STATE BOARD OF COMMUNITY COLLEGES

CURRICULUM PROGRAM APPLICATION
(New to the System)

The State Board of Community Colleges is asked to approve the curriculum program at the listed college on the condition that equipment funds are available to the college and operating funds generated by the budget formula will permit the offering of the program without any special allocation of funds.

Durham Technical Community College
Medical Product Safety/Pharmacovigilance (A45XXX)

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PROGRAM APPLICATION
SUMMARY EVALUATION REPORT
Durham Technical Community College
Medical Product Safety and Pharmacovigilance (A45XXX)

I. Program Planning

Durham Technical Community College is seeking approval for the Medical Product Safety and Pharmacovigilance (A45XXX) program to begin Spring 2014 (mid-semester). The planning area is defined as the college's service area of Durham and Orange counties. All colleges were notified of the planning process for this program.

The proposed program was approved by the Board of Trustees at Durham Technical Community College on September 24, 2013. Minutes from this Board meeting were attached to the program application. The President and the Board of Trustees of Durham Technical Community College have certified the following:

- The proposed program will enhance the workforce of North Carolina, will provide educational and training opportunities consistent with the mission of the college, and will not duplicate the opportunities currently offered.
- They have assessed the need for the proposed program and the resources required to maintain a viable program and certify that the college can operate the proposed program efficiently and effectively within the resources available to the college.
- The college will complete a program accountability report including student success measures, enrollment trends, completion rates, and employment data three years after implementation of the program.

II. Program Rationale

Durham Technical Community College indicates the following:

- North Carolina is home to the third largest cluster of biotechnology, pharmaceutical, and life science companies. The development of the Medical Product Safety (MPS) and Pharmacovigilance program addresses the critical need that has been voiced by the industry. In the Research Triangle Park (RTP) area alone, there are more than twenty-three companies either focused on product safety as their primary service or which incorporate product safety services.
- According to the college's 2011 industry survey, sent to thirty-four biopharma employers in the Research Triangle area, it was projected more than two hundred and fifty pharmacovigilance/product safety-related positions will be open over the next four years.
- According to the Association of Clinical Research professions, the average clinical research professional salary in the RTP is $65,000. A Clinical Research Associate position is named as #4 in the 2012 Best Jobs in America survey by CNN Money (money.cnn/best-jobs).

- On January 17, 2013, Durham Technical Community College received a grant of $46,742 from the North Carolina Biotechnology Center to develop and implement the program.
- Letters of support for the Medical Product Safety and Pharmacovigilance program were submitted to Durham Technical Community College by local employers including RTI Health Solutions, Drug Safety Alliance of Durham, OCKHAM Oncology, Ethos Clinical Group, and DATATRACK.
- The college's Medical Product Safety and Pharmacovigilance Advisory Committee is composed of leaders in the medical product industry, including consultants and representatives from drug companies and contract research organizations. These industry professionals have been the resource and content experts in the development of the courses.
- DATATRAK International, Inc. has agreed to provide software for the Medical Product Safety and Pharmacovigilance program that is estimated to cost one million dollars.
- Durham Tech will initially launch the Medical Product Safety and Pharmacovigilance program as part of an academic certificate geared toward experienced clinical research professionals, allied health and medical professionals, and science majors.

III. Impact of the Proposed Program on Other Programs

This program would be new to the community college system and there are not any similar programs. The Clinical Trials Research Associate (A45190) program touches upon product safety during the operations of the research study, however the proposed program will be a specialized program focused on collecting, tracking, and evaluating data regarding medical product safety throughout the "life-cycle" of the medical product.

IV. Implementation of Collaborative Plan

Not Applicable

V. Curriculum Design

The proposed program of study is in compliance with the proposed curriculum standard.

Coordinator: Ms. Renee Batts

C. Institutional Certification: *Complete the following form and obtain required signatures. Form with original signatures should be included in the application.*

Institutional Certification

This curriculum program **Medical Product Safety/Pharmacovigilance** **(A45XXX)** *will enhance the workforce of North Carolina, will provide educational and training opportunities consistent with the mission of the college, and will not duplicate the opportunities currently offered.*

Durham Technical Community College *has assessed the need for this program and the resources required to maintain a viable program and certifies that the college can operate this program efficiently and effectively within the resources available to the college.*

The college understands that this proposed program will require a program accountability report that will include items such as student success measures, enrollment trends, completion rates, and employment data three years after implementation if the program is approved by the State Board.

(A copy of the minutes from the Board of Trustees meeting(s) where the proposed program was discussed and approved must be attached to the application.)

Signature, President of College	*Date* 9/26/2013
Signature, Board of Trustees Chair Mary Ann E. Black	*Date* September 24, 2013

MEDICAL PRODUCT SAFETY and PHARMACOVIGILANCE

MSP 110 Intro to Medical Product Safety

Class: 3 Lab: 0 Clinical: 0 Credit: 3

Prerequisites: None
Corequisites: None

This course provides a comprehensive introduction to medical product safety and pharmacovigilance. Topics include an overview of the key components of product safety, product safety terminology, the processes for monitoring product safety, and the regulations that govern product safety and pharmacovigilance. Upon completion, students should be able to describe the processes for monitoring the safety of drugs, diagnostics, medical devices, and biologics throughout a product's life cycle.

MSP 115 Med Product Safety Regulations

Class: 3 Lab: 0 Clinical: 0 Credit: 3

Prerequisites: None
Corequisites: None

This course provides an overview of national and global regulations governing the safety of medical products including drugs, diagnostics, medical devices, and biologics. Topics include a review of the regulatory agencies; regulations for pre-clinical, clinical, and post-market production safety; and regulations governing the process for monitoring product safety. Upon completion, students should be able to demonstrate a basic understanding of regulatory processes associated with clinical research and describe effective means of compliance.

MSP 120 Safety Reporting

Class: 3 Lab: 0 Clinical: 0 Credit: 3

Prerequisites: None
Corequisites: None

This course provides an overview of the criteria utilized in determining how safety data are reported. Emphasis is placed on learning the purpose, content, and format of the various reports that include safety information. Upon completion, students should be able to describe the difference between expedited and periodic reporting, the criteria used in this determination, as well as the purpose and content of each type of safety report.

MSP 130 Safety Systems and Processes

Class: 3 Lab: 3 Clinical: 0 Credit: 4

Prerequisites: None
Corequisites: None

This course provides an introduction to product safety systems, the collection and processing of safety data, and data coding. Emphasis is placed on the importance of quality data, the steps in case processing, and experience in entering case data. Upon completion, students should be able to discuss and perform the essential steps in processing a case from beginning to end for both pre-marketing and post-marketing cases.

MSP 150 Med Product Safety Fieldwork I

Class: 0 Lab: 0 Clinical: 15 Credit: 5

Prerequisites: MSP 110, MSP 115, MSP 120, and MSP 130
Corequisites: None

This course provides supervised work experience and observations in a medical product safety research setting. Emphasis is placed on the enhancement of professional skills and the practical application of curriculum concepts in a research setting. Upon completion, students should be able to describe research theory effectively to medical product safety/pharmacovigilance research practices.

MSP 220 Signal Detection and Risk Assess

Class: 3 Lab: 3 Clinical: 0 Credit: 4

Prerequisites: None
Corequisites: None

This course provides a basic understanding of the analysis of data to identify safety signals and to determine a product's risk profile to ensure a medical product has a favorable benefit-risk balance through its life cycle. Topics include the rationale and methods used in analyzing single cases versus aggregate data. Upon completion, students should be able to synthesize work in case processing, safety systems, safety reporting and regulations to assess a product's benefit-risk, as well as to identify the issues in ongoing benefit-risk assessments and demonstrate a basic understanding of how signaling and risk assessments are done.

MSP 250 Med Product Safety Research Fieldwork II

Class: 0 Lab: 0 Clinical: 24 Credit: 8

Prerequisites: MSP 110, MSP 115, MSP 120, MSP 130, and MSP 150
Corequisites: None

This course provides advanced work experience in a medical product safety/pharmacovigilance research setting. Emphasis is placed on the refinement of professional skills and the practice of curriculum concepts in diverse medical product safety research areas. Upon completion, students should be able to apply research theory to medical product safety/ pharmacovigilance practices.

PROPOSED CURRICULUM STANDARD

Effective Term
Spring 2014
*[2014*01]*

Curriculum Program Title	**Medical Product Safety and Pharmacovigilance**	Program Code	**A45XXX**
Concentration	**(not applicable)**	CIP Code:	**51.2099**

Curriculum Description

The Medical Product Safety and Pharmacovigilance curriculum prepares individuals to work with pharmaceutical, biologic, and medical device companies to monitor, track, and report product safety data during ongoing clinical trials, as well as after a product has been approved and marketed.

Course work includes in-depth study of federal regulations, components of a safety monitoring program, and procedures for reporting safety data. Supervised fieldwork focuses on reviewing adverse reports, writing safety case narratives, and creating safety reports in accordance with U.S. and international regulations.

Graduates of this program may be eligible to sit for national certification examinations. Employment opportunities may include medical centers, hospitals, pharmaceutical, medical device, biotechnology companies, and contract research organizations.

*Curriculum Requirements**

[for associate degree, diploma, and certificate programs in accordance with 1D SBCCC 400.97 (3)]

I. **General Education.** Degree programs must contain a minimum of 15 semester hours including at least one course from each of the following areas: humanities/fine arts, social/behavioral sciences, and natural sciences/mathematics. Degree programs must contain a minimum of 6 semester hours of communications. Diploma programs must contain a minimum of 6 semester hours of general education; 3 semester hours must be in communications. General education is optional in certificate programs.

II. **Major Hours**. AAS, diploma, and certificate programs must include courses which offer specific job knowledge and skills. Work-based learning may be included in associate in applied science degrees up to a maximum of 8 semester hours of credit; in diploma programs up to a maximum of 4 semester hours of credit; and in certificate programs up to a maximum of 2 semester hours of credit. *(See second page for additional information.)*

III. **Other Required Hours.** A college may include courses to meet graduation or local employer requirements in a certificate, diploma, or associate in applied science program. These curriculum courses shall be selected from the Combined Course Library and must be approved by the System Office prior to implementation. Restricted, unique, or free elective courses may not be included as other required hours.

	AAS	**Diploma**	**Certificate**
Minimum General Education Hours	15	6	0
Minimum Major Hours	49	30	12
Other Required Hours	0-7	0-4	0-1
Total Semester Hours Credit (SHC)	**64-76**	**36-48**	**12-18**

**Within the degree program, the institution shall include opportunities for the achievement of competence in reading, writing, oral communication, fundamental mathematical skills, and basic use of computers.*

Proposed *Major Hours*

[ref. 1D SBCCC 400.97(3)]

A. Core. The subject/course core is comprised of subject areas and/or specific courses which are required for each curriculum program. A diploma program offered under an approved AAS program standard or a certificate which is the highest credential level awarded under an approved AAS program standard must include a minimum of 12 semester hours credit derived from the subject/course core of the AAS program.

B. Concentration *(if applicable).* A concentration of study must include a minimum of 12 semester hours credit from required subjects and/or courses. The majority of the course credit hours are unique to the concentration. The required subjects and/or courses that make up the concentration of study are in addition to the required subject/course core.

C. Other Major Hours. Other major hours must be selected from prefixes listed on the curriculum standard. A maximum of 9 semester hours of credit may be selected from any prefix listed, with the exception of prefixes listed in the core or concentration. Work-based learning may be included in associate in applied science degrees up to a maximum of 8 semester hours of credit; in diploma programs up to a maximum of 4 semester hours of credit; and in certificate programs up to a maximum of 2 semester hours of credit.

Medical Product Safety and Pharmacovigilance A45XXX

	AAS	Diploma	Certificate
Minimum Major Hours Required	**49 SHC**	**30 SHC**	**12 SHC**
A. CORE	**41 SHC**		
Required Courses:			
CTR 110 Intro to Clinical Research 3 SHC MSP 110 Intro to Medical Product Safety 3 SHC MSP 115 Medical Product Safety Regulations 3 SHC MSP 120 Safety Reporting 3 SHC MSP 130 Safety Systems and Processes 4 SHC MSP 150 Med Product Safety Fieldwork I 5 SHC MSP 220 Signal Detection and Risk Assess 4 SHC MSP 250 Med Product Safety Research Fieldwork II 8 SHC			
Required Subject Areas: **Anatomy & Physiology.** Select one sequence: BIO 165 Anatomy and Physiology I 4 SHC & BIO 166 Anatomy and Physiology II 4 SHC *or* BIO 168Anatomy and Physiology I 4 SHC & BIO 169 Anatomy and Physiology II 4 SHC			
B. CONCENTRATION *(Not applicable)*			
C. OTHER MAJOR HOURS *To be selected from the following prefixes: BIO, BUS, CIS, COE, CTR, DBA, HIT, MED,PHM, SOC and *WBL* Up to three semester hour credits may be selected from the following prefixes: *ARA, ASL, CHI, FRE, GER, ITA, JPN, LAT, POR, RUS and SPA* **WBL prefix will be available in fall 2014.*			