BRITISH COLUMBIA INSTITUTE OF TECHNOLOGY *Course Outline **Part A***

Bachelor of Technology in Technology Management
Program: Biomedical Engineering Technology
Option: Health Option

BMET7102 MEDICAL DEVICE DEVELOPMENT AND STANDARDS

Hours/Week	**Total Hours:**	**Term/Level:**
Lecture:	**Total Weeks:** 12	**Credits:** 3
Lab:		
Other:		

Prerequisites

BMET Diploma or similar Diploma or Degree or
with special permission of the Dean

Course Description

Introduces students to a systematic approach in medical device design/development, standards and regulations. The course emphasizes engineering/design methodolgy. It consists of three modules: The first module provides an overview and compares medical device regulations and standards applicable in Canada, the US and Europe. In the second module students will focus on design control. Topics include design input/output, verification/validation and hazard analysis. The discussion will be reinforced with medical device design examples. The third module is an overview of the Medical Electrical Equipment (IEC60601.1) and the Medical Electromagnetic Compatibility (IEC60601.1.2) standards. Specific emphasis will be on how these standards relate to medical device design.

Course Goal

- To develop a general understanding of medical device regulations.
- To be able to classify a medical device in Canada, the US and Europe and know what standards are applicable.
- To be able to discuss, analyze and apply design control to a medical device development.
- To be able to carry out a medical device development that is compliant with design control standards.
- To develop a general understanding of the IEC60601.1 Medical Electrical Equipment and the IEC60601.1.2 Medical Electromagnetic Compatibility standard.

Evaluation

Assignments	50%	**Note:** Students must pass both i) the assignments and ii) the final, otherwise UNSATISFACTORY will be given as the final term grade.
Final	50%	
TOTAL	100%	

Course Outcomes and Sub-Outcomes

Upon successful completion of this course, the student will be able to:

1. Describe all phases of the medical device life cycle.
2. Identify and analyze all phases of the medical device development process.
3. Summarize the Canadian, US and European medical device regulations.
4. Outline a medical device regulatory approval process.
5. Identify the elements contained in the Quality System Requirements.
6. Analyze all elements of Design Control.
7. Analyze and develop Requirement Specifications of a simple medical device.
8. Develop the format, purpose and methods for Design Input/Output.
9. Develop the format, purpose and methods for Verification and Validation.
10. Carry out and analyze a Hazard Analysis of a simple medical device.
11. Summarize and explain the concepts in the IEC60601.1 Medical Electrical Equipment and the IEC60601.1.2 Medical Electromagnetic Compatibility standard.

Course Record

Developed by: Bruno Jaggi, P. Eng., Biomed. Eng. Technology — Date: _____
Instructor Name and Department (signature)

Developed by: Consultant 1 — Date: _____
Consultant Name and Affiliation (signature)

Developed by: Consultant 2 — Date: _____
Consultant Name and Affiliation (signature)

Reviewed by: Anthony Chan, P.Eng., Biomed. Eng. Technology — Date: _____
Instructor Name and Department (signature)

Approved by: _____ — Date: _____
Program Head Name and Department (signature)

BMET7102 MEDICAL DEVICE DEVELOPMENT AND STANDARDS

Effective Date: January 2003

Instructor(s)

Office No.: Phone:

Office Hrs.:

Text(s) and Equipment

Required:

Recommended:

References:

Handbook of Medical Device Design: Richard C. Fries, Marcel Dekker, New York 2000, ISBN: 0-8247-0399-5

Product Development Planning for Health Care Products Regulated by the FDA: Elaine Whitmore, ASQC Quality Press, Wisconsin 1997, ISBN: 0-87389-416-2

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices: Kimberly A. Trautman, ASQC Quality Press, Wisconsin 1997, ISBN: 0-87389-377-8

Canadian Medical Devises Regulations: Department of Health, Extract Canadian Gazette, Part I, May 27th, 1998.

US Code of Federal Regulations 2001: Title 21 – Food and Drugs, Chapter I – Subchapter H Medical Devices.

Medical Electrical Equipment – Part 1 General Requirements for Safety: IEC 60601-1, 3rd edition 2000.

Medical Electrical Equipment – Part 1 General Requirements for Safety Section 1.2 Collateral Standard: Electromagnetic Compatibility: IEC 60601-1-2, 1993.

Course Notes (Policies and Procedures)

Assignment Details

Assignment#1: Product Development Process

Assignment#2: Regulations: Internet Research

Assignment#3: Standards: Internet Research

Assignment#4: ISO13485/88

Assignment#5: FDA Warning Letters, Recalls: Internet Research

Assignment#6: Design Control I: General

Assignment#7: Design Control II: Requirement Specification

Assignment#8: Design Control III: Design Input/Output

Assignment#9: Design Control IV: Hazard Analysis

Assignment#10: Medical Electrical Equipment (IEC60601.1): General

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Course-Outline

SECTION	REQ'D TIME	TOPIC	DESCRIPTION
Introduction		1.Course Objective	1.-as per course outline
		2.Course Outline	2.-as per course outline
		3.Overview of Medical Device Development	3.-Medical Device Market: description -Product Development Process: discussion of all medical device life cycle elements.
Module 1: Regulation & Standards (overview)		4.Basis and Types of Regulation & Standards	4.-Legal basis of Regulations, Harmonization -Professional Associations and Standards -Type of standards
		5. Classification	5.-Types of classification -Classification rules -Classification list
		6. Canadian Health Product and Food Branch Regulation, Medical Device Bureau	6.-Approval Process -Applicable Standards -Canadian Medical Device Regulation
		7.US Food and Drug Regulation, Center for Devices and Radiological Health	7.-Approval Process -Applicable Standards -Quality System Requirements
		8.European Medical Device Directives	8.-Approval Process -Applicable Standards -EN 46001
		9.Basics of ISO13485/88	9.-Certification -Elements of ISO13485/88

Module 2: Design Control		10.Rational of Design Control 11.Elements of Design Control 12.Example of a Medical Device Development DESIGN INPUT: 13.Product Definition and Device Requirement Specification 14.Architectural Design DESIGN OUTPUT: 15.Hardware Detailed Design 16.Software Detailed Design VERIFICATION AND VALIDATION 17.Test Plan 18.Test Report HAZARD ANALYSIS: 19.Hazard Analysis and mitigation	12.-Discuss a Medical Device that will serve to illustrate all aspects of design control.
Module 3: IEC60601-1 and IEC60601-1-2		MEDICAL ELECTRICAL EQUIPMENT (IEC60601-1): 20.Overview , Definitions and Rational 21.General Requirements MEDICAL ELECTROMAGNETIC COMPATIBILITY (IEC60601-1-2): 22.Scope, Definition 23.Emission Radiated and Conducted CISPR11 24.Susceptibility Radiated and Conducted IEC801	20.-clause 1,2, 3 and 4 21.-Mechanical, Electrical, Environmental, Radiation, Flammable, Excessive Temperatures Hazards and Constructional Requirements