procurement of medical devices
- Use of medical devices
- Disposal of medical devices at the end of useful life
- Environmental considerations
- Refurbishment or reprocessing of medical devices
- Methods of enforcing regulations

These topics will not be included in this first version of the curriculum, but will be canvassed among attendees at the MDPWG meeting to determine interest and relevance.

It should be noted that other relevant topics may also be requested for inclusion at that time.

Accordingly, this document should be considered ‘dynamic’ and subject to change depending on member economies wishes for included subject material.
Curriculum structure

The curriculum is divided into XXXX sections, broadly aligned with the five Study Groups, the Steering Committee of GHTF and the ‘out of GHTF scope’ elements previously identified.

The global model

- Interaction of the guidance produced by all study groups

Premarket

- Establishment and implementation of a Quality Management System
- The product life cycle, beginning with design control
- QMS documentation requirements
- Risk management
- Classification
- Essential Principles of Safety and Performance
  - Labelling, IFU
  - Clinical evidence
- Use of Standards
- The conformity assessment process
- The STED/CSDT

Assessment of Conformity Assessment processes

- Options for the RA/CAB
- Quality management systems
  - ISO 13485
  - Assessment
- Roles and responsibilities of
  - Regulatory Authority
  - CAB
  - Manufacturer
  - Authorised representative
  - Importer

Placing on the market

- Roles and responsibilities of
  - Regulatory Authority
- CAB
- Manufacturer
- Authorised representative
- Importer
- Distributor

- Establishment of registers of
  - Responsible entities
  - Medical devices

**Postmarket**

- Establishment of postmarket surveillance systems for
  - Manufacturers
  - Authorised representatives
  - Regulatory Authorities,
- Incorporating –
  - Incident reporting
  - Vigilance monitoring
  - Incident investigation
  - Information sharing (NCAR/SADS)
  - The product improvement cycle

The core elements of the curricula, identified above, will be further broken down into subjects, as appropriate.

For example the STED/CSDT has two facets-
- Documentation and compilation of the STED by the manufacturer, for submission to the Regulatory Authority
- Assessment, or what to look for, in the review of the STED, by the Regulatory Authority

In turn, these requirements can be further reduced to provide basic information on topics such as
- Process verification and validation
- Engineering aspects and electrical safety
- Biocompatibility of materials
- Biological Safety
- Sterilisation
• Software verification and validation
• Verification of the performance of an ancillary medicinal component
• Pre-clinical (animal) studies
• Clinical evidence

Attachment 2 to this document provides more detail in relation to suggested breakdown of the core elements subject matter, along with detail, including –

• Core topic group
• Subject heading
• Learning element and sub-element
• Suggested pre-requisites
• Key learning objectives
• Duration
• Practical Exercises
• Reference material
• Assessment
• Intended audience

Training for different sectors

Much of the training material to be developed, will be common for both industry members and official of Regulatory Authorities, and can be delivered to mixed audiences.

However, some elements will be aimed primarily at one sector or the other – for example the assessment and partnering process between a Regulatory Authority and a CAB or CABS.

Targeted audiences will be detailed in the subject matter pages at Attachment 2.

Training delivery

A number of options are available for training delivery -

• Handbook delivery using multiple authors and technical experts to develop a comprehensive textbook on identified topics.
• Distance learning using a course handbook and specially developed internet based presentation modules.
- Self contained **DVD-based delivery** of abovementioned handbook and presentation modules.

- **Workshop delivery** within the region, associated with regular MDPWG meetings.

The first three options all require similar technical input to develop the syllabus content, but have the disadvantage of no face to face interaction with the subject experts or fellow participants and the ability to learn and understand from such interactions.

Further, they have relatively slow response times to new and emerging information, policies or directions from MDPWG-ACCSQ or ASEAN itself.

While a handbook, once prepared, is relatively easy and inexpensive to reproduce, both internet delivery and DVD based delivery have significant associated production costs before the material is ready for delivery.

Internet based learning is becoming easier to implement now, and a good example of this model in that offered by the World Medical Device Organisation (WMDO), operated out of Switzerland [www.wmdo.org](http://www.wmdo.org).

WMDO has developed a platform for delivery of the training material, including examination on completion, and offers a series of modules, currently focused primarily of European regulation of medical devices, but it also has some other GHTF member economy based modules as well.

In addition, WMDO can ‘convert’ training material developed for face-to-face workshop delivery into a web based format for delivery across their platform.

Utilisation of the WMDO platform to deliver training as an adjunct to workshops delivered in the region would enable those officers of ASEAN regulators attending the workshops to facilitate training back in their agencies to those unable to attend …. In effect making the face-to-face workshops ‘train-the-trainer’ events.

Interested parties from both the regulated industries and the Regulatory Agencies should be canvassed for preferences, but given the relatively short lead up time to implementation of AMDD, it would appear workshop presentations are the most suitable option for training delivery in the first instance.

**Examination**
Regardless of which option, or mix of options, is chosen delivery of training should be accompanied by a short form question and answer and a multiple choice exam on completion of each element.

**Workshop size**

Previous workshops have been delivered in a number of formats ranging from small groups of 15-20 and up to 100+ attendees in focused workshop sessions (Manila 2010 and Kuala Lumpur 2011), to numbers of 200 + in mixed topic workshops and past MDPWG meetings.

Experience suggests learning is maximised in smaller groups of 20-30 participants, with an absolute ceiling of 40 attendees, but only for some of the higher level topics, and it is suggested these sessions be associated with the regular MDPWG meeting.

**Workshop location and timing**

Participants at the MDPWG meeting in Siem Reap in April 2011 were canvassed regarding anticipated levels of training required, by both the industry and the Regulatory Authorities.

Although preliminary thinking, responses indicated that it was likely up to four training workshops would be required per annum leading up to 2015, two associated with the bi-annual MDPWG meetings and two in between those meetings. It was proposed that training workshops should be alternated between host economies in the northern and southern parts of the region, at approximately three monthly intervals.

In addition, there was a need identified to hold national training workshops in each of the ASEAN Member States, where the training would address not only the ASEAN MDD, but also local issues for both regulators and the industry. It was proposed that these workshops, ten in number, commence in 2012.

**A staged approach to introduction**

It should also be noted, that the model developed by the GHTF also documents a phased approach to the introduction of a regulatory framework for those economies which have no existing regulations.
The curriculum will also discuss this approach, particularly for those economies starting from a position of no, or almost no, current regulations, or knowledge of operators and products within their market.
Attachment 1

Requested follow up activities

Manila, October 2010

Kuala Lumpur, June 2011
Manila, October 2010

1. What other topics would you like to see included

- Case studies: Possibly experiences of countries in the region concerning their own unique challenges in setting up a regulatory body etc.
- Medical devices terminology should be included
- Section 3, 4 and 5
- More homework and to train the medical device again
- In the training can do more different medicine and medical device with medicine and how and what can do approve in medicine and medical device with medicine
- Classification of IVD
- Pre and Post Market regulation (2 respondents)
- Enough topic but should be increase the letter because I can’t read, it’s too small
- No
- What document are required for MD registration for each classification
- More seminar/training on STED
- QMS
- Risk analysis, product verification + validation clinical evaluation
- Product recall and complaint handling
- Definition of medical terminologies and application
- More detailed procedures on EU-Conformity Assessment.
- More detailed workshop on conformity assessment procedures and STED
- Establishing a register
- Post market monitoring, surveillance and reporting systems
- Essential principles of safety and performance

2. What sort of follow-up activities for this meeting would you find useful

- More in depth workshops concerning medical devices
• More workshop will be organized
• Providing exercises to be done (with samples) and making correction on it
• All session are useful for us
• The meeting is good subject because it is the first time for training of medical devices. Next time please train again. This is an important subject for other people, for example pharmacist, doctor, engineer.
• Interest to training again special classification medical device and regulatory
• Post market surveillance
• Discussion
• Monitoring and update training
• Every activities I find useful
• Develop training model
• STED
• QMS
• Product testing (particularly testing of medical equipment as against IEC 60601-1)
• Thorough understanding of the STED;
• ISO 13485-utilized to assess/evaluate existing manufacturers and in-coming manufacturers
• Medical devices with drug components-evaluating classifying
• Pre and Post Market regulation
• Product recall and complaint handling
• Definition of medical terminologies and application
• The other is the exact harmonization of medical device classification by developed countries or the common stand they should have. As well as other significant factors relating to medical devices regulation
• Updates on classification and the conformity assessment procedures, pre- and post-market surveillance procedures.
• Training on regulatory authorities regarding regulations on medical device manufacturers
• Detailed workshop on conformity assessment procedures and STED
• Clinical evidence evaluation
• Risk analysis
• Take part a working group fro classification of medical devices in Vietnam
Kuala Lumpur, June 2011

What other topics would you like to see included?

- Classification and practical examples
- Detail on CSDT & practical examples
- Labelling requirement
- Advertisement on product
- Malaysia Health Ministry Regulation vs USAID
- Classification exercises
- Guidance & procedures for submitting registration of medical devices in ASEAN countries
- USDA rules & regulation
- Status update on registration process in ASEAN countries
- Differences of medical devices regulation in each ASEAN countries
- Further on STED and its examples
- Essential principles of safety & performance checklist
- Examples of common mistakes made by manufacturers / distributors during submission
- Regulatory on parallel imports
- Current grouping / classification on medical devices in ASEAN
- Further details on conformity reement[assessment ??]
- Classification of common Malaysian marketed products (IVD’s)
- New technology / new invention in medical devices
- Quality Management Systems
- In-vitro devices: Examples of accessories
- The effects of harmonisation throughout the local market / ASEAN market
- Distribution route / control
- GMDN & UMDN Code
- Risk Management for Medical Devices & post market surveillance
- Details on CE, EC, ISO 13485, ISO 9011 and IEC 61010, IEC 60601
- Technical Basic [barriers??] To Trade (TBT)

**What sort of follow-up activities for this workshop would you find useful?**

- Guidance & Contents of CSDT for registration submission (Documents examples)
- Continuous workshop on medical devices info
- Slides of presentations
- Activities of Medical Devices Classification Practice
- Classification & Identification
- Home work on classification & group discussion / case study & tutorial
- Guidance on document submission for medical devices registration
- Follow-up workshop on annual basis to update changes
- In depth of classification information
- List of medical devices and its classifications for further reference
- Another workshop on Essential principles & clinical evaluation
- Classification of IVD
- Info on new development & standards
- Post market compliances
- Description and example of software verification and validation
- Difference between clinical evidence and clinical trial
- Actively share information to all health sciences of all AMS countries on regular event like this
- Pre-evaluation & post-evaluation
• Product testing, STED application
Attachment 2

Training Curricula

Core Elements
<table>
<thead>
<tr>
<th>Core Topic Group</th>
<th>Subject/Topic</th>
<th>Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>The GHTF Global Model</td>
<td>G 1.0</td>
</tr>
</tbody>
</table>

**Suggested pre-requisites**
Nil

**Learning Elements & Sub-elements**
- Elements of the product life cycle
- Relationship and relevance to activities of GHTF SG’s
- Roles & responsibilities of
  - National Competent Authorities
  - Conformity Assessment Bodies
  - Manufacturers
- Broad overview of elements of
  - Quality management Systems
  - Premarket evaluation phase
  - Postmarket surveillance/vigilance phase
- Progressive implementation of regulatory framework

**Key learning objectives**
- Understanding of the fundamentals of the GHTF model
- Awareness of the ability to progressively implement a regulatory framework

**Practical Exercises**
Nil

**Reference material**

*GHTF Document GHTF/AHWG-GRM/N1R13:2011 – The GHTF Regulatory model*

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<th>Duration</th>
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<td>Core Topic Group</td>
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<tr>
<td>Global</td>
<td>Definition of a medical device</td>
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**Suggested pre-requisites**
Nil

<table>
<thead>
<tr>
<th>Learning Elements &amp; Sub-elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What is a medical device</td>
</tr>
<tr>
<td>• What is not a medical device</td>
</tr>
<tr>
<td>• What is a combination product</td>
</tr>
<tr>
<td>○ Principle mode of therapeutic action</td>
</tr>
</tbody>
</table>

**Key learning objectives**

• Understanding of the definition of a medical device

**Practical Exercises**

Practical examples and discussion throughout workshop

**Reference material**

*GHTF Document GHTF/SG1/N29R16:2005 – Information concerning the definition of the term “Medical Device”*

**Assessment**
Nil

**Duration**
2 hours
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<tr>
<th>Core Topic Group</th>
<th>Subject/Topic</th>
<th>Identifier</th>
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<tbody>
<tr>
<td>Premarket</td>
<td>Establishment and implementation of a Quality Management System</td>
<td>PM 1.1</td>
</tr>
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</table>

**Suggested pre-requisites**
G1.0 – The GHTF global regulatory Model

**Learning Elements & Sub-elements**
- Core elements of ISO 13485
  - Quality management systems
  - Management responsibility
  - Management review
  - Resource Management
  - Product realization
  - Measurement, analysis and improvement

**Key learning objectives**
- For a manufacturer –
  Basic understanding of Quality Management Systems in the manufacture of medical devices
  Full QMS v’s Production QMS, based on device classification
  Issues to be addressed in development of a QMS
- For a regulatory Authority –
  Understanding of the elements of a QMS
  Fundamental understanding of assessment of a manufacturer’s QMS
- ISO 9000 for Good Distribution Practice

**Practical Exercises**
By example through training documents

**Reference material**

*ISO 13485:2003 – Medical Devices – Quality management systems – Requirements for regulatory purposes*
*ISO 9000:2005 - Quality management systems — Fundamentals and vocabulary*

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<th>Duration</th>
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<tr>
<td>Premarket</td>
<td>The product life cycle, beginning with design control</td>
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**Suggested pre-requisites**

- G1.0 – The GHTF global regulatory Model
- PM1.1 – Establishment of a QMS (or at least in conjunction with)

**Learning Elements & Sub-elements**

- The medical device product life cycle
  - Concept
  - Design development
  - Verification
  - Manufacture
  - Placing on the market – registration
  - Postmarket monitoring
  - Product/Process improvement through CAPA
  - End of life/disposal

**Key learning objectives**

- For a manufacturer –
  Understanding of the linkages between the product life cycle and the QMS

- For a regulatory Authority –
  Understanding of the elements the medical device life cycle
  Ability to assess risk management reports submitted by a medical device manufacturer

**Practical Exercises**

By example through training documents

**Reference material**

*ISO 14971:2007 – Medical Devices – Application of risk management to medical devices.*

<table>
<thead>
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<tbody>
<tr>
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<tr>
<td>Premarket</td>
<td>QMS documentation requirements</td>
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### Suggested pre-requisites

- G1.0 – The GHTF global regulatory Model
- PM1.1 – Establishment of a QMS (or at least in conjunction with)

### Learning Elements & Sub-elements

- Core elements of ISO 13485  
  Section 4.0 - QMS (particularly 4.2 – Documentation requirements)
- The need for documentation
- The quality manual
- Documentation control
- Quality records
- Record control
- Documentation and the STED/CSDT

### Key learning objectives

- For a manufacturer –  
  The need for adequate and appropriate documentation and records throughout the design, manufacturing and postmarket phases of the product life cycle

- For a regulator -  
  A working knowledge of documentation held by a manufacturer  
  Ability to assess documentation and records held by a manufacturer, in both the premarket assessment and postmarket monitoring phases of the product life cycle

### Practical Exercises

- By example through training documents
- Simple multiple group exercise to develop a documentation and records assessment ‘checklist

### Reference material

*ISO 13485:2003 – Medical Devices – Quality management systems – Requirements for regulatory purposes*

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<thead>
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**Suggested pre-requisites**

- G1.0 – The GHTF global regulatory Model
- PM1.1 – Establishment of a QMS (or at least in conjunction with)

**Learning Elements & Sub-elements**

- Core elements of ISO 14971
  - Inter-relationship with QMS
  - Concepts and definitions
  - Documentation of risk analysis
  - Risk analysis
  - Estimation of risk
  - Risk evaluation
  - Risk mitigation
  - Risk benefit analysis
  - Acceptable risk
  - Residual risk v’s acceptable risk
  - Risk management in the postmarket phase

**Key learning objectives**

- For a manufacturer –
  - Risk analysis in the device design process
  - Risk analysis in the postmarket phase

- For a regulatory Authority –
  - Understanding of the elements of risk management
  - Ability to assess risk management reports submitted by a medical device manufacturer

**Practical Exercises**

By example through training documents
Simple exercise using a class A medical device

**Reference material**

*ISO 14971:2007 – Medical Devices – Application of risk management to medical devices*
*ISO 31000:2009 – Risk management – principles and guidelines*

**Assessment**

Short written assessment using a class A medical device

**Duration**

4 hours
### Core Topic Group
- Premarket

### Subject/Topic Classification

#### Identifier
- PM 1.5

### Suggested pre-requisites
- G1.0 – The GHTF global regulatory Model

### Learning Elements & Sub-elements
- Classification of medical devices based on risk to –
  - The patient
  - The user
  - The environment
- Taking into account the –
  - Level and duration of invasiveness
  - Site of interaction with the patient
  - Presence of an energy source
  - ‘Special rules’

### Key learning objectives
- For a manufacturer –
  - The ability to apply the classification rules to their product at the beginning of the product life cycle
- For a regulatory Authority –
  - Understanding of the classification rule
  - Ability to assess the classification rationale of a medical device manufacturer

### Practical Exercises
- By example through training documents
- Multiple group exercises using product literature for a variety of medical devices

### Reference material
- GHTF/SG1/N15:2006 – Principles of medical device classification
- MEDDEV 2.4/1 Rev 9 – Medical device guidance document – Classification of medical devices

### Assessment
- By review of outcomes of group exercises

### Duration
- 4 hours
### Core Topic Group

**Premarket**

**Subject/Topic**

**Essential principles**

**Identifier**

PM 1.6

### Suggested pre-requisites

- G1.0 – The GHTF global regulatory Model

### Learning Elements & Sub-elements

- The essential principles in the context of –
  - Chemical physical and biological properties
  - Infection and microbial contamination
  - Manufacturing and environmental properties.
  - Devices with a diagnostic or measuring function.
  - Protection against radiation.
  - Requirements for medical devices connected to or equipped with an energy source.
  - Protection against mechanical risks.
  - Protection against the risks posed to the patient by supplied energy or substances.
  - Protection against the risks posed to the patient for devices for self-testing or self-administration.
  - Information supplied by the manufacturer.
  - Performance evaluation including, where appropriate, clinical evaluation

### Key learning objectives

- For a manufacturer –
  The ability to adequately assess a medical device against the essential principles as part of the design and validation process

- For a regulatory Authority –
  Understanding of the essential principles
  Ability to assess the correct application of the essential principles by a medical device manufacturer as part of the premarket review process

### Practical Exercises

- Group exercises using simple medical devices

### Reference material

- ISO/TR 19142 – Medical Devices – guidance on the selection of standards in support of recognized essential principles of safety and performance
- Checklist – Essential principles of safety and performance [to be developed]

### Assessment

**By review of outcomes of group exercises**

**Duration**

2 hours
### Core Topic Group
- **Premarket**

### Subject/Topic
- **Labeling and Instructions for Use**

### Identifier
- **PM 1.7**

## Suggested pre-requisites
- G1.0 – The GHTF global regulatory Model
- PM 1.6 – Essential principles of safety and performance

## Learning Elements & Sub-elements
- Definition of ‘label’ as applied to medical devices
- Labelling requirements for a medical device to indicate -
  - its identity and intended use/purpose;
  - how it should be used, maintained and stored;
  - any residual risks, warnings or contra-indications;
- Labelling commensurate with the technical knowledge, experience, education or training of intended users;
- Use of symbols.

## Key learning objectives
- **For a manufacturer** –
  - The ability to develop compliant labeling that is useful and informative to the user
- **For a regulatory Authority** –
  - Understanding of the labeling requirements to allow assessment of labeling for compliance

## Practical Exercises
- Examples through workshop notes
- Practical workshop group exercises on assessment of compliant and non-compliant labeling

## Reference material
- GHTF/SG1/N43:2005 – Labeling for medical devices
- ISO 15223-1: Medical Devices – Symbols to be used on medical device labels, labeling and information to be supplied

## Assessment
- By review of outcomes of group exercises

## Duration
- 2 hours
### Core Topic Group
Premarket

### Subject/Topic
Clinical evidence

### Identifier
PM 1.8

#### Suggested pre-requisites
- G1.0 – The GHTF global regulatory Model
- PM 1.6 – Essential principles of safety and performance

#### Learning Elements & Sub-elements
- Types of clinical evidence
- Trial in humans v’s literature revue
- Ethical considerations
- Declaration of Helsinki
- Clinical investigation
- The expert report
- Clinical evaluation
- Clinical evidence in the postmarket phase of the product life cycle

#### Key learning objectives
- For a manufacturer –
  - Understanding of the need for clinical evidence in support of compliance with the essential principles
  - Knowledge to generate appropriate clinical evidence
- For a regulatory Authority –
  - Understanding of the clinical evidence requirements and the ability to review evidence submitted by a medical device manufacturer

#### Practical Exercises
- By way of example in the workshop

#### Reference material
- *GHTF/SG5/N1R8:2007 - Clinical Evidence – Key Definitions and Concepts*
- *GHTF/SG5/N2R8:2007 - Clinical Evaluation*
- *GHTF/SG5/N3:2010 - Clinical Investigations*
- *Reportable Events During Pre-Market Clinical Investigations*
- *GHTF/SG5/N4:2010 - Post Market Clinical Follow-Up Studies*
- *ISO 14155.1:2004 – Clinical Investigations of medical devices for human subjects*
- *MEDDEV 2.7/4:2010 – Guidelines on clinical investigation: A guide for manufacturers and notified bodies*
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<tr>
<td>Premarket</td>
<td>Use of Standards</td>
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</table>

**Suggested pre-requisites**

- G1.0 – The GHTF global regulatory Model
- PM 1.6 – Essential principles

**Learning Elements & Sub-elements**

- The standards development process
- Local v’s international standards (or local adoption of international standards)
- Recognised standards development bodies
  - a lengthy list
- Recognised standards
- Alternatives to recognised standards
- The transition process to new versions of a standard

**Key learning objectives**

- Understanding of the standards development process
- Understanding of relevant and appropriate standards in demonstrating compliance of a medical device with the essential principles of safety and performance
- Understanding of the alternatives to recognized standards

**Practical Exercises**

By example through training documents

**Reference material**

*GHTF/SG1/N044:2008 – Role of standards in the assessment of medical devices*

*ISO/TR 19142 – Medical Devices – guidance on the selection of standards in support of recognized essential principles of safety and performance*

**Assessment**

Multiple choice questionnaire

**Duration**

2 hours
## Core Topic Group
Premarket

### Subject/Topic
The Conformity Assessment Process

### Identifier
PM 1.10

## Suggested pre-requisites
- G1.0 – The GHTF global regulatory Model
- PM 1.1 - Establishment and implementation of a Quality Management System
- PM 1.6 – Essential principles

## Learning Elements & Sub-elements
- Linkages of device classification to conformity assessment
- Conformity assessment for the different classifications of medical devices
- The role of –
  - the manufacturer in applying a conformity assessment procedure
  - the CAB in assessing the correct application, by the manufacturer of a conformity assessment procedure
- Assessment of the QMS
- Design & production QMS v’s production only QMS
- Assessment of device safety and performance – the role of the STED/CSDT
- The declaration of Conformity

## Key learning objectives
- Understanding of the linkage between classification and allowable Conformity Assessment processes
- For a manufacturer –
  - Knowledge to select an appropriate conformity assessment process for his product and circumstance
- For a regulatory Authority –
  - Knowledge to allow assessment of the application, by a manufacturer, of an appropriate conformity assessment process

## Practical Exercises
By examples through training documents

## Reference material
*GHTF/SG1/N40:2006 – Principles of conformity assessment for medical devices*

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Core Topic Group | Premarket
---|---
Subject/Topic | The STED/CSDT – An overview
Identifier | PM 1.11

Suggested pre-requisites

- PM 1.5 – Classification
- PM 1.9 - The Conformity Assessment Process

Learning Elements & Sub-elements

- Preparation and use of the STED/CSDT
  - Pre-market
  - Postmarket
- Components of the STED/CSDT
  - Device description/specification
  - Labeling
  - Design & manufacturing information
  - EP Checklist
  - Risk management report
  - Product Verification and validation
  Content, depth and detail of the STED relative to device classification

Key learning objectives

- Role of the STED/CSDT in liaising with the CAB or Regulatory Authority
- Understanding of the broad contents of the STED
- For a manufacturer – Knowledge to assemble a STED/CSDT, when asked by a CAB or Regulatory Authority, from existing QMS documentation
- For a regulatory Authority – Knowledge to allow assessment of the STED/CSDT in either a premarket assessment or a postmarket review of a medical device

Practical Exercises

By example through training documents

Reference material

*GHTF/SG1/N011:2008 – Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)*

*AHWP- Common Submission Dossier Template (CSDT)*

Assessment | Nil
---|---
Duration | 2 hours
### Core Topic Group
Premarket

### Subject/Topic
The STED/CSDT – Device Description & Product Specification

### Identifier
PM 1.11 - 1

#### Suggested pre-requisites
- PM 1.10 - The STED/CSDT

#### Learning Elements & Sub-elements
- Vale of this element undetermined
- Not sure if formal guidance is really necessary here, but invite comment from the MDPWG [editor]

#### Key learning objectives
- 

#### Practical Exercises

#### Reference material

#### Assessment
Multiple choice questionnaire

#### Duration
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<table>
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<td>- For a manufacturer –</td>
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<tr>
<td>The ability to develop compliant labeling that is useful and informative to the user</td>
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<tr>
<td>- For a regulatory Authority –</td>
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<tr>
<td>Understanding of the labeling requirements to allow assessment of labeling for compliance</td>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>- Examples through workshop notes</td>
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<tr>
<td>- Practical workshop group exercises on assessment of compliant and non-compliant labeling</td>
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<tr>
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</table>

**Suggested pre-requisites**

- PM 1.10 - The STED/CSDT

**Learning Elements & Sub-elements**

- Consideration in documenting the device design and manufacturing process
  - Familiarity of the manufacturer with, and maturity of technology – old … new
  - Complexity of design
- Description of design stages
- Description of manufacturing processes
  - Identification of sub-contractors
  - General description of manufacturing process flow
  - Process flow chart as an option
  - Identification of manufacturing sites and process flow between sites
  - Certification of sites, and sub-contractors

**Key learning objectives**

- For a manufacturer –
  An understanding of the level of detail required to describe the design and manufacturing processes of the medical device

- For a regulatory Authority –
  Understanding of the complexities of a modern manufacturing environment
  Knowledge to be able to satisfactorily review the design and manufacturing process of the manufacturer

**Practical Exercises**

- Examples through workshop notes

**Reference material**

*GHTF/SG1/N011:2008 – Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)*

*AHWP- Common Submission Dossier Template (CSDT)*

**Assessment**

- Multiple choice questionnaire

**Duration**

- 2 hours
Core Topic Group | Subject/Topic | Identifier
---|---|---
Premarket | The STED/CSDT – Product Verification and Validation | PM 1.11 - 4

### Suggested pre-requisites

- PM 1.10 - The STED/CSDT

### Learning Elements & Sub-elements

- Differences between verification and validation
- Verification by observation/measurement
- Validation through establishing objective evidence of consistent results/outputs
- Processes which should be validated
  - IQ: installation qualification
  - OQ – Operational qualification
  - OQ – Operational qualification
- Maintaining validation

### Key learning objectives

- For a manufacturer –
  An understanding of the key differences between verification and validation, and where each process is appropriate
  Knowledge to develop validation programs to ensure consistency of manufactured product

- For a regulatory Authority –
  An understanding of the key differences between verification and validation, and where each process is appropriate
  Knowledge to understand and undertake the assessment of a manufacturer’s verification and validation activities within the manufacturing process

### Practical Exercises

Practical exercise in group activities

### Reference material

- GHTF/SG1/N011:2008 – Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)
- AHWP- Common Submission Dossier Template (CSDT)

### Assessment

- Multiple choice questionnaire

### Duration

- 2 hours
Core Topic Group | Subject/Topic | Identifier
--- | --- | ---
Premarket | The STED/CSDT - Biocompatibility of medical devices | PM 1.11-5

**Suggested pre-requisites**

- G1.0 – The GHTF Global Regulatory Model
- PM1.1 – Establishment of a QMS
- PM1.2 - The product life cycle, beginning with design control

**Learning Elements & Sub-elements**

- Particular requirements for determining biocompatibility for medical devices, including
  - Relevant Essential Principles and how to demonstrate compliance
  - Applicable standards
  - Testing requirements

**Key learning objectives**

- For a manufacturer –
  - Basic understanding of the regulatory requirements for demonstration of biocompatibility of medical devices
  - Issues to be addressed in demonstrating initial and ongoing compliance with the Essential Principles
- For a Regulatory Authority –
  - Fundamental understanding of assessment of biocompatibility for medical devices

**Practical Exercises**

Nil

**Reference material**

GHTF/SG1(PD)/NO68R05 – *Essential Principles of Safety and Performance of Medical Devices*

The ISO 10993 set of Standards on *Biological evaluation of medical devices*

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<tr>
<td>Premarket</td>
<td>The STED/CSDT – Combination products – devices containing a medicinal substance</td>
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</table>

**Suggested pre-requisites**

PM 1.10 - The STED/CSDT

**Learning Elements & Sub-elements**

- Consideration of “what is a combination product?”
- An overview of the global situation in relation to combination products
- The GHTF requirements for medical devices incorporating a medicinal substance
- How to demonstrate compliance with the relevant Essential Principles

**Key learning objectives**

- For a manufacturer –
  
  Basic understanding of the regulatory requirements for devices containing a medicinal substance
  
  Issues to be addressed in demonstrating compliance with the Essential Principles

- For a Regulatory Authority –
  
  Fundamental understanding of assessment of medical devices containing a medicinal substance

**Practical Exercises**

Exercise in determining whether a product is a combination product and where it may sit in the regulatory scheme

**Reference material**

GHTF/SG1(PD)/NO68R05 – *Essential Principles of Safety and Performance of Medical Devices*

**Assessment**

Nil

**Duration**

3 hours
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<td>Premarket</td>
<td>The STED/CSDT - Biological Safety of Medical Devices</td>
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### Suggested pre-requisites
- G1.0  – The GHTF Global Regulatory Model
- PM1.1 – Establishment of a QMS
- PM1.2 - The product life cycle, beginning with design control

### Learning Elements & Sub-elements
- Particular requirements for devices containing material of biological origin, including
  - Relevant Essential Principles and how to demonstrate compliance
  - Classification issues
  - QMS requirements for manufacture of devices containing material of animal material
  - Relevance to reprocessed medical devices
  - Labelling issues

### Key learning objectives
- For a manufacturer –
  - Basic understanding of the regulatory requirements for demonstration of biological safety
  - Understanding of the particular requirements for manufacture of devices containing material of animal origin
  - Issues to be addressed in demonstrating compliance with the Essential Principles for medical devices of biological origin (can also be related to manufacture of reprocessed medical devices)

- For a Regulatory Authority –
  - Fundamental understanding of assessment of biological safety for medical devices containing material of biological origin, or reprocessed medical devices

### Practical Exercises
Nil
## Reference material

GHTF/SG1(PD)/NO68R05 – *Essential Principles of Safety and Performance of Medical Devices*
ISO 22442-2:2007 - Medical devices utilizing animal tissues and their derivatives -- Part 2: Controls on sourcing, collection and handling
ISO 22442-3:2007 - Medical devices utilizing animal tissues and their derivatives -- Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
ISO/TR 22442-4:2010 - Medical devices utilizing animal tissues and their derivatives -- Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes
*MEDDEV 2.5-8 - Evaluation of medical devices incorporating products of animal origin*

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**Suggested pre-requisites**

- PM1.1 – Establishment of a QMS
- PM 1.10 - The STED/CSDT

**Learning Elements & Sub-elements**

- Discussion on the types of sterilisation processes
- Outline of validation and monitoring requirements
- Brief discussion of the specific requirements for each type of process
- Requirements for sterility testing

**Key learning objectives**

- For a manufacturer –
  - Basic understanding of the regulatory requirements for sterilisation processes
  - Understanding of the QMS requirements for validation, monitoring and testing
  - Issues to be addressed in demonstrating compliance with the Essential Principles

- For a Regulatory Authority –
  - Fundamental understanding of assessment of sterilisation processes for medical devices

**Practical Exercises**

**Reference material**

GHTF/SG1(PD)/NO68R05 – *Essential Principles of Safety and Performance of Medical Devices*

**Assessment**

Multiple choice questionnaire

**Duration**

4 hours
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<td>PM 1.11 - 9</td>
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**Suggested pre-requisites**

- PM 1.10 - The STED/CSDT

**Learning Elements & Sub-elements**

- Verification v’s validation
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
- Software development as part of system design
- Design Review
- Principles of Software validation
- Software life cycle activities
  - Planning
  - Coding
  - Testing
  - Maintenance

**Key learning objectives**

- For a manufacturer –
  Understanding of the role of the software verification and validation as an element of the medical device design and validation process
  Basic Knowledge to understand the importance of, and need for software verification and validation
- For a Regulatory Authority –
  Knowledge to understand and undertake the assessment of a manufacturer’s software verification and validation processes

**Practical Exercises**

- Examples through workshop notes

**Reference material**

*FDA Guidance – General principles of software validation; Final guidance for industry and staff*

**Assessment**

- Multiple choice questionnaire

**Duration**

- 2 hours
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<tr>
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<th>Subject/Topic</th>
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<td>Premarket</td>
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<td>PM 1.11 - 10</td>
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### Suggested pre-requisites
- PM 1.10 - The STED/CSDT

### Learning Elements & Sub-elements
- Status of the Declaration of Conformity in the GHTF regulatory framework
- Role of the Declaration of conformity in a legal regulatory framework
- Content of the Declaration of conformity
  - Dependent of classification and chosen conformity assessment procedure by the manufacturer
- Self declaration by a class A medical device manufacturer

### Key learning objectives
- For a manufacturer –
  - Understanding of the role of the Declaration of Conformity within the Regulatory framework
  - Knowledge to complete a Declaration of conformity taking into account the classification of the medical device and the chosen conformity assessment process
- For a Regulatory Authority –
  - Knowledge to understand and undertake the assessment of a manufacturer’s Declaration of Conformity

### Practical Exercises
- Examples through workshop notes

### Reference material
- GHTF/SG1/N011:2008 – Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)
- AHWP- Common Submission Dossier Template (CSDT)
- Sample Declaration of Conformity Templates (to be developed)

### Assessment
- Multiple choice questionnaire using example DoC’s

### Duration
- 2 hour
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<th>Subject/Topic</th>
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</table>

**Suggested pre-requisites**

- G1.0 – The GHTF Global Regulatory Model
- PM1.1 – Establishment of a QMS (or at least in conjunction with)
- PM1.2 - The product life cycle, beginning with design control

**Learning Elements & Sub-elements**

- Particular requirements for in vitro diagnostic medical devices, including
  - Essential principles
  - Classification
  - Conformity Assessment pathways
  - Labelling
  - Elements of the STED

**Key learning objectives**

- For a manufacturer –
  - Basic understanding of the regulatory requirements for IVDs
  - Issues to be addressed in the design, development and production of IVDs

- For a Regulatory Authority –
  - Understanding of the GHTF framework for IVDs
  - Fundamental understanding of assessment of a manufacturer’s technical file

**Practical Exercises**

Exercise in classification of IVDs

**Reference material**

- GHTF/SG1/NO45:2008 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- GHTF/SG1/NO46:2008 – Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
- GHTF/SG1/NO63:2011 – Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices
- GHTF/SG1(PD)/NO70 – Label and Instructions for Use for Medical Devices
- GHTF/SG1(PD)/NO68R05 – Essential Principles of Safety and Performance of Medical Devices

**Assessment**

Multiple choice questionnaire

**Duration**

8 Hours
### Core Topic Group Framework

**Subject/Topic:** Review of Conformity Assessment Processes  
**Identifier:** CAB 1.0

### Suggested pre-requisites

- PM 1.9 – The conformity assessment process

### Learning Elements & Sub-elements

- Options for the Regulatory Authority
- Review of manufacturer’s QMS by –
  - The Regulatory Authority
  - A CAB appointed by the Regulatory Authority
- Review of the STED/CSDT by –
  - The Regulatory Authority
  - A CAB appointed by the Regulatory Authority
- Overview of review processes and interaction of the Regulatory Authority and CAB’s in other major jurisdictions
- Responsibility for making the regulatory decision

### Key learning objectives

- For a regulatory Authority -
  - Understanding the options for a Regulatory Authority in developing a regulatory framework
  - Examination and understanding of these options as they exist in the GHTF economies
  - Considerations in engaging the services of CAB’s in the regulatory approval process

### Practical Exercises

Nil

### Reference material

Workshop notes

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**Suggested pre-requisites**

- PM 1.10 - The STED/CSDT

**Learning Elements & Sub-elements**

- Defining the roles and responsibilities of -
  - Regulatory Authority
  - CAB
  - Manufacturer
  - Authorised representative
  - Importer
  - Engaging the CAB(s)
  - Assessment of the CAB(S)

**Key learning objectives**

- For a regulatory Authority -
  - Understanding the options for a Regulatory Authority in developing a regulatory framework
  - Clear understanding of roles and interaction between Authority and CAB
- Understanding of assessment processes in engaging the services of a CAB(s)

**Practical Exercises**

Nil

**Reference material**

- ISO/IEC 17011:2004 – Conformity Assessment - General requirements for accreditation bodies accrediting CAB’s
- ISO/IEC 17021:2006 – Conformity Assessment – Requirements for bodies providing audit and management of certification systems
- MEDDEV 2.10/2 – Designation and monitoring of Notified Bodies within the framework of the EC Directives on medical devices

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### Suggested pre-requisites
- G1.0 – The GHTF Global Regulatory Model

### Learning Elements & Sub-elements
- Roles and responsibilities of key stakeholders
- Listing and registration framework
- Listing of responsible entities
  - Manufacturer
  - Authorised representative
  - Core data set
- Registration requirements for medical devices
  - Nomenclature system(s)
  - Core data set

### Key learning objectives
- Understanding of roles and responsibilities of key stakeholders in establishing an accurate and well maintained register
- Understanding of the essential elements and datasets for a listing and registration scheme
- Core data sets for establishing a registration scheme

### Practical Exercises
Demonstration of Australian Register of Therapeutic Goods (or Singapore’s register)

### Reference material
- GHTF/SG1/N55:2009 - Definition of the Terms Manufacturer, Authorised Representative, Distributor and Importer
- GHTF/SG1/N65:2010 - Registration of Manufacturers and other Parties and Listing of Medical Devices

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**Suggested pre-requisites**
- G1.0 – The GHTF Global Regulatory Model

**Learning Elements & Sub-elements**
- Postmarket programs overview
  - Surveillance
  - Vigilance
- Responsibilities of the manufacturer
  - Postmarket surveillance within the QMS
- Responsibilities of the authorised representative
- Responsibilities of the importer
- Responsibilities of the distributor
- Recalls and corrective actions and responsibilities
- Key definitions
- Reporting requirements

**Key learning objectives**
- For a manufacturer –
  - Broad respective understanding of the postmarket monitoring program activities within their QMS
  - Understanding of the surveillance programs implemented by the Regulatory Authority
- For a Regulatory Authority –
  - Broad understanding of the needs of a postmarket surveillance system
  - Broad understanding of a manufacturer’s postmarket obligations within their QMS

**Practical Exercises**
Nil

**Reference material**
- GHTF/SG2/N57:2006 - Medical Devices Post Market Surveillance: Content of Field Safety Notices
- GHTF/SG2/N8 - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- MEDDEV2.12-1:2009 – Guidelines on a medical device vigilance system
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**Suggested pre-requisites**

- POS 1.0 - Postmarket Surveillance and Vigilance – Overview

**Learning Elements & Sub-elements**

- Definitions
- Elements of a Regulatory Surveillance program
  - Adverse event reporting
  - Event investigation
  - Evidence and investigation protocols
  - Communication with the reporter
  - Co-operation with the manufacturer
- Pro-active surveillance
  - Postmarket auditing of key stakeholders activities, eg procedures, storage conditions, record keeping, etc
  - Assessment of device performance during the postmarket phase of the product lifecycle
  - Laboratory testing

**Key learning objectives**

- Understanding of
  Postmarket monitoring and surveillance programs operated by a Regulatory Authority
  Reporting obligations and timeframes for manufacturers
- Knowledge of
  Options for enhanced postmarket surveillance by the Regulatory Authority
  Need for open communications between Regulatory Authority, adverse event reporter, authorised representative and/or manufacturer during the investigation process

**Practical Exercises**

Practical examples discussed during workshop

**Reference material**

- GHTF/SG2/N57:2006 - Medical Devices Post Market Surveillance: Content of Field Safety Notices
- GHTF/SG2/N8 - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- MEDDEV2.12-1:2009 – Guidelines on a medical device vigilance system
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</table>

**Suggested pre-requisites**

- POS 1.0 - Postmarket Surveillance and Vigilance – Overview

**Learning Elements & Sub-elements**

- Postmarket monitoring requirements within the QMS
- Reactive and proactive monitoring activities
  - Report analysis and trending
  - Relationships with Authorised representative, importer, distributor
- CAPA and the product lifecycle
  - Product improvement
- Regulatory reporting
  - The decision process
- Recalls and product corrections

**Key learning objectives**

- Understanding of
  Postmarket monitoring requirements with the manufacturer’s QMS
  Adverse event reporting obligations to the Regulatory Authority
- Knowledge of
  CAPA processes in product improvement throughout the product lifecycle
  Reporting relationships to/from Authorised representative, import, distributor
  Need for procedures for recalls, product corrections, etc

**Practical Exercises**

Practical examples discussed during workshop

**Reference material**

- GHTF/SG2/N57:2006 - Medical Devices Post Market Surveillance: Content of Field Safety Notices
- GHTF/SG2/N8 - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- MEDDEV2.12-1:2009 – Guidelines on a medical device vigilance system

**Assessment**
Multiple choice questionnaire

**Duration**
2 hours
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**Suggested pre-requisites**

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**Learning Elements & Sub-elements**

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**Key learning objectives**

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**Practical Exercises**

**Reference material**

**Assessment**  
Multiple choice questionnaire

**Duration**  
2 hours
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**Suggested pre-requisites**

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**Learning Elements & Sub-elements**

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**Key learning objectives**

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**Practical Exercises**

**Reference material**

**Assessment**
Multiple choice questionnaire

**Duration**
2 hours
Attachment 3

Bibliography of reference documents and sources for training materials
GHTF Documents

Steering Committee Ad Hoc Working Group

AHWG-GRM/N1R13:+ – The GHTF Regulatory model

Study Group 1

SG1/N11 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
SG1/N15: Principles of Medical Devices Classification.
SG1/N29: Information Document Concerning the Definition of the Term ‘Medical Device’
SG1/N40 Principles of Conformity Assessment for Medical Devices
SG1/N41: Essential Principles of Safety and Performance of Medical Devices.
SG1/N43: Labelling for Medical Devices.
SG1/N44: Role of Standards in the Assessment of Medical Devices.
SG1/N45: Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
SG1/N46: Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
SG1/N55: Definitions of the Terms Manufacturer Authorised Representative, Distributor and Importer.
SG1/N65 Registration of Manufacturers and other Parties and Listing of Medical Devices

Study Group 2

SG2/N8: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
SG2/N38: Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program
SG2/N47: Review of Current Requirements on Postmarket Surveillance
SG2/N54: Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
SG2/N57: Medical Devices Post Market Surveillance: Content of Field Safety Notices

Study Group 3

SG3/N17: Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
SG3/N18: Guidance Quality management system-Medical Devices- Guidance on corrective action and preventive action and related QMS process
SG3/N99 Quality Management Systems - Process Validation Guidance

Study Group 4

SG4 (00) 3  Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements - Supplement 2)
SG4/N83: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers –
SG4/N84 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers

Study Group 5
SG5/N1  Clinical Evidence – Key Definitions and Concepts
SG5/N2  Clinical Evaluation
SG5/N3  Clinical Investigations
SG5/N4  Post Market Clinical Follow-Up Studies

AHWP Documents
AHWP/WG2/SADS/001 - Framework for AHWP Safety Alert Dissemination System (SADS)

Common Submission Technical Dossier

International Standards
ISO 9000  Quality Management Systems - Fundamentals and Vocabulary
ISO 10993  set of Part 1 and Part 2 Standards on Biological evaluation of medical devices
ISO 13485 Medical Devices- Quality management Systems – Requirements for Regulatory purposes
ISO 14155.1  Clinical Investigations of medical devices for human subjects
ISO 14971  Medical Devices – Application of risk management to medical devices
ISO 15223-1  Medical Devices – Symbols to be used on medical device labels, labeling and information to be supplied
ISO 31000  Risk management – principles and guidelines
ISO 22442-1  Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
ISO 22442-2  Medical devices utilizing animal tissues and their derivatives -- Part 2: Controls on sourcing, collection and handling
ISO 22442-3  Medical devices utilizing animal tissues and their derivatives -- Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
ISO/TR 22442-4 Medical devices utilizing animal tissues and their derivatives -- Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes
ISO/TR 19142 – Medical Devices – guidance on the selection of standards in support of recognized essential principles of safety and performance
ISO/IEC 17011:2004 – Conformity Assessment - General requirements for accreditation bodies accrediting CAB’s
ISO/IEC 17021:2006 – Conformity Assessment – Requirements for bodies providing audit and management of certification systems
**MEDDEV Documents**

MEDDEV 2.4/1 Rev 9 – Medical device guidance document – Classification of medical devices

MEDDEV 2.5-8 - Evaluation of medical devices incorporating products of animal origin

MEDDEV 2.7/4:2010 – Guidelines on clinical investigation: A guide for manufacturers and notified bodies

MEDDEV 2.10/2 – Designation and monitoring of Notified Bodies within the framework of the EC Directives on medical devices

MEDDEV2.12-1:2009 – Guidelines on a medical device vigilance system

**More MEDDEV Documents**


**Australian Guidance Documents**


**Canadian Guidance Documents**


**EU Notified Bodies Operations Group Documents**

http://www.nbog.eu/2.html

**Expansion of this bibliography**

There are many sources of detailed information on the establishment and implementation of GHTF regulatory frameworks, from many GHTF members, and other economies who are well down the path of implementation of these frameworks.

This bibliography is a ‘living document’ and will be expanded as this syllabus expands to provide a comprehensive reference to all users.