REGULATORY AFFAIRS Specialization Sample Plans of Study

AUTUMN ENTRY – Full-time 12-Month Plan

Please note: 12-month plan of study is only available to students entering the program in autumn semester.

Year 1 – Autumn		Year 1 – Spring		Year 1 – Summer	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical	3	NURSING 7781: Responsible Conduct of	3	PHR 5010: Fundamentals of	3
Product Development and Regulation		Research		Pharmacology [1]	
(AU & SU)		(SP)		(SU)	
NURSING/PHR 7782: Clinical Research	3	NURSING/PHR 7405: Clinical Research	3	NURSING/PHR 7482: Prin. of Quality	3
Design and Methods		Study and Site Management		Management for Medical Product Dev.	
(AU)		(SP, prerec 7770)		(SU, prerec 7405)	
PHR 7784: Data Analysis and	3	PHR 7580: Principles of Safety	3	PHR 7460: Regulatory Strategy and	3
Interpretation in Clinical Research [2]		Pharmacology		Clinical Trial Reporting	
(AU)		(SP)		(SU, prerec 7770)	
PHR 7570: Pharmaceutical Safety and	3	PHR 7572: Global Regulation of Medical	3	NURSING/PHR 7599: Culminating	3
Risk Management		Products		Project in Clinical Research	
(AU)		(SP, prerec 7770)		(AU, SP, SU)	
	12		12		12

[1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)

The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) or a graduate biostatistics course may substituted:

CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)

PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)

PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)

PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

[2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)



REGULATORY AFFAIRS Specialization Sample Plans of Study

AUTUMN ENTRY – Part-time 24-Month Plan

Year 1 – Autumn		Year 1 – Spring		Year 1 – Summer	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical	3	NURSING 7781: Responsible Conduct of	3	PHR 5010: Fundamentals of	3
Product Development and Regulation		Research		Pharmacology [1]	
(AU & SU)		(SP)		(SU)	
NURSING/PHR 7782: Clinical Research	3	NURSING/PHR 7405: Clinical Research	3	NURSING/PHR 7482: Prin. of Quality	3
Design and Methods		Study and Site Management		Management for Medical Product Dev.	
(AU)		(SP, prereq 7770)		(SU, prerec 7405)	
	6		6		6
Year 2 – Autumn		Year 2 – Spring		Year 2 – Summer	
Course	credits	Course	credits	Course	credits
PHR 7784: Data Analysis and	3	PHR 7580: Principles of Safety	3	PHR 7460: Regulatory Strategy and	3
Interpretation in Clinical Research [2]		Pharmacology		Clinical Trial Reporting	
(AU)		(SP)		(SU, prerec 7770)	
PHR 7570: Pharmaceutical Safety and	3	PHR 7572: Global Regulation of Medical	3	NURSING/PHR 7599: Culminating	3
Risk Management		Products		Project in Clinical Research	
(AU)		(SP, prerec 7770)		(AU, SP, SU)	
	6		6		6
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[1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)

The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) or a graduate biostatistics course may substituted:

CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)

PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)

PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)

PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

[2] _Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)



REGULATORY AFFAIRS Specialization Sample Plans of Study

SPRING ENTRY – Part-time 24-Month Plan

Year 1 – Spring		Year 1 – Summer		Year 1 – Autumn	
Course	credits	Course	credits	Course	credits
NURSING 7781: Responsible Conduct of	3	NURSING/PHR 7770: Fund. of Medical	3	NURSING/PHR 7782: Clinical Research	3
Research		Product Development and Regulation		Design and Methods	
(SP)		(AU & SU)		(AU)	
PHR 7580: Principles of Safety	3	PHR 5010: Fundamentals of	3	PHR 7784: Data Analysis and	3
Pharmacology		Pharmacology [1]		Interpretation in Clinical Research [2]	
(SP)		(SU)		(AU)	
	6		6		6
Year 2 – Spring		Year 2 – Summer		Year 2 – Autumn	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7405: Clinical Research	3	NURSING/PHR 7482: Prin. of Quality	3	PHR 7570: Pharmaceutical Safety and	3
Study and Site Management		Management for Medical Product Dev.		Risk Management	
(SP, prereq 7770)		(SU, prerec 7405)		(AU)	
PHR 7572: Global Regulation of Medical	3	PHR 7460: Regulatory Strategy and	3	NURSING/PHR 7599: Culminating	3
Products		Clinical Trial Reporting		Project in Clinical Research	
(SP, prerec 7770)		(SU, prerec 7770)		(AU, SP, SU)	
	6		6		6

[1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)

The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) or a graduate biostatistics course may substituted:

CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)

PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)

PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)

PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

[2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)



REGULATORY AFFAIRS Specialization Sample Plans of Study

SUMMER ENTRY – Part-time 24-Month Plan

Year 1 – Summer		Year 1 – Autumn		Year 1 – Spring	
Course	credits	Course	credits	Course	credits
NURSING/PHR 7770: Fund. of Medical	3	NURSING/PHR 7782: Clinical Research	3	NURSING 7781: Responsible Conduct of	3
Product Development and Regulation		Design and Methods		Research	
(AU & SU)		(AU)		(SP)	
PHR 5010: Fundamentals of	3	PHR 7784: Data Analysis and	3	NURSING/PHR 7405: Clinical Research	3
Pharmacology [1]		Interpretation in Clinical Research [2]		Study and Site Management	
(SU)		(AU)		(SP, prereq 7770)	
	6		6		6
Year 2 – Summer		Year 2 – Autumn		Year 2 – Spring	
Year 2 – Summer		Year 2 – Autumn		Year 2 – Spring	
Year 2 – Summer Course	credits	Year 2 – Autumn Course	credits	Year 2 – Spring Course	credits
	credits 3		credits 3		credits 3
Course		Course		Course	
Course NURSING/PHR 7482: Prin. of Quality		Course PHR 7570: Pharmaceutical Safety and		Course PHR 7572: Global Regulation of Medical	
Course NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev.		Course PHR 7570: Pharmaceutical Safety and Risk Management		Course PHR 7572: Global Regulation of Medical Products	
Course NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405)	3	Course PHR 7570: Pharmaceutical Safety and Risk Management (AU)	3	Course PHR 7572: Global Regulation of Medical Products (SP, prerec 7770)	3
Course NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405) PHR 7460: Regulatory Strategy and	3	Course PHR 7570: Pharmaceutical Safety and Risk Management (AU) NURSING/PHR 7599: Culminating	3	Course PHR 7572: Global Regulation of Medical Products (SP, prerec 7770) PHR 7580: Principles of Safety	3
Course NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405) PHR 7460: Regulatory Strategy and Clinical Trial Reporting	3	Course PHR 7570: Pharmaceutical Safety and Risk Management (AU) NURSING/PHR 7599: Culminating Project in Clinical Research	3	Course PHR 7572: Global Regulation of Medical Products (SP, prerec 7770) PHR 7580: Principles of Safety Pharmacology	3

[1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)

The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) or a graduate biostatistics course may substituted:

CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)

PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)

PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)

PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)

[2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)

