PREPARING RISK MANAGEMENT REPORT







RISK MANAGEMENT

RISK ASSESSMENT

RISK MANAGEMENT PROCESS

RISK ANALYSIS

- INTENDED USE AND REASONABLY FORSEEABLE MISUSE
- IDENTIFICATION OF CHARACTERISTICS RELATED TO SAFETY
- IDENTIFICATION OF HAZARDS AND HAZARDOUS SITUATIONS
- RISK ESTIMATION

RISK EVALUATION

RISK CONTROL

- RISK CONTROL OPTION ANALYSIS
- IMPLEMENTATION OF RISK CONTROL MEASURES
- RESIDUAL RISK EVALUATION
- BENEFIT-RISK ANALYSIS
- RISKS ARISING FROM RISK CONTROL MEASURES
- COMPLETENESS OF RISK CONTROL

EVALUATION OF OVERALL RESIDUAL RISK

RISK MANAGEMENT REVIEW

PRODUCTION AND POST-PRODUCTION ACTIVITIES

- GENERAL
- INFORMATION COLLECTION
- INFORMATION REVIEW
- ACTIONS

PREPARING RISK MANAGEMENT REPORT

RISK MANAGEMENT

RISK MANAGEMENT PLAN

- 1. SCOPE
- 2. DEVICE DESCRIPTIONS
- 3. PERSONNEL AND RESPONSIBILTIES
- 4. RISK MANAGEMENT PROCESS
- 5. RISK ANALYSIS PROCESS
- 6. RISK EVALUATION PROCESS
- 7. RISK CONTROL MEASURE PROCESS
- 8. OVERALL RESIDUAL RISK
- 9. VERIFICATION OF RISK CONTROL MEASURES
- 10. RISK MANAGEMENT REVIEW
- 11. PRODUCTION AND POST-PRODUCTION ACTIVITIES

RISK MANAGEMENT REPORT

- 1. SCOPE
- 2. EVIDENCE AND VERIFICATION REPORTS
- 3. RISK ANALYSIS RESULTS
- 4. RISK EVALUATION
- 5. RISK CONTROL
- **6. EVALUATION OF OVERALL RISK**
- 7. RISK MANAGEMENT REVIEW
- 8. PRODUCTION AND POST PRODUCTION ACTIVITIES
- 9. CONCLUSION
- 10. DESIGN RISK TRACEABILITY WORKSHEET
- 11. PROCESS RISK TRACEABILITY WORKSHEET
- 12. USER RISK TRACEABILITY WORKSHEET

Vee Care

Your All-in-One Regulatory and Compliance Solution Provider

Please visit our website for more information:

www.vee-med.com



HONG KONG* USA

17/F, Chung Pont Commercial Building 300 Hennessy Road, Wanchai Hong Kong 4610 Highland Drive Salt Lake City, UT 84117 **USA**

TAIWAN*

AUSTRALIA

Unit 25, 9th Floor No. 188, Section, 4 ChengGong Road Neihu District, 114 Taipei City Taiwan Level 25, 100 Mount Street North Sydney, NSW 2060 Australia

CHINA UK

9-11 Jiangong Road, Zhongshan Avenue TianHe District, Guangzhou China

Room 100, 212, 2nd Floor Unit 808, 54 Bloomfield Avenue Belfast, BT5 5AD, Northern Ireland **United Kingdom**