

# CURRICULUM STANDARD

Effective Term  
Spring 2014  
[2014\*01]

Curriculum Program Title	<b>Medical Product Safety and Pharmacovigilance</b>	Program Code	<b>A45810</b>
Concentration	<b>(not applicable)</b>	CIP Code	<b>51.2099</b>

## 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 400.10]*

- 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.

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

*\*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.*

## **Major Hours**

**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 A45810**

	<b>AAS</b>	<b>Diploma</b>	<b>Certificate</b>
<b>Minimum Major Hours Required</b>	<b>49 SHC</b>	<b>30 SHC</b>	<b>12 SHC</b>
<b>A. CORE</b>	<b>41 SHC</b>		
<b>Required Courses:</b>			
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		
<b>Required Subject Areas:</b>			
<b>Anatomy &amp; Physiology.</b> Select one sequence:			
BIO 165 Anatomy and Physiology I	4 SHC &		
BIO 166 Anatomy and Physiology II	4 SHC		
<i>or</i>			
BIO 168 Anatomy and Physiology I	4 SHC &		
BIO 169 Anatomy and Physiology II	4 SHC		
<b>B. CONCENTRATION</b> ( <i>Not applicable</i> )			
<b>C. OTHER MAJOR HOURS</b> <i>To be selected from the following prefixes:</i> BIO, BUS, CIS, CTR, DBA, HIT, MED, PHM, SOC and WBL			
<i>Up to two semester hour credits may be selected from ACA.</i>			
<i>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.</i>			