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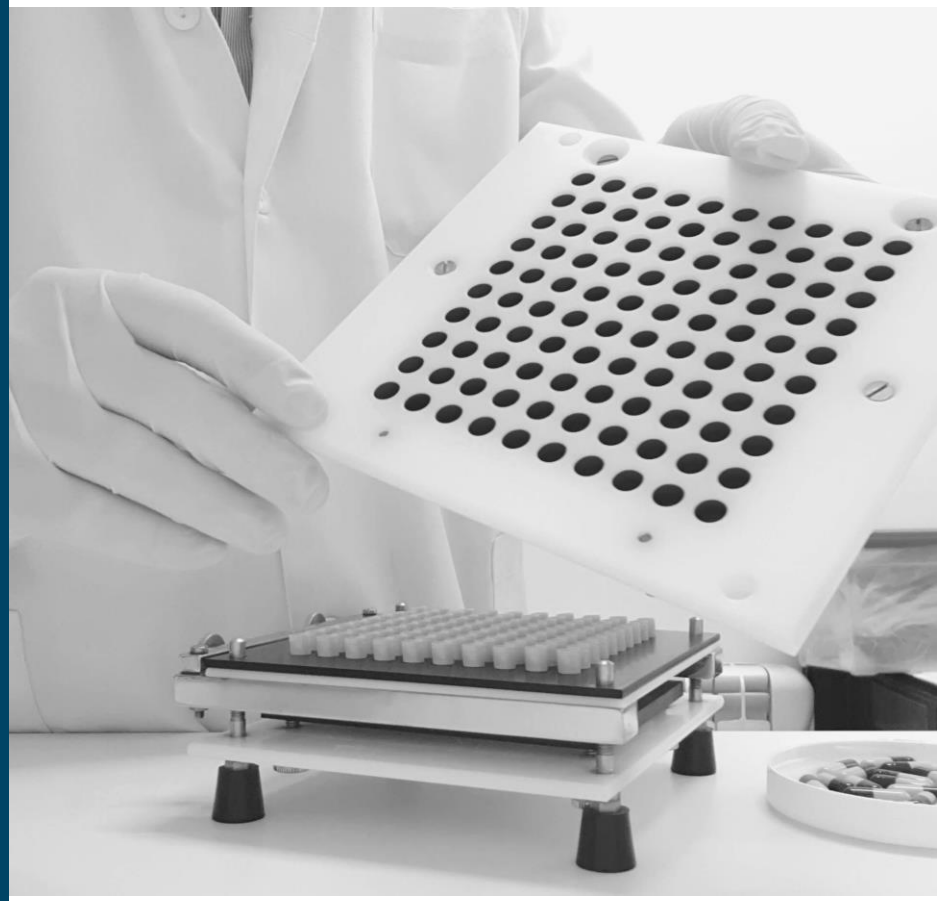
EDUCATIONAL RESOURCES

PHARMACY



USP 800

It’s in Play and I’m not Playing

Objectives & Program Intent

- Discuss the proper receipt, storage, compounding, dispensing, administration, and disposal of sterile Hazardous drug products and preparations.
- Discuss Facility and engineering controls required when handling Hazardous drugs
- Discuss the Proper use of appropriate Personal Protective Equipment (PPE) when handling Hazardous drugs
- Discuss personnel competency and safe work practices when handling Hazardous drugs

Summary of USP 800

- Final Version released November 1, 2022, and now compendially enforceable November 1, 2023
- All drugs on the current National Institute for Occupational Safety and Health (NIOSH) list of HDs must undergo risk assessment
- ALL places where they are prepared, stored , transported, & administered
- ALL personnel who compound or handle Hazardous Drugs (HDs)
- Addresses from receipt of drug through disposal
- Roles of the Designated Person

NIOSH List / Categories

- Hazardous Drug (HD): Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:
  1. Carcinogenicity (cancer causing)
  2. Teratogenicity (birth defects) or other developmental toxicity
  3. Reproductive toxicity in humans
  4. Organ toxicity at low doses in humans or animals
  5. Genotoxicity (gene mutations)
  6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

NIOSH List / Categories

- National Institute for Occupations Safety and Health (NIOSH) defines three groups of drugs:
  - Group 1: Antineoplastic drugs (i.e., chemotherapy)
  - Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug.
  - Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast-feeding.

Poll Question #1

- Drugs on the NIOSH list that must follow the requirements in USP chapter 800 include:
  - Any HD API
  - Any antineoplastic requiring HD manipulation
  - Not if an assessment of risk is performed and implemented
  - All of the above

Exposure to Hazardous Drugs

- The toxic effects of hazardous drugs administered to patients in therapeutic doses are well known.
- However, a safe level of occupational exposure to hazardous drugs for healthcare workers has **not** been determined.
- The safest level is **NO** exposure.
- That is why precautions and guidelines are in place to reduce or eliminate exposure.
- Goal of USP 800 is to minimize exposure to hazardous drugs

Potential for Exposure

Activity	Potential Opportunity of Exposure
Administration (inhalation, absorption, ingestion, accidental injection)	• Generating aerosols during administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming an IV administration set
Patient-care activities (absorption, ingestion)	• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills (inhalation, absorption, ingestion)	• Spill generation, management, and disposal
Transport (absorption)	• Moving HDs within a healthcare setting
Waste (absorption, ingestion, accidental injection)	• Collection and disposal of hazardous waste and trace contaminated waste

Hazardous Communication Program

- All personnel who routinely handle HDs will receive training that includes the following items:
  - Labeling
  - Transport
  - Storage
  - Disposal
  - The use of Safety Data Sheets (SDS)
  - Acknowledgement of risk documented

Risk Acknowledgement

- All healthcare team members who handle hazardous drugs must sign an acknowledgement form documenting their consent.
- Team members are expected to:
- Read & understand policies and procedures related to proper handling of hazardous drugs.
- Notify their supervisor, manager, or other designated individual with questions or safety concerns related to HDs.
- Confirm they understanding the risk of handling HDs when of reproductive capability.
- Discuss alternative job duties with their supervisor, manager, or other designated individual when appropriate.

Hazardous Drug Receiving and Storage

- HDs must be delivered to the HD storage area immediately after unpacking.
- HDs must be unpacked in neutral to negative pressure
- Antineoplastic HDs must be stored separately from non-HDs and in negative pressure

Transport

- Group 1 HDs (chemotherapy) are transported in impermeable plastic zip top bags, with prominent labeling indicating “chemotherapy”

- Group 1 HDs (chemotherapy) and any other Group 2/3 HD in liquid form must NOT be transported via pneumatic tube.

Personal Protective Equipment (PPE)

- The following PPE may apply to HD handling depending on the circumstance. PPE Specified below must meet the following requirements:
  - **Gloves**
    - ASTM standard D6978
    - Powder free
    - Sterile
  - **Gowns**
    - Disposable
    - Resistant to permeability of HDs
    - Close in back and have longs sleeves, seamless with elastic or knit cuffs
    - Always used when risk of splash or spill

Personal Protective Equipment (PPE)

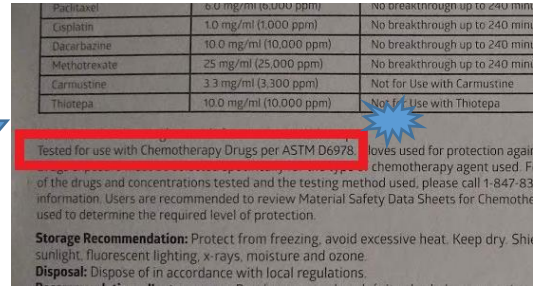
- The following items must be worn during preparation, administration, and disposal of ALL Group 1 HDs (chemotherapy), and liquid Group 2/3 HDs
  - Double gloves*
  - Disposable protective gown*
  - Goggles/eye/face protection (with risk of splashes or spills)

*Note: Items are ASTM-rated for chemotherapy permeability.

Personal Protective Equipment (PPE)

- The following items must be worn during preparation, administration, and disposal of intact oral Group 2/3 HDs
  - Single gloves
  - See order / labeling for comprehensive PPE requirements prior to administration.

Gloves meet ASTM D6978 requirements



Personal Protective Equipment (PPE)

Activity Based PPE Approach

NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings
Table 5. Personal protective equipment and engineering controls for working with

Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Subcutaneous/ intra-muscular injection from a vial	Preparation (withdrawing from vial)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash[†]	no	N/A
Withdrawing and/or mixing intravenous or intramuscular solution from a vial or am-poule	Compounding	yes[§]	yes	no	no	yes, BSC or CACI; use of CSTD rec-ommended
	Administration of prepared solution[¶]	yes	yes	yes; if liquid that could splash[†]	no	N/A; CSTD required per USP 800 if the dosage form allows

Reference: Antineoplastic & Other Hazardous Drugs in Healthcare, 2016 | NIOSH | CDC

Personal Protective Equipment (PPE)

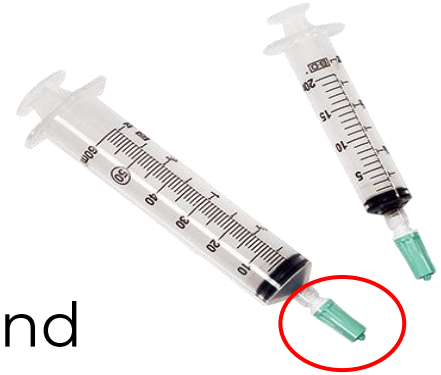
- For all other activities, there is a policy for PPE based on activity and risk
- Appropriate PPE must be worn when handling HDs during:
    - Receipt
    - Storage
    - Transport
    - Compounding
    - Administration
    - Deactivation/decontaminating, Cleaning and Disinfecting
    - Waste disposal
    - Spill Management

*Refer to your facility's policies and procedures for required PPE based on activity

Poll Question #2

- True or False: Chemo gowns must close in the front

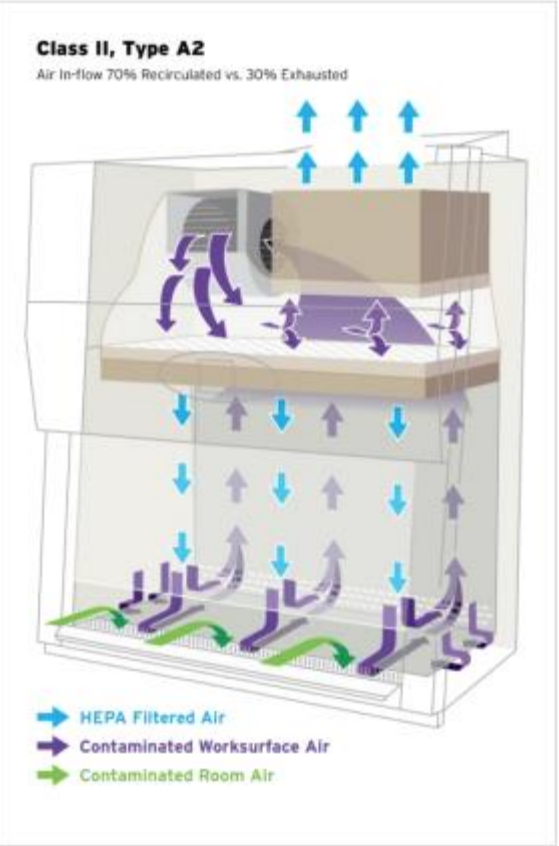
Engineering Control



- In addition to PPE, all Group 1 HDs (chemotherapy) and select Group 2 HDs are administered utilizing a contained or “closed” medication system. These closed system transfer devices (CSTD) will be utilized by pharmacy and attached to completed intravenous (IV) & intramuscular (IM) products when applicable.
- When using CSTD, pharmacy will spike all IV products and prime tubing with compatible non-HD fluid (e.g. 0.9% sodium chloride or dextrose 5% solution)
- All of this equipment helps reduce the risk of exposure to healthcare workers.

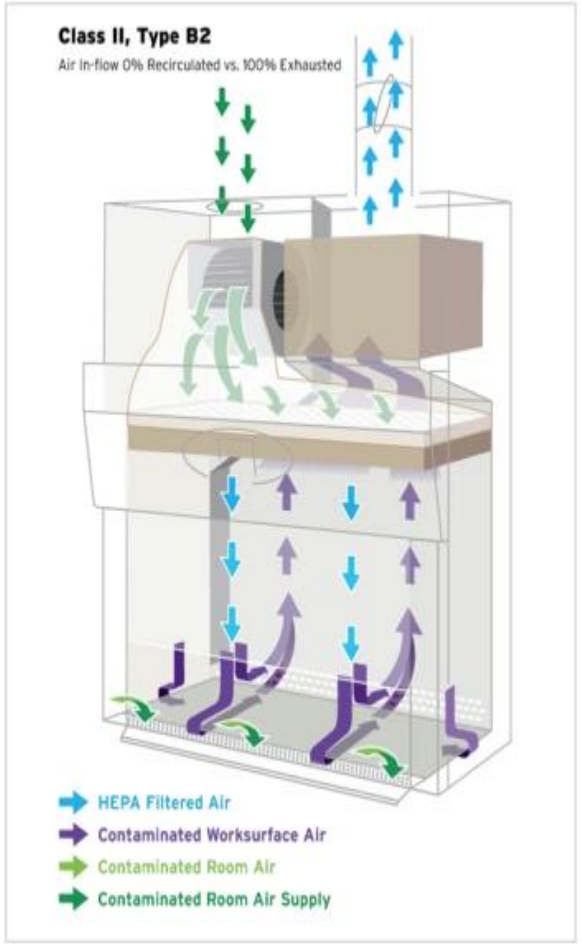
Hazardous Drug C-PEC

- **BSC Class II Type A2**
  - These devices partially recirculate ISO Class 5 air before eventually exhausting it to the external environment
  - These are the most common type of BSCs used for the sterile compounding of HDs
  - If a Type A is being used, the third-party certifier must ensure that the BSC is canopy-connected and has an alarm to monitor proper operation.



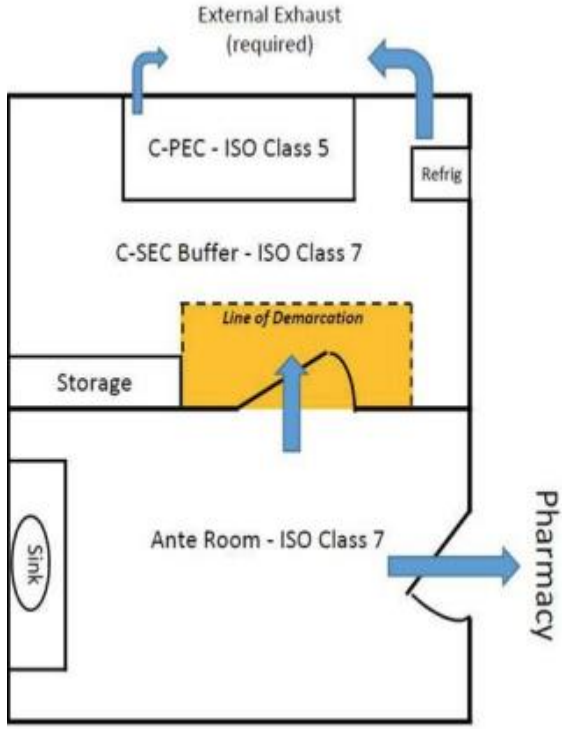
Hazardous Drug C-PEC

- **BSC Class II Type B2**
  - Because no air is recirculated, these devices are useful when handling volatile HDs
  - Provides HEPA-filtered ISO Class 5 unidirectional air
  - Allowing for the movement of materials in and out through defined openings that have been designed and validated to preclude the transfer of contamination
  - All C-PECs used for manipulation of sterile HDs must be externally vented and provide ISO 5 or better air quality



Hazardous Drug Buffer Room

- **Air Flow**
  - Air must flow from the anteroom into the C-SEC buffer room, from which it is externally vented
  - ISO Class 7 or better air, the air in the anteroom must also be ISO Class 7 or better
  - Pressure: A negative pressure differential of 0.01 – 0.03 inches of water must exist between the CSEC buffer room and the anteroom
  - HEPA filters must be in the ceiling and exhaust grills low on the wall
  - 30 ACPH minimum requirment



Hazardous Drug Storage Room

- **Exhaust**
  - Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage form and any HD API must:
    - Be store separately from non-HDs in a manner that prevents personnel exposure
    - Be stored in an externally ventilated, negative pressure room
    - 12 ACPH
    - A Fixed-wall room with smooth, impervious, crack-free walls, ceilings, and floors
    - ISO Air Class: Unclassified

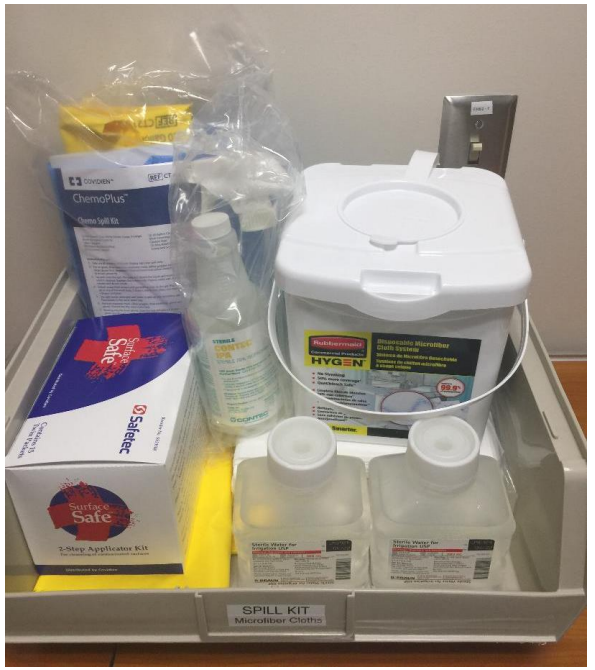
Deactivation, Decontamination, Cleaning and Disinfecting (DDCD)

Process	Purpose	Examples	
Expanded Requirements (for all HD) **Required during spill clean-up, compounding, and decontaminating reusable PPE.**			
Decontamination /Deactivation	Remove Hazardous Drug (HD) residue/render compound inert or inactive	Oxivir Tb, PDI Bleach, Peridox RTU	 
Old Requirements			
Cleaning	Remove organic and inorganic material	Virex II, Oxivir 5:16, Peridox RTU	   
Minimum daily and routinely after compounding different hazardous drug categories			
Disinfection (where specified)	Destroy microorganisms	70% Isopropyl Alcohol	

Small Spills

- Small Spills: < 5 mL
- Isolate area

- Obtain Spill kit



HAZARDOUS DRUG SPILL – KEEP OUT!

- Contact Emergency Response Team & Pharmacy for assistance if necessary.
- Follow Spill Control and Management for Hazardous Drugs – Standard Operating Procedure

Large Spills

- Large Spills: ≥ 5 mL
- Activate Emergency Response:
  - Facility Alert: **Hazardous Material Spill**
  - Follow Spill Control and Management for Hazardous Drugs – Standard Operating Procedure

Primary Containment	Secondary Containment
Isolate Area Triage exposures Obtain spill kit Deactivate/decontaminate HD	Brings additional cleaning supplies Bring Hazmat cart Triage Personnel Assist with Cleaning

HD Disposal and Containment

Pharmaceutical Waste

NOT for HD disposal or trace contaminate disposal

Controlled Substance (CS) Waste

All CS that are also HDs follow normal CS waste procedures

Trace Contamination Waste

All PPE, empty IV bags/tubing, empty vials, and any preparation mats

Hazardous Waste

Any HD >3% unused (pourable amount)

Seal & return to pharmacy if bin unavailable

Poll Question #3

- Which of the following should be considered "bulk" NIOSH Table 1 hazardous waste?
  - Supplies used to clean up a spill
  - Containers with less than three percent by weight of the HD remaining
  - Disposable mats that are not visibly contaminated
  - Wipes used for routine C-SEC cleaning
  - All of the above

References

- Centers for Medicare and Medicaid Services (CMS) §482.25(b)
- United States Pharmacopeia and National Formulary (USP 42-NF 37). USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. Rockville, MD: United States Pharmacopeial Convention; 2019.
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- (1) Tomkins, J. Ensuring Health Care Worker Safety When Handling Hazardous Drugs: The Joint Position Statement From the Oncology Nursing Society, the American Society of Clinical Oncology, and the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2015 Jul;11(4):278-9.
- (2) OSHA: Controlling Occupational Exposure to Hazardous Drugs: Section IV.D: Surveys of Current Work Practices
- ASHP Guidelines on Handling Hazardous Drugs: Background: OSHA. https://www.ashp.org/- /media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx (Accessed August 2023)

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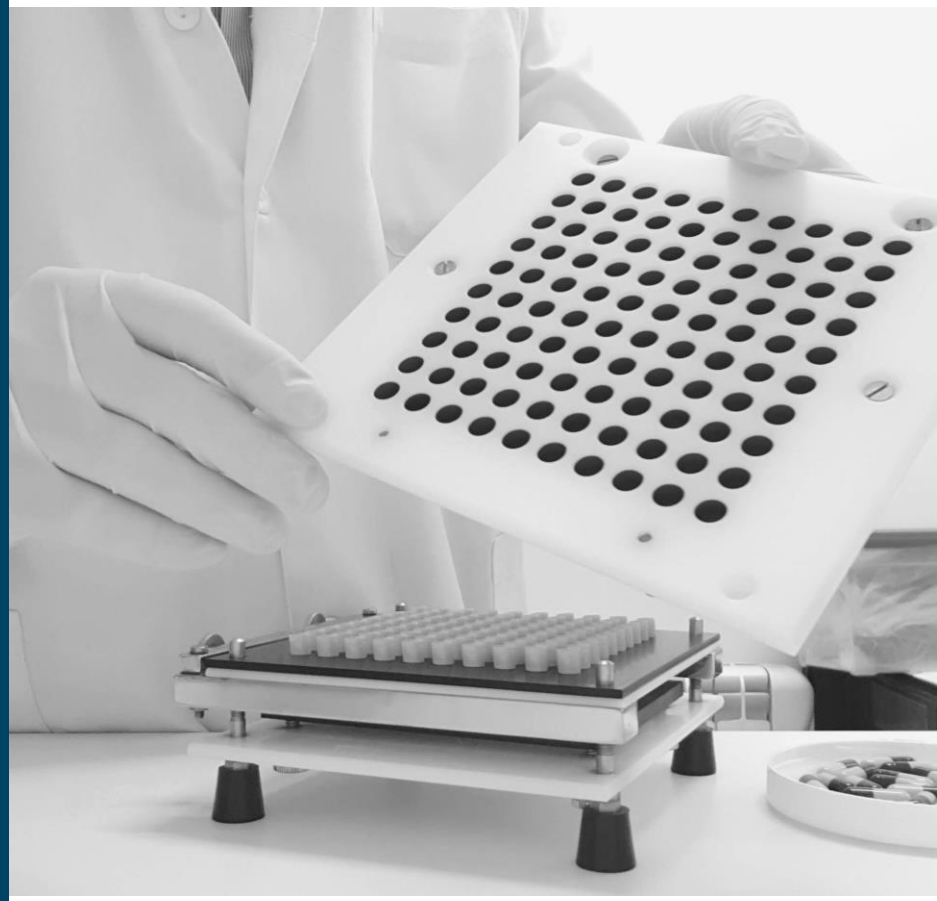

Thank you