VII. THE LITERATURE ROUTE FOR CLINICAL EVALUATIONS

Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device according to the relevant annexes of the Medical Devices Directives and by the MOH charged with safeguarding public health.

References

Medical Device Directive (MDD 93/42/EEC) new EU MDR, MEDDEV 2.7/1 rev.4, The IMDRF SG5/N2R8, local regulation, EUM MDR.

This sub-system provide a practical solution on evaluation of clinical data as a necessary part of the European technical file or design dossier for CE marking medical devices and local regulation. This part focuses on the literature route for providing clinical data. Sample procedures and forms will be provided.

- ☐ Clinical Evidence - Basic Terms and Concepts
- ☐ Back Ground Applicable Regulation & Guidance Standards
- ☐ Clinical Literature Review Process Stages
  - General principles of clinical evaluation
  - Data generated through literature searching
  - Data generated through clinical experience
  - Appraisal of clinical data
  - Analysis of the clinical data
  - The Clinical Evaluation Report

Our services:

A. Clinical Evaluation Training for Medical Device Companies

This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.

B. Clinical Evaluation Auditing for Medical Device Companies

Full or partial internal Clinical Evaluation Validation audit. We provide internal auditing services which allow for an independent review of this part of your quality system.

C. Clinical Evaluation - System Implementation Consulting and maintenance

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.