Medical Devices in Pharmacy Practice

2023 Alberta Pharmacy Technician Conference

September 9, 2023

Personal Disclosure

- I have no current or past relationships with commercial entities.
- I have received a speaker's fee from the Pharmacy Technician Society of Alberta for this learning activity.

Commercial Disclosure

- This program has received no financial or in-kind support from any commercial or other organization.

Learning Objectives

01

Identify medical devices commonly encountered in pharmacy practice and understand related regulatory requirements.

02

Apply medical device risk classification to the use of pharmacy equipment.

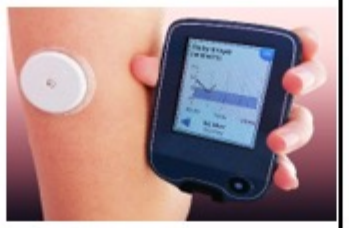
03

Describe how quality control and quality assurance relates to the use of pharmacy equipment and devices.

Activity

Which devices commonly used in pharmacy practice are classified as medical devices?


Figure 1



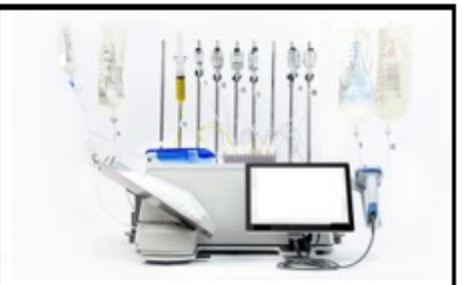


Figure 2


Figure 3

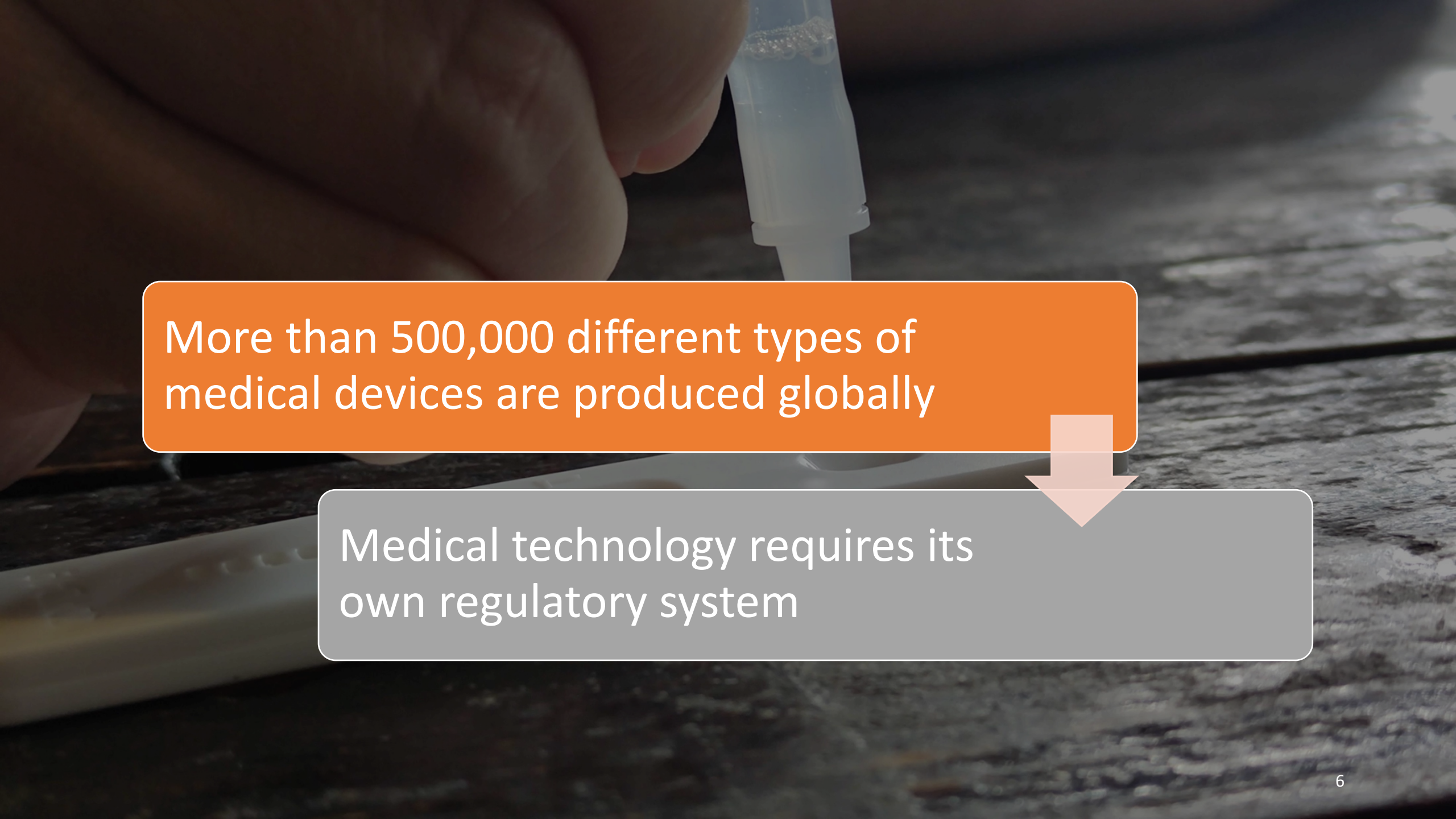

Figure 4

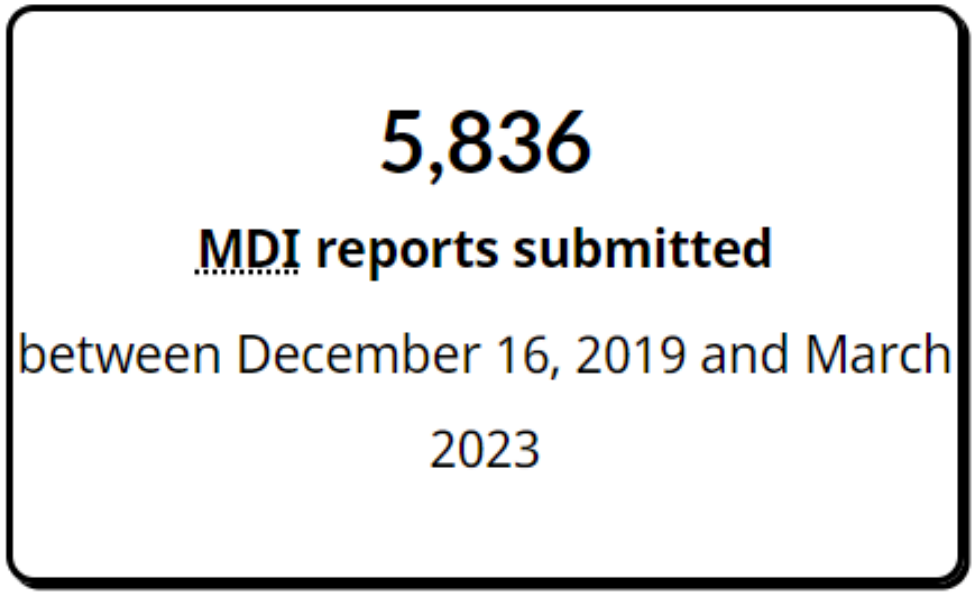

Figure 5


Figure 6


Figure 7


Figure 8

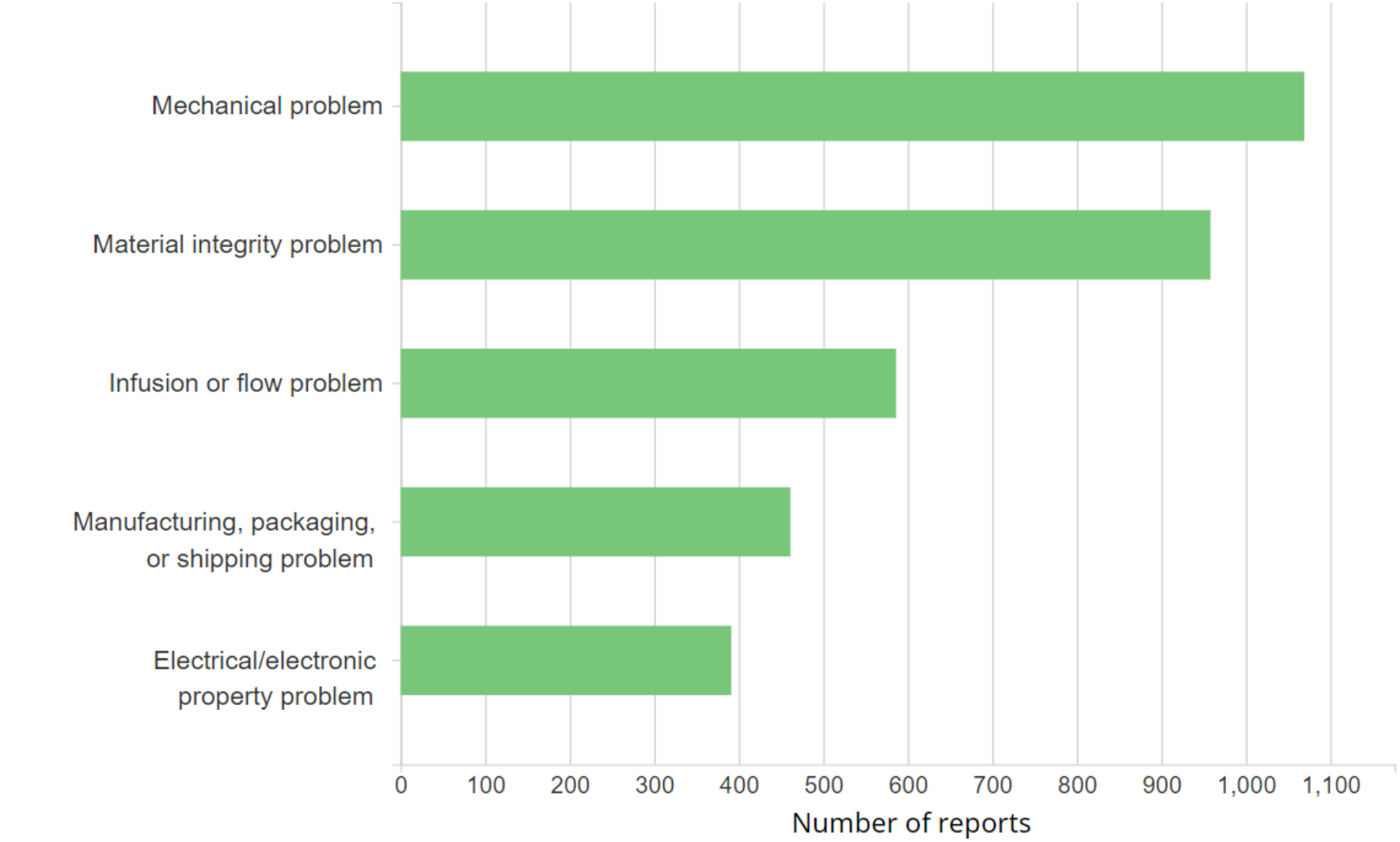

More than 500,000 different types of medical devices are produced globally
Medical technology requires its own regulatory system



Health Canada monitors the use of drugs and medical devices to protect public health and patient safety.

Medical Device Directorate

Figure 6. Number of 5 most common device problems in MDI reports over time



Serious adverse drug reactions and medical device incidents - Canada.ca

Medical Device Regulations (SOR/98-282)

The term Medical Devices, as defined in the *Food and Drugs Act*, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

Risk Posed by Medical Devices

- All medical devices pose some level of risk that arises from:
  - Inherent risk when used as intended
  - Human error (e.g., using a device incorrectly)
  - Device failure or malfunction

- Risk indicators for classification include invasiveness, body system affected, expertise of the device user.

Medical Device Program

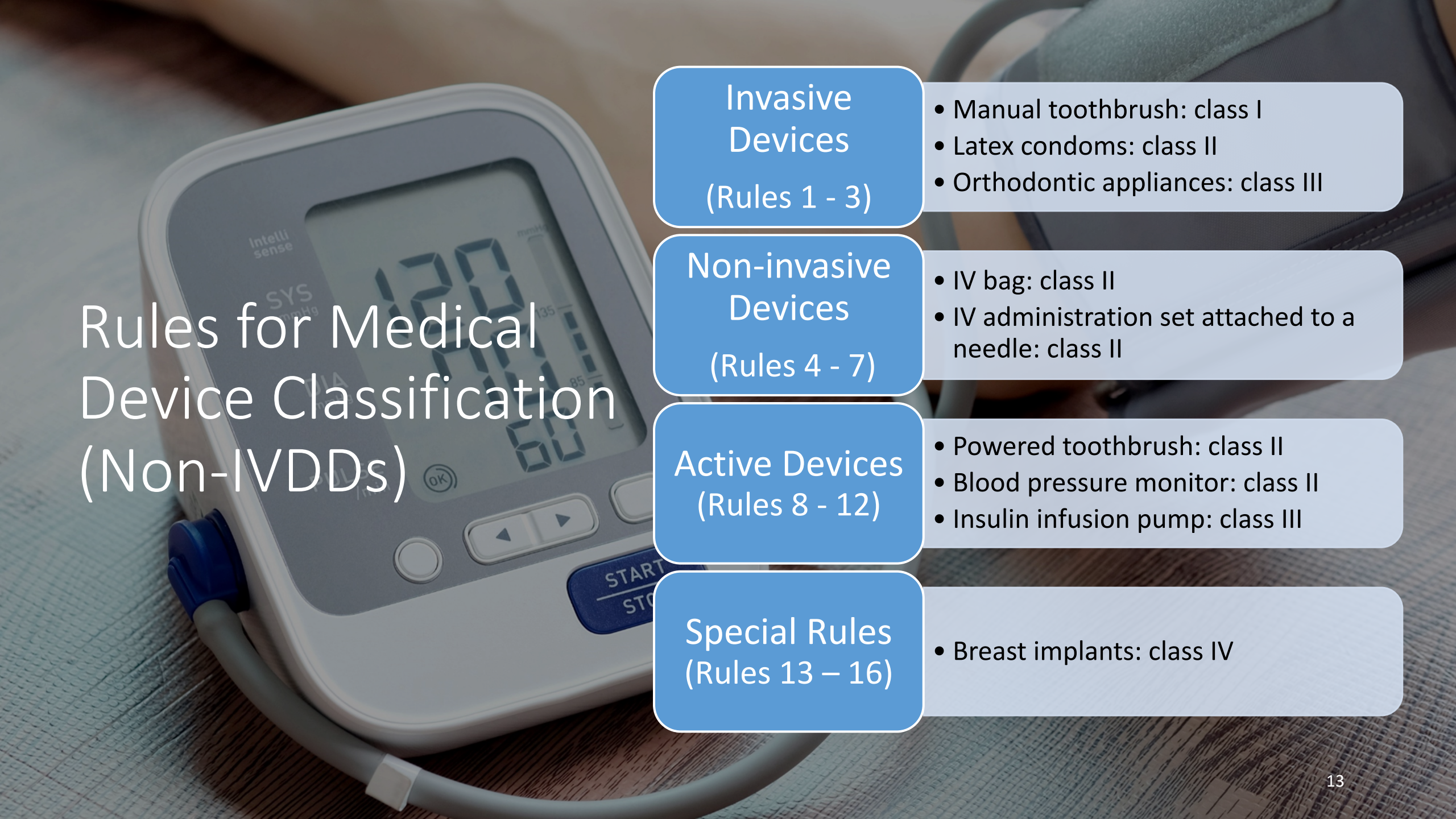
- Uses a risk-based rule system to regulating products within its scope:
  - the sale, advertising for sale, and importation for sale of medical devices in Canada.
- The intended use of a device primarily determines the class of the device.
- Classification of combination products is addressed in separate policy documents: "Policy on Drug/Medical Device Combination Products - Decisions" and "Drug/Medical Device Combination Products"

Medical Device Classification

- Four regulatory classes I, II, III, IV
  - Class I devices have the lowest risk and class IV have the highest risk.

- Class II, III, and IV medical devices: manufacturers need to register individual devices (or groupings) to obtain a Medical Device License
- Class I medical devices: manufacturers need to register their company with Health Canada to obtain a Medical Device Establishment License
  - Must comply with all general sections of the regulations including labelling requirements, problem reporting and recall.

Rules for Medical Device Classification (Non-IVDDs)



Invasive Devices
(Rules 1 - 3)

- Manual toothbrush: class I
- Latex condoms: class II
- Orthodontic appliances: class III

Non-invasive Devices
(Rules 4 - 7)

- IV bag: class II
- IV administration set attached to a needle: class II

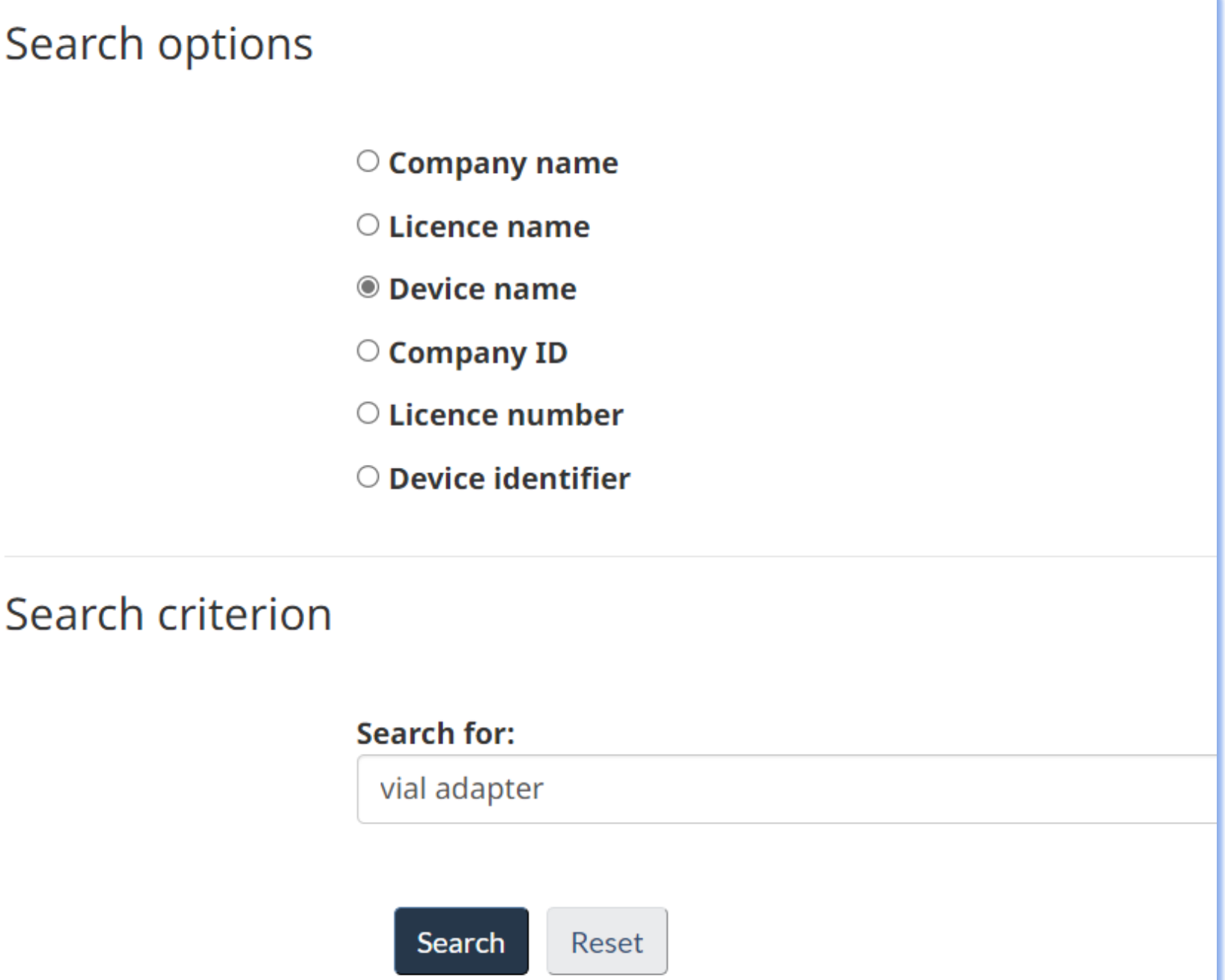
Active Devices
(Rules 8 - 12)

- Powered toothbrush: class II
- Blood pressure monitor: class II
- Insulin infusion pump: class III

Special Rules
(Rules 13 – 16)

- Breast implants: class IV

Medical Devices



MDALL

- Website tool for health care providers and the general public to check if a specific Class II, III or IV medical device is licensed in Canada.

How does medical device risk classification apply to the use of other pharmacy equipment?

Pharmaceutical Grade Equipment???

Pharmaceutical grade means that products have been manufactured under Good Manufacturing Practices (GMP) conditions.

Applying GMP to Equipment

GMP is a system for ensuring that products are consistently produced and controlled according to quality standards.

Designed to minimize risks.

Elements of GMP

qualified and trained staff

adequate premises and space

suitable equipment and facilities

correct materials, containers and labels

approved procedures and instructions

suitable storage and transport

GMP Compliant Equipment

- The system may not influence the product quality in a negative way
- The system must be easy to clean
- The system must comply with applicable technical rules
- The system must be suitable for its purpose

UNDERSTANDING THE WHY

AUTOMATION RELIANCE

WORKFLOWS AND SHORTCUTS

TRAINING AND COMPETENCY

Understanding the Why

Ensure pharmacy personnel understand the importance of quality assurance and quality control as part of their role in assuring patient safety.

Equipment use can be dangerous if not used in accordance with the instructions or operators do not meet requirements.

Case Example

- A community pharmacy introduces an automated prescription-filling device.
- Pharmacy workflow well defined using distinct roles pre-implementation.
- 17 different workflow sequences were observed before installation and 38 after installation.
- Technicians observed deviating from current procedures nearly four times more frequently after compared with before robot installation

Figure 9

Case Example

- A long-term care pharmacy uses automated medication repackaging machine.
- Workflow requires pharmacy personnel to manually fill packager canisters from stock bottles.
- Unregulated pharmacy personnel assigned to operate the packager, including refilling canisters.
- Medication errors due to canisters refilled with the wrong medications.

Figure 10

Case Example

- A hospital pharmacy uses automated peristaltic pumps for sterile compounding.
- New pharmacy technician fails to calibrate the device as frequently as needed.
- Quality assurance processes using gravimetrics for reconstituted drugs identifies deviations.
- Incomplete training materials and processes identified as a contributing factor.

Figure 11

Workflows and Shortcuts

- Qualify equipment for their intended use and validate critical steps of processes.
- Human factors principles are used when designing workflows.
- Create records that show all steps required by the defined procedures were followed.
- Investigate deviations and ensure proper correction and preventative action is taken.

Automation Reliance

- Confidence in decision-making and diligence for verifying operational indicators.
- “Stop the Line” when there is a safety concern.
- Vendor-suggested preventative maintenance is followed.
- Downtime procedures are available.

Training and Competency

- Read the operator manuals! Helps with familiarity and prevents incorrect usage.
- Write step-by-step instructions and procedures that are applicable to the pharmacy setting and specific equipment.
- Train operators to carry out procedures, including what to do when there are failures.
- Stay informed of changes and be aware of guidance documents and best practice references.

Questions?

Teresa.Hennessey@ahs.ca

References

Health Canada. Serious adverse drug reactions and medical device incidents reported by Canadian hospitals. Ottawa: Health Canada; December 2022. https://health-infobase.canada.ca/hospital-adverse-events-dashboard/. Accessed April 18, 2023.

How Medical Devices are Regulated in Canada – Premarket Regulation eLearning course. Accessed April 17, 2023.

Health Canada. Guidance Document – Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs). https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-non-vitro-diagnostic.html. Accessed May 1, 2023

Health Canada. Medical Devices Active License Listing (MDALL). https://health-products.canada.ca/mdall-limh/. Accessed July 7, 2023.

Health Canada. Good manufacturing practices guide for drug products (GUI-0001). https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001/document.html. Accessed July 7, 2023

U.S Food and Drug Administration. Questions and Answers on Current Good Manufacturing Practice Requirements – Equipment. https://www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-requirements-equipment. Accessed July 7, 2023.

Yusuff KB, Mustafa M, Al-Qahtani NH. Prevalence, types and severity of medication errors associated with the use of automated medication use systems in ambulatory and institutionalized care settings: A systematic review protocol. PLoS One. 2021 Dec 3;16(12):e0260992. doi: 10.1371/journal.pone.0260992. PMID: 34860852; PMCID: PMC8641865.

Institute of Safe Medication Practices. ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. Revised 2016. https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines%20for%20Safe%20Preparation%20of%20Compounded%20Sterile%20Preperations_%20revised%202016.pdf. Accessed July 8, 2023.

Alberta College of Pharmacy. Standards of Practice for Pharmacists and Pharmacy Technicians. June 2023. https://abpharmacy.ca/sites/default/files/ACP_SPPPT.pdf. Accessed July 8, 2023.

Walsh KE, Chui MA, Kieser MA, Williams SM, Sutter SL, Sutter JG. Exploring the impact of an automated prescription-filling device on community pharmacy technician workflow. J Am Pharm Assoc (2003). 2011 Sep-Oct;51(5):613-8. doi: 10.1331/JAPhA.2011.09166. PMID: 21896459; PMCID: PMC3304454.

M Boyd A, W Chaffee B. Critical Evaluation of Pharmacy Automation and Robotic Systems: A Call to Action. Hosp Pharm. 2019 Feb;54(1):4-11. doi: 10.1177/0018578718786942. Epub 2018 Jul 9. PMID: 30718928; PMCID: PMC6333949.

Grissinger M. Understanding Human Over-Reliance On Technology. P T. 2019 Jun;44(6):320-375. PMID: 31160864; PMCID: PMC6534180.

ISMP Canada. Understanding human over-reliance on technology. *ISMP Canada Safety Bulletin.* 2016;16(5):1–4. [Google Scholar] [Ref list]

Image Credit

Figure 1: ICU Medical. Vial adapter and syringe. https://www.medicalexpo.com/prod/icu-medical/product-119492-821246.html. Accessed July 7, 2023.

Figure 2: Baxter. PN compounding device. https://www.baxter.com/baxter-newsroom/baxter-introduces-exactamix-pro-next-generation-automated-nutrition-compounder-0. Accessed July 7, 2023.

Figure 3: Bottle adapter. https://specializedrx.com/products/adapta-cap-b-20mm-bottle-adapter. Accessed July 7, 2023.

Figure 4: B Braun. Disc filter. https://www.bbraun.ca/en/products/b1/0-2-micron-suporaspirationinjectiondiscfilter.html. Accessed July 7, 2023.

Figure 5: Pill splitter. https://www.gosupps.com/acu-life-pill-splitter-cutter.html?gclid=Cj0KCQjwkqSlBhDaARIsAFJANkjcVg7GOZVeWF1Ku034Plpuz0wHfYrvQoX6-mOalbpSYwm57j1eN6oaAkaCEALw_wcB. Accessed July 7, 2023.

Figure 6: JVM. Automated tablet packager. https://www.myjvm.com/en/product/view.php?idx=42&ckattempt=1. Accessed July 7, 2023.

Figure 7: Electric mortar and pestle. https://totalpharmacysupply.com/unguator-reg-emp.html. Accessed July 8, 2023.

Figure 8: BD. Pyxis anesthesia system. https://www.bd.com/en-ca/offerings/capabilities/medication-and-supply-management/medication-and-supply-management-technologies/bd-pyxis-medication-technologies/pyxis-anesthesia-station-es. Accessed July 7, 2023.

Figure 9: Ghia Marie Photography. Pharmacy technician with automated packaging machine. https://ptsa.ca/about/pharmacy-technician-roles/. Accessed July 8, 2023.

Figure 10: Swisslog Healthcare. Pharmacy employee with automated packaging machine. https://swissloghealthcarevirtualtour.com/autopack/. Accessed July 8, 2023.

Figure 11: ICU Medical: https://www.icumed.com/media/15779/df-4369-en-mc-rev-04-diana-peristaltic-pump-20-manual_english.pdf. Accessed July 8, 2023

All other images are credited to Adobe Stock.