SPEP 2-6: Industrial Elective Rotation Learning Objectives

Pharmacy students are trained in accordance with the competency elements of the National Association of Pharmacy Regulatory Authorities (NAPRA)[1]. The table below reflects 9 competency elements associated with learning objectives and specific learning activities. By the end of the SPEP Industrial Elective Rotation, the student will be able, but not limited, to do the following:

Professional Competency #1: Ethical, Legal and Professional Responsibilities
1.1 Practice within legal requirements
• Determine the licensing requirements and regulatory procedures to operate a pharmaceutical manufacturer.
• Discuss the requirements for obtaining a pharmacist license to work in a pharmaceutical manufacturer in Qatar.
• Review existing laws which affect the operation of a pharmaceutical manufacturer, and its compliance with cGMP set by FDA.
• Apply intellectual property regulations to the collection, use, storage, disclosure and destruction of manufacturer information.
1.2 Uphold Ethical Principles
• Behave in an ethical manner for the interest of the organization and the profession.
• Apply ethical principles in the decision-making process within the manufacturer setting.
1.3 Manage actual and potential illegal, unethical, or unprofessional situations

[1]http://www.napra.ca/Content_Files/Files/competencies.pdf
(http://napra.ca/content_files/files/comp_for_cdn_pharmacists_at_entrytopractice_march2014_b.pdf

• Identify illegal, unethical or unprofessional actions or situations that may occur in any manufacturer setting and discuss with the preceptor.
1.4 Apply principles of professionalism
• Identify and act upon learning opportunities proactively and independent from instructor prompting.
• Practice self-assessment by recognizing one's limitation and implementing a self-learning plan.
• Seek guidance from preceptors when uncertain about own knowledge, skills, abilities, and scope of practice.
• Demonstrate respect for personnel, maintaining appropriate professional boundaries.
• Maintain confidentiality when engaging in site specific information.
• Discuss with preceptors situations of actual and perceived conflict of interest.
• Adhere to professional attire.
• Demonstrate accountability for actions and decisions and respond openly to constructive feedback.
1.5 Document activities in compliance with the standard and policies at the setting
• Identify situations in which documentation should and should not be shared with third parties.
• Describe appropriate methods to share documentation within the setting site.
Professional Competency #2: Patient Care
N/A

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[a]NAPRA Reference Standard

Professional Competency #3: Product Manufacture and Distribution
3.1 Dispense a product safely and accurately that is appropriate for the patient
• Identify the processing steps involved in the manufacture and in-process quality control testing of drug products in different dosage forms.
• Stress the importance of documentation and independent double checking during all production steps following a systematic approach.
• Discuss active ingredients and excipients selection using knowledge of bio-equivalency, therapeutic equivalency, interchangeability, quality, integrity and stability of drugs.
• Perform pharmaceutical and compounding calculations.
• Develop master compounding formulas.
• Prepare and compound non-sterile and sterile products according to recognized guidelines and standards of practice.
• Determine official pharmacopeia specifications, methods and procedures for microbiological quality testing and pyrogen detection to ensure sterility.
• Understand the different activities in packaging of drug products and compliace with cGMP requirements, through in-process quality control tests
• Gain comprehensive understanding on the activities and documents involved prior to product distribution to the market.
• Check the documents needed during finished product quarantine and delivery to the warehouse.
• Determine the step-by-step procedure and requirements in product registration application.
• Recognize the laws affecting the application of product registration.
Professional Competency #4: Practice Setting

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[a]NAPRA Reference Standard

4.1. Optimize the safety, efficacy and efficiency of operations in the practice setting
• Identify the major activities, organizational set-up, and lay-out of the pharmaceutical manufacturer to carry out their mission and vission.
• Maintain awareness of emerging issues, products, services that may impact product manufacturing.
• Discuss with the preceptor cGMP/GLP guidelines and relate to manufacturer settings and operations.
• Discuss with the preceptor the qualifications, training, and role of manufacturer personnel (such as administrators, technicians, assistants).
4.2. Oversee manufacturer inventory to ensure safe, effective and efficient product manufacturing.
• Familiarize with the operations in the practice setting.
• Identify who is responsible for inventory control at the site.
• Discuss how often it occurs and how long it takes to receive the raw material order once it has been placed.
• Describe the procedures for storing, ordering, recording, and distributing of raw material.
4.3. Familiarize with record keeping activities to ensure safe, effective and efficient product manufacturing.
• Review the policies and procedures of the manufacturer on raw material and product storage, security, and quality assurance as per cGMP/GLP
Professional Competency #5: Health Promotion
5.3. Contribute to the maintenance of a healthy environment for the public
• Ensure the proper handling and disposal of drugs and hazardous materials.

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Professional Competency #6: Knowledge and Research Application	
6.1	Apply knowledge, research skills and judgment to the decision-making process
	• Classify the drug products developed in the pharmaceutical manufacturer.
	• Identify activities involved in drug product development and determine the documents that can be generated from this process.
6.2	Respond to questions and post-marketing issues using appropriate strategies
	• Demonstrate the steps that must be done on returned drug products and identify the conditions when to salvage these returned drug products.
	• Perform a literature search for at least 1 recent journal article that pertains to post-marketing surveillance and pharmacovigilance; read and analyze the article with your preceptor.
6.3	Apply relevant information to manufacturer settings
	• Gather an example of a post-marketing surveillance of pharmaceutical products and evaluate the procedure in conducting these surveillances.
Professional Competency #7: Communication and Education	
7.1	Establish and maintain effective communication skills
	• Act and communicate in a self-assured, confident manner.
	• Communicate at the appropriate level for a given situation.
	• Use listening skills consistently when performing professional functions.
	• Use correct grammar, punctuation, and spelling in written communication.

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7.2	Implement safe, effective, and consistent communication systems
	• Use correct pronunciation of technical, medical, and pharmaceutical terminology.
7.3	Deliver an education session to an individual or group
	• Perform a literature search for at least 1 recent journal article that pertains to R&D currents =7in pharmaceutical industry; read and analyze the article with your preceptor and present it to the cite team.
	• Verbally present in an organized and systematic manner 2 cases you have encountered in the production pipelines during rounds to your preceptor.
Professional Competency #8: Intra and Inter-Professional Collaboration	
8.1	Create and maintain collaborative professional relationships
	• Under preceptor arrangement, shadow and interview other members of the pharmaceutical manufacturer team, this can include administrators, scientists, laboratory technicians or other employees who are involved in the setting.
8.2	Contribute to the effectiveness of working relationships in collaborative teams
	• Under preceptor supervision, have at least 2 interactions with the manufacturer team (from various departments) during rounds within the manufacturer facilities and 1 interaction with a product leader regarding a production pipeline issue and briefly discuss the case.
Professional Competency #9: Quality and Safety	
9.1	Contribute to a culture of personnel and patient safety
	• Describe sanitation and hygiene practices in the setting site to ensure personnel safety, and to ensure quality products as per cGMP.
	• Share information about problems, resolutions, system changes and lessons learned with the workplace team.

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9.2	Contribute to continuous quality improvement and risk management activities related to pharmacy practice
	• Discuss with the preceptor how adverse events and medication use errors are reported in practice and handled at the pharmaceuticcal manufacturer.
	• Identify one formula error or adverse event that occurred at the site and discuss with the preceptor the measures used to prevent this error from occurring again.
	• Identify high-alert drugs and high-risk processes in order to respond effectively.
9.3	Ensure the quality, safety and integrity of products
	• Employ training programs for the personnel about product quality and safety.
	• Ensure the cleanliness, functionality and integrity of raw material, compounding, packaging, and storage equipment.
	• Gain comprehensive understanding on the activities and documents involved in receipt and storage of raw materials.
	• Ensure that products are stored and transported under the conditions required to maintain product quality, safety and integrity.
	• Evaluate the quality of supplies and products using recognized quality assurance techniques including visual inspection, verification of the legitimacy of the supplier and use of manufacturers' quality markers.

Resources used in the development of 'Industrial Elective Rotation Learning Objectives':

- Professional Competencies for Canadian at Entry to Practice Pharmacists, NAPRA 2014.
- AFPC Educational Outcomes for First Professional Degree Programs in Pharmacy in Canada, AFPC 2017.
- PharmD Mandatory Elective Descriptions, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, May 2016.
- Syllabus for Internship III: Phar 6 and Manufacturing Pharmacy internship, Faculty of Pharmacy, University of Santo Tomas, Philippines, May 2011.

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