

Use of Closed System Transfer Devices at CCDHB

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Objectives

- ▶ Overview on safety use of closed system device in the health care settings
- ▶ To discuss the advantage and disadvantage of the use CSTD in the Pharmacy and on the ward
- ▶ To highlight the benefit of the use of CSTD at CCDHB

Hazardous drugs

- ▶ Short-term HD exposure: headaches, skin rash, light-headedness, hair loss
- ▶ Long-term HD exposure: organ damage, genotoxicity, cancer, adverse reproductive outcomes
- ▶ Potential routes of exposure:
 - Inhalation
 - Absorption through the skin
 - Accidental injection
 - Ingestion of contaminated food or by mouth contact with contaminated hands

Guidelines for Minimizing HD Exposure

- ▶ *USP <800>: Hazardous Drugs—Handling in Healthcare Settings* (published 2016)
- ▶ *ASHP Guidelines on Handling Hazardous Drugs* (published 2018)
- ▶ *Oncology Nursing Society (ONS)*
- ▶ *Health and Safety Executive: Safe Handling of Cytotoxic Drugs in the Workplace*
- ▶ *Health and Safety at Work Act* (published 2015-NZ)
- ▶ *NZNO Cancer Nurses Section Position Statement on the Minimum Safety Requirement for Nurses involved in the administration of Anti-Cancer Drugs within Oncology and Non-Oncology Setting*
- ✓ Ventilated engineering controls
 - Class II or III BSC or a compounding aseptic containment isolator (CACI) for compounding sterile HDs
 - Externally vented ISO class 7 buffer room
- ✓ Personal protective equipment (PPE) (e.g., gowns, gloves, hair coverings, facemask, shoe coverings)
- ✓ Supplemental containment engineering controls (e.g., CSTDs)
- ✓ Identify all areas where HDs are stored or handled; restrict access to these areas



Closed System Transfer Devices

Drug transfer devices that mechanically prohibit the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapor concentrations outside the system (NIOSH)

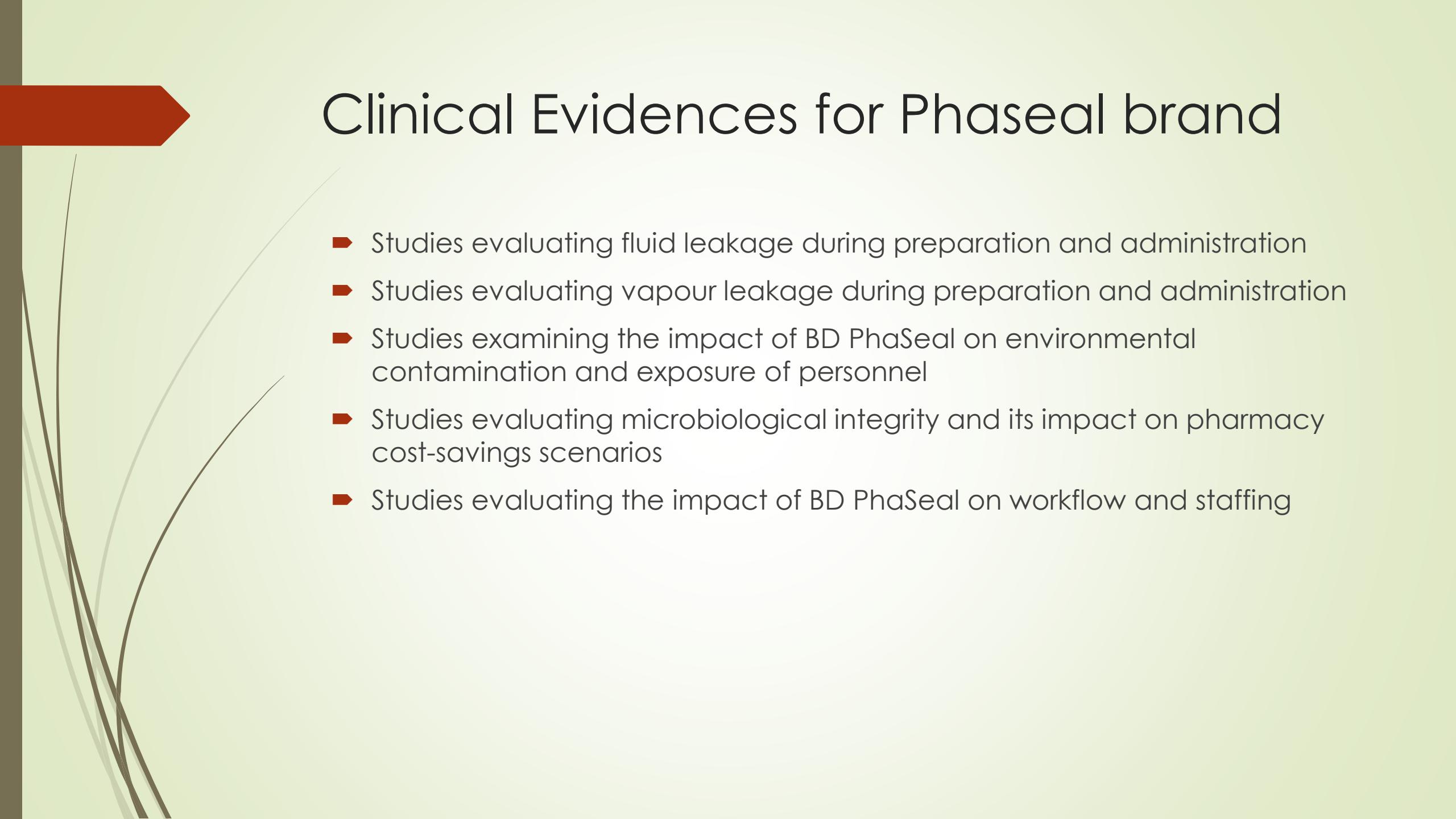
Generally follow one of two design concepts, using either a physical barrier or an air-cleaning technology to prevent the escape of hazardous drugs into the work environment.

Choosing the Brand of CSTD

- ▶ Safety of usage
- ▶ Registered medical devices (Pharmac)
- ▶ Our needs and preference (Nurses and Pharmacy staff)
- ▶ Sustainability of supply in Australasia
- ▶ Reputation
- ▶ Availability of competitive analysis

3 Brands which were reviewed prior to choosing the product:

- Equishield
- Codan
- BD Phaseal /Phaseal Optima



Clinical Evidences for Phaseal brand

- ▶ Studies evaluating fluid leakage during preparation and administration
- ▶ Studies evaluating vapour leakage during preparation and administration
- ▶ Studies examining the impact of BD PhaSeal on environmental contamination and exposure of personnel
- ▶ Studies evaluating microbiological integrity and its impact on pharmacy cost-savings scenarios
- ▶ Studies evaluating the impact of BD PhaSeal on workflow and staffing

Conclusion

- ▶ The **first** FDA cleared CSTD indicated to reduce exposure to hazardous drugs.
- ▶ The BD PhaSeal system is leakproof and airtight and satisfies the NIOSH, ASHP and ISOPP definitions of a closed-system drug transfer device (CSTD).
- ▶ Introduction of the BD PhaSeal system can prevent three sources of environmental contamination with cytotoxic drugs. These are:
 - Aerosols formed during drug preparation
 - Drug vapours released during drug preparation
 - Droplets released during transfer
- ▶ Introduction of the BD PhaSeal system has been proven to reduce occupational exposure of healthcare personnel to cytotoxic drugs.
- ▶ Staff quickly become adept at handling the BD PhaSeal system without sacrificing efficiency. Use of the BD PhaSeal system may help facilities realise an economic benefit in pharmacy.

The BD PhaSeal™ Optima System

With design innovations to address your clinical and economic concerns

Safety

- Injectors designed to prevent needle exposure and accidental needlesticks
- Self-sealing membranes on all components for leakproof connections
- Two injector options available, with or without locking feature

Performance

- Proprietary protector design designed to minimize residual drug loss in vials*[†]
- Prevents microbial ingress for up to 168 hours and 10 penetrations^{‡#†}
- Compatible with ISO-compliant luer lock syringes and IV sets

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Ergonomics

- Design of components optimized for clinician comfort
- Power grip and straight motion to connect that align with NIOSH recommendations to avoid pinch grip[‡]

Ease of use

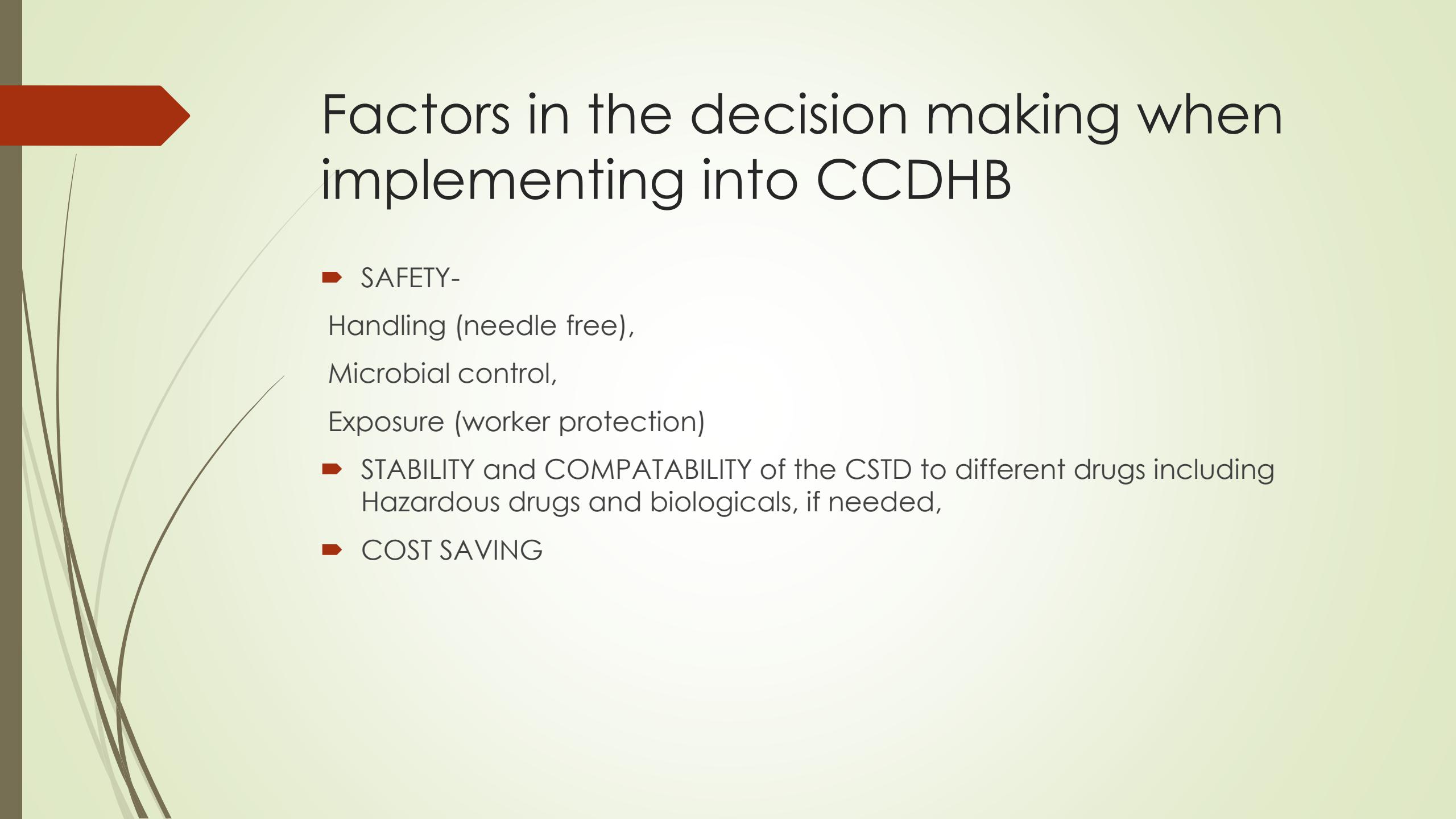
- Intuitive one-step straight-push connection to aid workflow integration
- No alignment or orientation needed to connect, minimizing learning curve
- Spinning collar enables to see syringe markings and helps to prevent tangling of IV lines

*Compared to similar systems.

[#]Beach test results may not necessarily be indicative of clinical performance.

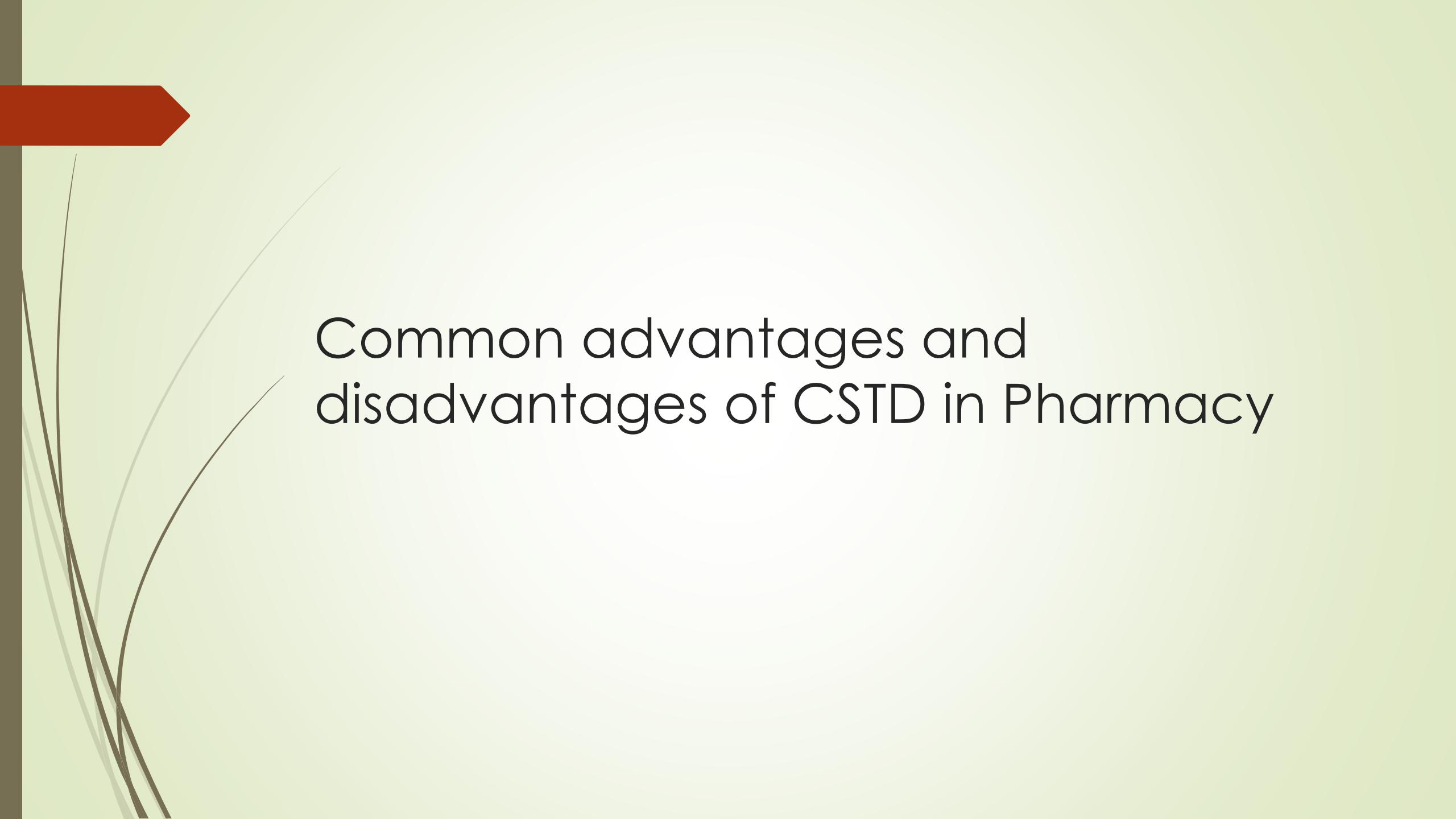
[†]Within an ISO Class V environment following aseptic technique.

[‡]The ability to prevent microbial ingress for up to 168 hours should not be interpreted as modifying, extending, or superseding a manufacturer's labeling recommendations for the storage and expiration dating of the drug vial. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.



Factors in the decision making when implementing into CCDHB

- ▶ SAFETY-
 - Handling (needle free),
 - Microbial control,
 - Exposure (worker protection)
- ▶ STABILITY and COMPATABILITY of the CSTD to different drugs including Hazardous drugs and biologicals, if needed,
- ▶ COST SAVING

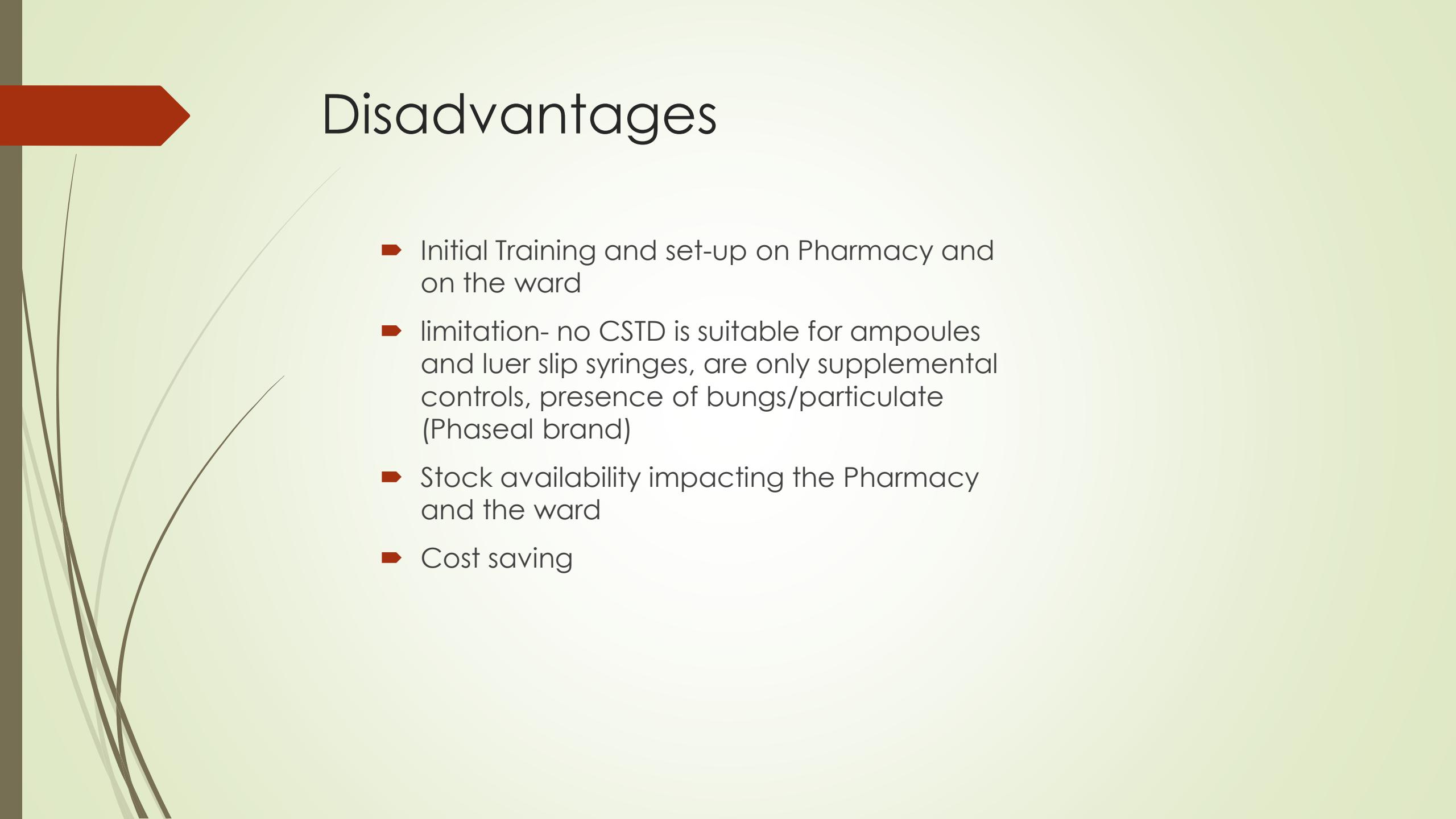


Common advantages and disadvantages of CSTD in Pharmacy



Advantages

- ▶ Ease of use
- ▶ Ergonomics
- ▶ Training
- ▶ Cost saving
- ▶ Improve efficiency
- ▶ Safety-Reduced contamination, spill and exposure, needle stick injury
- ▶ Positive impact on morale



Disadvantages

- ▶ Initial Training and set-up on Pharmacy and on the ward
- ▶ limitation- no CSTD is suitable for ampoules and luer slip syringes, are only supplemental controls, presence of bungs/particulate (Phaseal brand)
- ▶ Stock availability impacting the Pharmacy and the ward
- ▶ Cost saving



Benefits with the use of CSTD

- ▶ Reduced time spent cleaning the negative isolator/s when the gloves tear
- ▶ Minimal to non existent spillage while compounding and administrating the HD
- ▶ Saving bag- when there is drug reaction and the patient still takes the remaining dose after the treatment
- ▶ Able to apply push and pull method in compounding HD

2024/2025 COST/Saving Report

The vial waste savings do not offset the cost of implementing CTSD in the APU; **Overall, 2024 cost the department about \$300k extra, rather than saving us money.** This year so far appears to be delivering better vial waste savings as some of the newer expensive drugs are funded.

Month-Year	CTSD	Needle	Difference	Theoretical waste	Actual waste	Waste savings	APU CTSD COST/SAVINGS
2024	\$ 399,194.05	\$ 44,273.85	\$ 354,920.20	\$ 391,416.73	\$ 336,683.74	-\$ 54,732.99	\$ 300,187.21
2025	\$ 196,943.05	\$ 19,980.00	\$ 176,963.05	\$ 249,422.08	\$ 141,760.07	-\$ 107,662.01	\$ 69,301.04



How to use the product

- ▶ <https://bd.showpad.com/share/urnhaYohcLvaRkuGPWYFw/0>