Non-sterile compounding essentials

All existing pharmacies performing non-sterile compounding must meet or exceed the standards involving human factors, like policies and procedures, risk assessment, personal protective equipment (PPE), and additional training, by **January 1, 2020**. Other areas that may require structural changes or additional equipment have a compliance deadline of **July 1, 2021**. All new pharmacies must be in compliance with the standards for their pre-opening inspections.

- Read the Standards for Pharmacy Compounding of Non-sterile Preparations and Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

- Assign a compounding supervisor to oversee the implementation of standards.

- Determine who will be responsible for creating the compounding policy and procedures.
    - Do you work for a pharmacy that provides centralized support? Inquire if they will provide standardized policies and procedures. If so, ensure that the material provided covers all relevant elements stated in the guidance document, then ensure that all staff review the policies and procedures.

- Begin creating required policies and procedures if needed (see guidance document for template to begin).

- Review the NIOSH list of hazardous drugs.
    - Create a list of all hazardous drugs you deal with on site.
    - Organize according to where on the NIOSH table they are found and document the known risks.
    - Review all Active Pharmaceutical Ingredients (APIs) on site, gather all Safety Data Sheets (SDS), and create a binder or file of this information that is easily accessible to all compounding staff.
    - Canada has aligned the Workplace Hazardous Materials Information System (WHMIS) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Consult Section 2 of your SDS for WHMIS/ GHS Hazards Identification.
        - The SDS must be updated at minimum every three years. The document date is printed on each sheet to facilitate upkeep.
    - Review the SDS for each compound, paying special attention to Section 8 for exposure controls and personal protective equipment (PPE).
    - Determine if you have the physical facilities, PPE, and/or specific engineering controls required to compound with that chemical. If not, consider all options available to you:
        - Transfer the prescription to a compounding pharmacy that meets these requirements, if appropriate.
        - Outsource compounds you are not able to prepare by signing a compounding and repackaging agreement with a compounding pharmacy that meets these requirements.

        - Consider a renovation to include the required engineering controls. You must inform ACP's registration department of your intent to renovate.
        - Collaborate with the prescriber to determine if an alternative product would be appropriate.

- Create a list of required PPE you will need to have on hand and begin sourcing this equipment.

- Begin reviewing and updating all Master Formulation Sheets.
    - Assess risk for each compound and assign Risk Level A, B, or C.
    - Assess risk for each compound using Section 2 of the SDS and NIOSH tables. Assign Risk Level A, B, or C to each compound.
        - See Diagram 1 in the guidance document to help determine risk level.
        - When there is any uncertainty as to the level of risk, then the higher standard must always be adhered to.

- Update the master formulation sheet with all required information (GPCNP 6.2). Ensure that the following elements are included:
    - The source of original formula and that the formula is current.
    - Your risk assessment (Level A, B, or C) and risk mitigation strategies.
    - The required equipment, instruments, and materials, including PPE and engineering controls needed as per the SDS.
    - The compounding method.
    - The packaging requirements and storage.
    - A Beyond-Use Date (BUD) assigned based on stability studies. In the absence of stability data, maximum BUDs recommended for non-sterile compounded preparations that are packaged in air-tight, light resistant containers and stored at controlled room temperatures (refer to GPCNP Table 4).
        - Request stability studies from the formula source if you intend to assign BUDs greater than the maximum recommended.
    - The date the formula was revised and by whom.
        - Start with your most common compounds. If you no longer use a formula, deactivate the drug file. However, when considering changing any computer record, be aware of what might happen to existing records (e.g., prescriptions with that compound or linked to the drug file).

- Develop a training and skills assessment program for all compounding personnel (GPCNP 5.2.1).

- Ensure that all personnel involved in cleaning are appropriately trained (GPCNP 5.2.2), all equipment and facilities are cleaned regularly, and a log is kept.

- Review the facilities and equipment requirements and ensure that the pharmacy meets all requirements based on the level of risk and type of compounds:
    - Ensure hoods are certified every six months.
    - Arrange for regular maintenance and certification of equipment as needed, such as powder containment hoods.
    - All compounding facilities require an eyewash station and any other emergency or safety equipment required based on the SDS.
    - Compounding personnel must wear a disposable gown or a clean, dedicated lab coat, powder free gloves, and any other PPE indicated on the master formula.

- Develop a quality assurance process (GPCNP 7).