Exam 2

Course Title:	**Taller de Traducción Ingeniería y Adelantos Tecnológicos**
Course ID:	**IT0628 (Marron, 25-2)**
Cohort ID:	**6A1**
Exam Date:	**11 Mar 2025**

General Instructions: Print your name in the upper right-hand corner of this paper. Read each item carefully. Be sure that you understand exactly what is being asked of you. Begin your answers on the backside of this paper if possible and add extra sheets of paper as needed. Be sure to write your name on any and all extra sheets of paper. Staple all exam papers together when you are finished.

Do not look at other student's exams. If you have a question or a request during the exam, raise your hand and the instructor will call on you.. Do not leave your desk without permission. If you finish early, raise your hand and the instructor will call on you.

This is a closed book exam; however, you may bring one (1) 8in. x 11 in. ¨cheat sheet" to the exam. Attempt to answer all questions, even if you are uncertain. Whenever possible, provide answers in bullet list format with complete content. Tasks will be evaluated by sub-tasks. Three (3) points are available for each sub-task: Accuracy (1 pt), Completeness (1 pt), and Sufficiency (1 pt). Points will be awarded in 0.1 increments. Answer in English unless requested to do so otherwise.

Task 1 (6 pts)

Translate the following into Spanish:

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result. The term "SOP" may not always be appropriate and terms such as protocols, instructions, worksheets, and laboratory operating procedures may also be used. For this document "SOP" will be used.

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations.

Task 2 (6 pts)
Translate the following into Spanish:

Each organization should develop a numbering system to systematically identify and label their SOPs, and the document control should be described in its Quality Management Plan. Generally, each page of an SOP should have control documentation notation, similar to that illustrated below. A short title and identification (ID) number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed. When the number of pages is indicated, the user can quickly check if the SOP is complete. Generally this type of document control notation is located in the upper right-hand corner of each document page following the title page.

Technical SOPs can be written for a wide variety of activities. Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover activities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation.

Task 3 (6 pts)
Answer and/or summarize the following:

1. What is a Standard Operating Procedure (SOP)?
2. Why are SOPs written? What is their purpose?
3. What are the organizational benefits from using SOPs?
4. Who should write SOPs?
5. What should be the technical level of information in an SOP? Why?
6. What is document control?

Task 4 (9 pts)
Translate the following technical terms into Spanish and provide definitions of the terms in both English and Spanish:

- analytical method
- archival
- calibration
- certification
- compliance
- conformance
- corrective action
- degradation
- deliverable

- document status
- functional programmatic procedure
- protocol
- Quality Assurance (QA)
- Quality Control (QC)
- regulatory
- replicates
- risk assessment
- specimen
- stakeholder “buy-in”
- troubleshooting
- validation

Task 5 (Extra Credit)

Answer the following:

1. What is a Version Control System (VCS) and why is version control an important part of a complete, records management system?
2. Define and explain the follow acronyms in relation to modern-day translation: API, LLM, GPT, SDK, IDE