

Automated Drug Delivery Systems - Clinics

Bob Ratcliff

Supervising Inspector

CA State Board of Pharmacy

Relevant Law Statutes

- Business and Professions Code section (B&P) 4180 et seq
- Health and Safety Code section (H&S) 1200 et seq
- Title 22 (most pertinent = sections 75026, 75029, 75032-75039)

B&P 4180 – Eligible Clinics

- Clinics entitled to benefits of this section shall have a board clinic license for each location.
- Licensed by CA Dept. of Public Health

B&P 4180 – Eligible Clinics

- Types of clinics eligible
 - Nonprofit community clinic or free clinic (H&S 1204[a])
 - Same as above, separate premises; open no more than 20hr/wk (H&S 1206[h])
 - County owned/operated primary care clinic (H&S 1206[b])
 - Clinic operated by federally recognized Indian tribe (H&S 1206[c])
 - Public institution or higher education operated student health center clinic (H&S 1206[j])
 - Nonprofit multispecialty clinic (H&S1206[l])

B&P 4186 Automated Drug Delivery Systems

- (h) defines Automated Drug Delivery System
 - Mechanical system
 - Controlled by a pharmacist
 - Performs operations or activities, other than compounding or administration, relative to
 - Storage
 - Dispensing
 - Distribution
 - Of prepackaged dangerous drugs or devices
 - Collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the ADDS for
 - Security
 - Accuracy
 - Accountability

B&P 4186 Automated Drug Delivery Systems

- (a)
 - Located in clinic licensed by board under B&P 4180
 - Develop and implement policies and procedures to ensure
 - Safety
 - Accuracy
 - Accountability
 - Security
 - Patient confidentiality
 - Maintenance of drugs
 - Quality
 - Potency
 - Purity

B&P 4186 Automated Drug Delivery Systems

- (b) Drugs removed from ADDS
 - Only upon authorization of pharmacist
 - Review of prescription
 - Review of profile for contraindications and adverse drug reactions
 - Shall be provided to patient by licensed health professional (B&P 4181[b] – pharmacist or other person lawfully authorized to dispense drugs)

B&P 4186 Automated Drug Delivery Systems

- (c) Pharmacist shall restock ADDS

B&P 4186 Automated Drug Delivery Systems

- (d) Clinic responsible for
 - Review of drugs within ADDS
 - Operation and maintenance of ADDS
 - Review of drugs done monthly by RPH
 - Inspection of drugs
 - Cleanliness of ADDS
 - Review transaction records in order to verify
 - Security of system
 - Accountability of system

B&P 4186 Automated Drug Delivery Systems

- (e) Consultation by RPH per CCR 1707.2 by two-way audio and video telecommunication



B&P 4186 Automated Drug Delivery Systems

- (f) Pharmacist operating the system shall be located in CA

B&P 4186 Automated Drug Delivery Systems

- (g) Labeling of drugs to be patient-centered

B&P 4186 Automated Drug Delivery Systems



Automated Drug Delivery and Dispensing Systems in Community Pharmacy

California State Board of Pharmacy

Anne Hunt, RPh
Supervising Inspector

Definition

- **Automated Drug Delivery/Dispensing Systems**
 - Definition pursuant to Title 21 CFR 1300.01:
 - A mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, counting, labeling, and dispensing of medications, and which collects controls, and maintains all transaction information.

Devices

- Automated Drug Delivery Systems
 - Example: Automated Kiosks, ie ScriptCenter
- Automated Dispensing Devices
 - Example: Baker, Kirby Lester, Parata, ScriptPro, Yuyama, etc.

Relevant Regulations

■ Automated Drug Delivery Systems

- California Code of Regulations section 1713 (Receipt and Delivery of Prescriptions and Prescription Medications)
- California Code of Regulations section 1714 (Security of Drugs)

Relevant Regulations continued...

■ **Automated Drug Delivery Systems**

- California Code of Regulations section 1707.2 (Duty to Consult)
- Business and Professions Code section 4125 (Quality Assurance Program)

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- (d) allows a pharmacy to use an automated delivery device to deliver previously-dispensed prescription medications provided:
 - Each patient must sign a written consent form.
 - Each patient using the device must meet inclusion criteria established by pharmacy.
 - The device has a means to identify each patient and only release that patient's prescription medication.

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- The pharmacy does not use the device to deliver any previously dispensed prescriptions determined to require consultation
- The pharmacy provides an immediate consultation with a patient, either in-person or via telephone, upon request.

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- The device is located adjacent to the secure pharmacy area
- The device is secure from access and removal by unauthorized individual
- The pharmacy is responsible for the prescription medications stored in the device

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program. (Business and Professions Code section 4125)
- The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- (e) Policies and Procedures - Pharmacy must maintain, and review annually, written policies and procedures providing for:
 - Maintaining security of automated delivery device and dangerous drugs within the device
 - Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- Policies and Procedures continued...
 - Ensuring that patients are aware that consultation with a pharmacist is available for any prescription, including those delivered via the automated delivery device.
 - Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- Policies and Procedures continued...
 - Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring patients use of the device does not interfere with delivery of prescription medications
 - Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- (f) Written policies and procedures shall be maintained at least three years beyond the last use for an automated delivery device.

CCR 1713 Receipt and Delivery of Prescriptions and Prescription Medications

- (g) defines "previously-dispensed prescription medications" as those prescription medications that do not trigger a non-discretionary duty to consult under section CCR 1707.2 (b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Relevant Regulations

■ **Automated Dispensing Devices**

- Title 21 CFR Part 210 and 211 (CGMP) (Current Good Manufacturing Practices)
- Business and Professions Codes section 4342 (Actions by Board to Prevent Sales or Preparations Lacking Quality or Strength)
- Health and Safety Code section 111355- (Misbranded)

Automated Dispensing Devices

- The drugs stored in automated dispensing units must be properly labeled:
 - Name of Drug
 - Strength and Dosage Form
 - Manufacturer and Manufacturer's Lot Number
 - Expiration Date

Automated Dispensing Devices

- Placing drugs into automated dispensing units
 - Pharmacists
 - Interns
 - Technicians (Under direct supervision of the pharmacist)

Questions?

CA State Board of Pharmacy Technology Summit

Oct. 24th, 2012

TCGRx to present it's solutions for all markets in
pouch packaging

www.tcgrx.com

Valerie Rose
Director of Sales, West Coast
425-269-2156



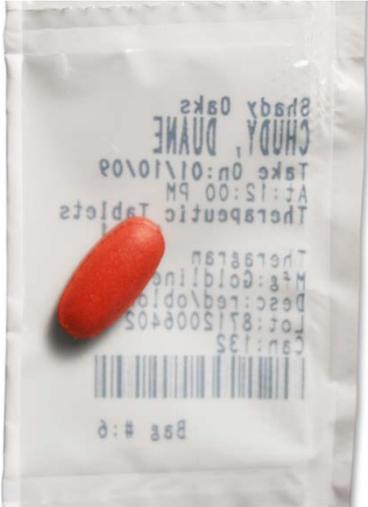
A Total Closed Loop Solution

- Brings Complete workflow to your pharmacy
- Safe and effective labor model from start to finish
- Interface to pharmacy management software
- Interface, facilitate medication access and replenishment

Multi-Dose and Unit-Dose Pouch Packaging



USP- B Class (1 year beyond use dating)



Serrated Edge for Ease of Opening





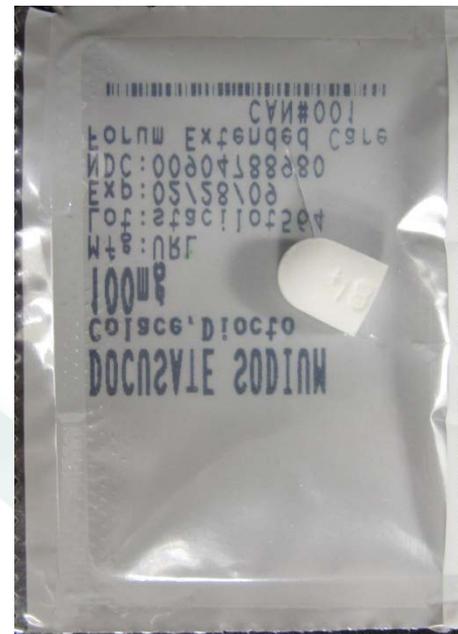
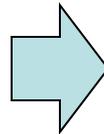
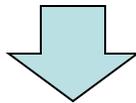
BullsEye Automated Tablet Splitter

Automated Half-Tabs

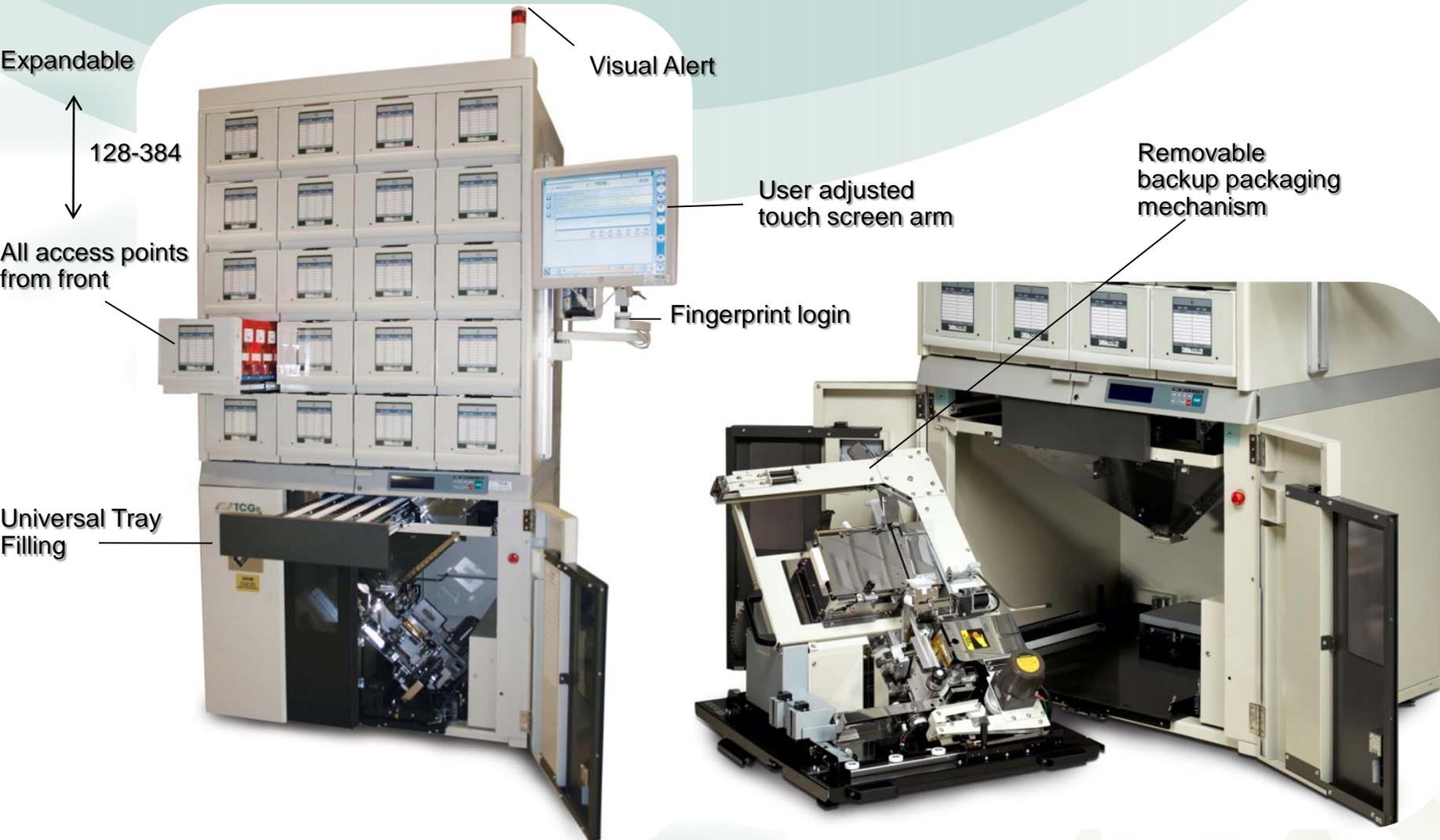
- Accurate
- Consistent
- Hands Free
- Safe
- Quiet
- Up to 16 Pills/Minute



**Striving for Additional Efficiency
Automated Dispensing of 1/2 Tabs**



Practical – Efficient – Reliable



Expandable



128-384

All access points from front

Universal Tray Filling

Visual Alert

User adjusted touch screen arm

Fingerprint login

Removable backup packaging mechanism

REMOTE MEDICATION ACCESS

AUTOMATED PACKAGING & MEDICATION CABINETS



Features:

Medication Canisters: 256

Universal Redundancy Unit; 1 unit for many machines

Compact Footprint for Med Rooms

Pharmacy/Facility Interchangeable

Panasonic
ideas for life



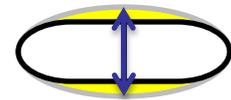
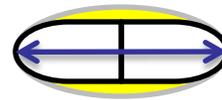
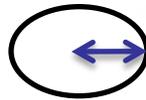
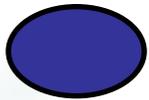
InspectRx Pouch Verification System



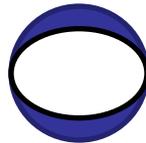
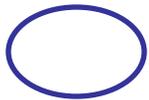
- Visual inspection during production
(answers the questions: How Many, What Shape, What Color, in Which Bag.)
- Visual archiving
(answers the question: which pills were in what bag for what patient, at any previous time.)
- Analysis
(answers the question: what goes wrong in the process)

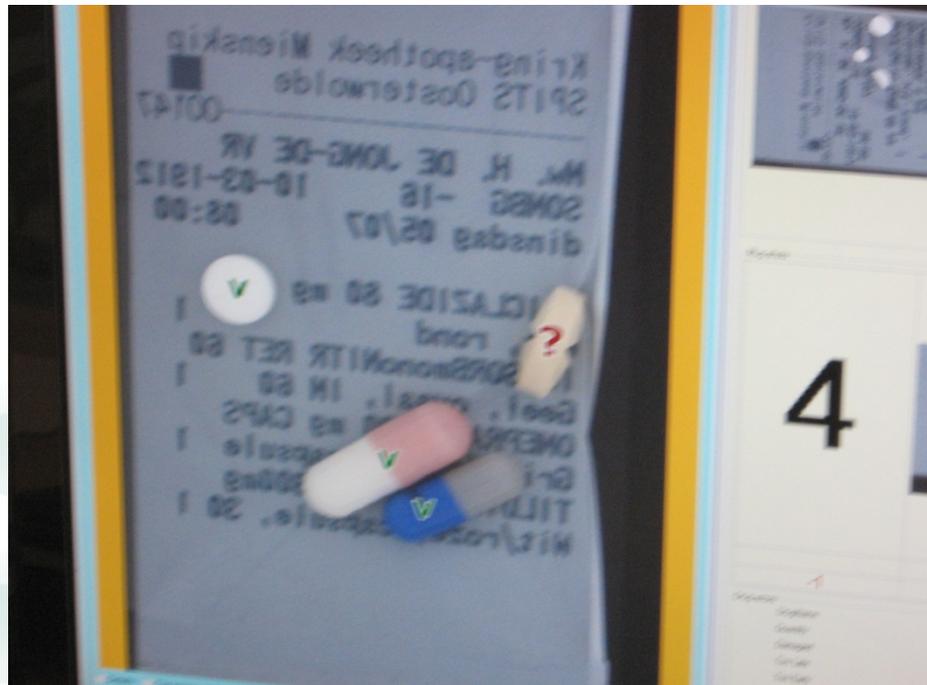
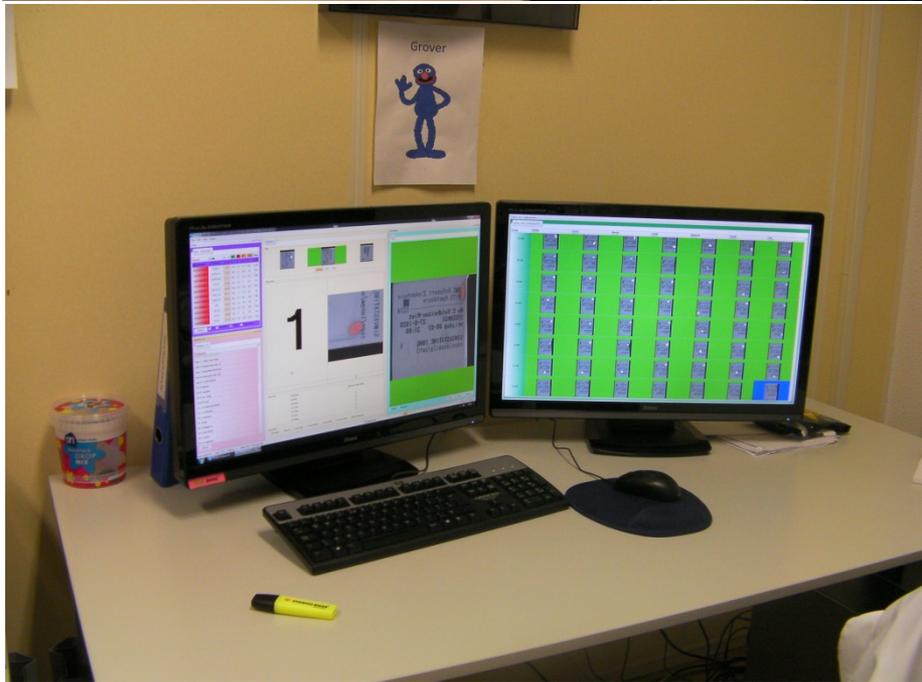
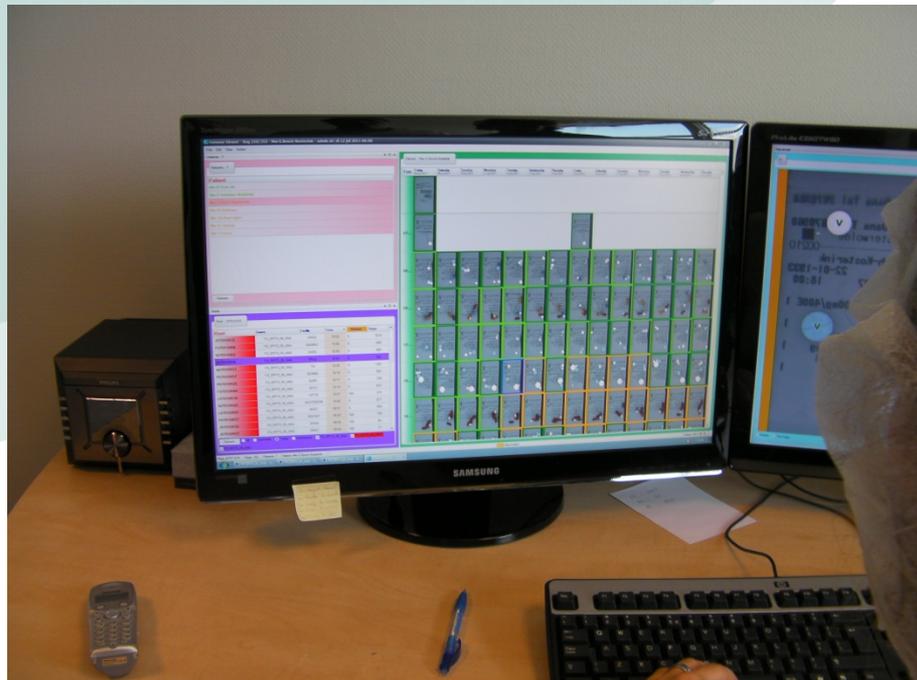
Pill identification: detail

Surface	Distance to center	Length	Width
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Contour	Roundness	Color (R, G, B)	Color; standard deviation (R, G, B)
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Our goal is to provide the most advanced and reliable technology on the market integrated with efficient workflow designs that will become the industry standard.”

THANK YOU
www.tcgrx.com

Patient Medication Access

Rick Vance

Executive Director, Physician Projects

Marshall Medical Center

Placerville, Ca



Who is Marshall Medical Center?

- 105 Bed Rural Hospital - Placerville
- Serves Western Slope of El Dorado County
- 160,000 people
- Inpatient pharmacy
- 13 1206 (d) Outpatient Clinics
- 1 Rural Health Clinic



Our Goal

- Provide better access to medications for patients
- Establish better coordination of care by improved medication tracking in an integrated health care delivery system



Medication Compliance

- Up to 28% of patients do not fill first time prescriptions
 - Journal of General Internal Medicine, online February 4, 2010



Current Patient Medication Access Models

- Outpatient Pharmacy - B&P 4110
- Prescriber Dispensing - B&P 4170
- Non-Profit or Free Clinics - B&P 4180
- Surgical Clinic - B&P 4190



Outpatient Pharmacy

- Costly due to pharmacist staffing at each location.
- Patients have to drive to secondary locations
- Strong competition



Prescriber Dispensing

- Prescriber must own dispensing device and medications
- Each prescriber has to maintain separate medication stock



Non-Profit or Free Clinics

- Workable process
- Utilizes pharmacist
- 1206 (d) clinics are not listed



Surgical Clinic

- Cannot be part of a hospital



Possible Solutions

1. Allow exceptions to prescriber requirements of owning equipment and medications as well as allowing combined stock - B&P 4170
2. Include 1206(d) clinics in free or non-profit clinics - B&P 4186



Interested Parties

- Lodi Memorial
- Tahoe Forest
- California Hospital Association



*Legal
Implications
with
Technology Use
in Hospital
Pharmacy*

Technology
Summit

October 24, 2012

William Young
Supervising Inspector
California State
Board of Pharmacy

Purpose

- To highlight legal requirements for the use of various technology in hospital pharmacy practice today.
- Purpose is not to provide an in-depth review of regulatory requirements for specific brands or models of equipment.

Agenda:

- Role of PIC
- Security
- Temperature Monitoring
- Remote Supervision of Ancillary Personnel
- Remote Order Entry
- Remote Order Verification
- Automated Dispensing Machines
- Pharmacist Check
- Bar Coding
- Reporting loss of Controlled Drugs
- Compounding
- Compounding Documentation
- CPOE
- ED dispensing

Legal Responsibility for use of Technology in Operations

BPC 4036.5. Pharmacist-in-Charge

“Pharmacist-in-charge” means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

Security

CCR 1714(d) states, possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

- Badge access to pharmacy
- Code access to pharmacy

Do your Tech's have access? Does house cleaning have access? Does administration have access? (except for emergency)

Temperature Monitoring

- Temperature Discs recoded/graphed on a disc. **Pharmacist needs to read it.**
- Electronic systems may produces alerts on a computer screen or page staff when temperature is out of range. **Pharmacist needs to take appropriate action.**

Supervision of Ancillary Personnel

- **BPC 4115(a)** A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.
- **CCR 1793.7(b)** Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications,
- **Use of Web cam to supervise work, i.e. "remote supervision" burden of proof on PIC to demonstrate it satisfies "direct supervision and control" and "fully aware of all activities involved "**

Remote Order Entry

BPC 4071.1. Electronic Prescription Entry into Pharmacy or Hospital Computer

(a) A pharmacist may electronically enter a prescription order into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital.

- “A Pharmacist” as defined in BPC 4036 is a California Licensed Active Status Pharmacist.
- Manage risk of PHI disclosure, Civil Code 56.10

Remote Order Verification

BPC 4071.1. Electronic Prescription Entry into Pharmacy or Hospital Computer

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

- "A Pharmacist" as defined in BPC 4036 is a California Licensed Pharmacist.
- Manage risk of PHI disclosure, Civil Code 56.10
- Remote RPh (via Pyxis Connect) may not be following protocols consistent with local P&T.

Automated Drug Delivery Systems (ADDS) Laws which apply:

BPC 4119.1. Pharmacy May Provide Services to Health Facility

Automated drug delivery systems must be owned and operated by Pharmacy and supervised by a pharmacist.

HSC 1261.6 Automated Drug Delivery Systems

An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Automated Drug Delivery Systems

HSC 1261.6(g) states, **the stocking of an automated drug delivery system shall be performed by a pharmacist.** If the automated drug delivery system utilizes **removable** pockets, cards, drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility...

Use of Technology & Tech-Check-Tech; Ensure all requirements are met

CCR 1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

- Only applies to acute care inpatient hospital pharmacies
- Pharmacists provide clinical services described in BPC 4052.1
- **Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.**
- Overall program shall be the responsibility of the PIC.
- Program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures .

Issues with ADDS:

- Common practice of TCHs pulling inventory from a “pick list” for RPH to check. After the RPH check, TCHs fill the machines unsupervised. When drug is in the wrong slot, who is responsible? CCR 1717(b)(1)? PIC.
- Bulk drawers: TCH / RN access to multiple drugs. Taking more than what is documented can occur. No way of really knowing when and who diverted a drug. Use of Cubies much better but cannot control quantity taken.
- Oversight to CII Safe should be restricted to RPH and not to TCHs.
- **OVERIDES** especially with regards to those which are non-profiled is a source of diversion

Issues with ADDS:

- Blind counts: Good, but not required
- Witnessing: Good, but not required
- Patient specific access: Good, but not required
- Discrepancies: Investigations may yield no conclusions
- Personnel with higher level of clearance access can be given to anyone. Not illegal to do that. Example: Admin do not need witness, blind count, can change inventory count, etc. Can be a non-licensed, tech or pharmacist. No regulation. Administrator can even use other staff's identity to be recorded and used as a transaction. No regulation and very hard to prove

The Pharmacist Check

- **CCR 1793.1(f)** states, Only a pharmacist may supervise the packaging of drugs and check the packaging procedure and product upon completion.
- **CCR 1717(b)(1)** states, the name or initials of the dispensing pharmacist shall be maintained for each prescription on file and shall be readily retrievable

Bar Coding

- There is no regulation which states a Bar Code Scan may replace a Pharmacist's final product check.
- Despite a bar code scan, a Pharmacist's check is necessary when Techs fill dispensing machines.

Schedule II & CIII-V Drugs

- Drugs can “disappear” in Robotic Drug Distribution Systems
- Perpetual inventory via CII Safe or CII Book is common practice. **For discrepancies from CII audit every 30 days, cannot merely update on hand inventory.**

CCR 1715.6 states, Loss of Controlled Drugs need to be reported to the Board

Compounding Technology

- Most of these machines are operated by technicians.
- Pharmacists must check the technician's work
BPC 4115(a)
- Pharmacists must check the final product
CCR 1735.3(a)(4)

Compounding Record by Digital Photography

- Digital Photo may satisfy CCR 1735.3(a) if it documents all 10 elements required and is readily retrievable within 72 hours

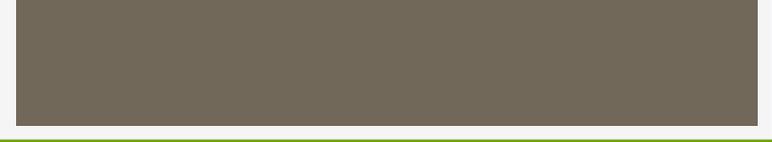
CPOE

- California Code of Regulations (CCR) 1711(c) requires the reporting of medication errors.
- In Computerized Physician Order Entry (CPOE), some systems allow Pharmacist users to delete the record, even after dispensing, thereby creating a vulnerability for cover up of medication errors.

Emergency Department Dispensing

BPC 4170. Dispensing by Prescriber: Requirements and Restrictions; Enforcement

- The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs to the patient packaged, labeled, and recorded in accordance with 4170(a)(4).
- See BPC 4068 for additional requirements



Questions?

Evaluating the Use of Automated Drug Delivery System (ADDS) in the Skilled Nursing Facilities, Intermedicate Care Facilities and Nursing Facilities

Presented by:

California State Board of Pharmacy

Janice Dang, Pharm.D.

Supervising Inspector

TRENDS ON THE USE OF ADDS

- ✓ Pharmacy services.
- ✓ Emergency pharmaceutical supply.
- ✓ Short cycle dispensing.

REGULATIONS:

- HSC 1261.6 – ADDS for SNF, ICF or NF.
- BPC 4119.1 – Operations of ADDS.
- BPC 4116 and 4117 – Security of dangerous drugs.
- BPC 4081 – record open for inspection.

REGULATIONS:

- BPC section 4076, 4076.5, 4077 – prescription label.
- BPC 4008(f) – allows inspector to enter SNF, ICF and NF to inspect ADDS.
- CCR 1714 – Security of drugs.

REGULATIONS:

- Title 22 CCR 72313(a)(4) – Preparation of more than one scheduled administration time.
- Title 22 CCR 72313(a)(6) – Medications shall be administered as soon as possible, but NMT 2 hours after doses are prepared.

DEFINITIONS:

“Automated Drug Delivery System” (ADDS)

HSC 1261.5(a)(1)

- A mechanical system that **performs operation or activities**, other than compounding or administration, relative to storage, dispensing, or distribution of drugs.
- An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

DEFINITIONS:

"Facility" – HSC 1261.6(a)(2)

- Skilled Nursing Facility – HSC 1250(c).
- Intermediate Care Facility – HSC 1250(d).
- Nursing Facility – HSC 1250(k)

DEFINITIONS:

“Unit Dose Medication System” – 22 CCR 72117.

- A system which single dosage units of drugs are pre-packaged and pre-labeled.
- The system includes all equipment and records.
- The pharmacist shall be in charge and responsible for the system.

DEFINITION:

“Unit dose packaging” – HSC 1261.6(i)

- Unit of use.
- Includes blister pack cards.
- Can be used in ADDS if the info required by BPC 4076 and HSC 111480 is readily available at time of administration.

EVALUATION:

- ✓ ADDS need not be located at the same location as the pharmacy.
- ✓ Drugs stored is part of the pharmacy's inventory.
- ✓ Drugs dispensed from the ADDS is considered to have been dispensed by the pharmacy.

EVALUATION:

- ✓ Pharmacy maintains records of acquisition and disposition for drugs stored in ADDS separate from other pharmacy records.
- ✓ Pharmacy owns and operates the ADDS.
- ✓ Pharmacy provides training to both pharmacy and healthcare facility.

EVALUATION:

- ✓ Operation of the ADDS must be under the supervision of a licensed pharmacist.
 - RPh does NOT need to be physically present where the ADDS is located.
 - RPh may supervise the system electronically.

EVALUATION:

- ✓ Pharmacy shall operate the ADDS in compliance with HSC 1261.6.
- For security, accuracy, and accountability. ADDS shall collect, control, and maintain all transactions info tracking movement of drugs into and out of the system.

EVALUATION:

- ❑ Can be used for Routine and Emergency drugs.
- ❑ Transaction info must be readily retrievable and maintained for minimum 3 years.
- ❑ Individualized and specific access to ADDS shall be limited to facility and contract personnel authorized by law to administer drugs.

EVALUATION:

- ✓ Policies and Procedures:
 - ❑ Safety
 - ❑ Accuracy
 - ❑ Accountability
 - ❑ Security
 - ❑ Patient Confidentiality
 - ❑ Maintenance of potency, quality and purity of stored drugs.
 - ❑ Maintained at the pharmacy and healthcare facility.

USE FOR EMERGENCY SUPPLY:

- ✓ Limited to a new drug order for administration prior to the next scheduled delivery from the pharmacy or 72 hours, whichever is less.
- ✓ Retrieved only upon authorization and review by the RPh.

USE FOR EMERGENCY SUPPLY:

- ✓ PRN drugs, subject to ongoing review by the RPh.
- ✓ Emergency drugs for emergency or immediate identified by Patient Care Policy Committee, use provided within 48 hours RPh reviews the case.

USE FOR PHARMACY SERVICE:

- ✓ Properly labeled units of administration containers (or) packages.
- ✓ RPh shall review all orders prior to removal of drug.
- ✓ Shall control access to the drugs stored.
- ✓ Access controlled and tracked using an identification or password system or biosensor.

USE FOR PHARMACY SERVICE:

- ✓ ADDS makes a complete and accurate record of transactions, including all users accessing ADDS, drugs added and removal of drugs.
- ✓ After RPh review, access by licensed personnel is limited ONLY to drugs ordered by the prescriber and are patient specific.

USE FOR PHARMACY SERVICE:

- ✓ When orders requires a dosage variation of the same drug, licensed personnel shall have access to the drug for the scheduled time of administration

STOCKING OF ADDS:

- Performed by a RPh.
- If utilizes removable pockets, cards, drawers or similar technology, stocking may be done outside the facility and delivered to the facility:
 - The task of placing drugs into the removable is performed by RPh, intern RPh, or Tch working under the direct supervision of a RPh.

STOCKING OF ADDS:

- The removable pockets, cards, or drawers are transported between phy and facility in a secure tamper-evident container.
- The facility, in conjunction with phy, develop policies and procedures to ensure proper placement into the ADDS.

MAINTENANCE OF ADDS:

- ✓ Review of drugs in ADDS, operation and maintenance is the pharmacy's responsibility.
- ✓ **Monthly review by RPh.**
- ✓ Drugs in unit dose packaging or unit of use and when info required by BPC 4076 and HSC 111480 are readily available at the time of administration, labeling requirements per BPC 4076 are not required.

CHALLENGES:

- No laws defining remote dispensing.
- ADDS machines dispensing drugs not physically checked by a pharmacist.
- Tracking locations where ADDS are located.

QUESTIONS

CALIFORNIA STATE BOARD OF PHARMACY TECHNOLOGY SUMMIT

Scott Huhn – Division Compliance Officer
Michael Szesko – VP of Automation



Omnicare
Pharmacy Services



October 24, 2012



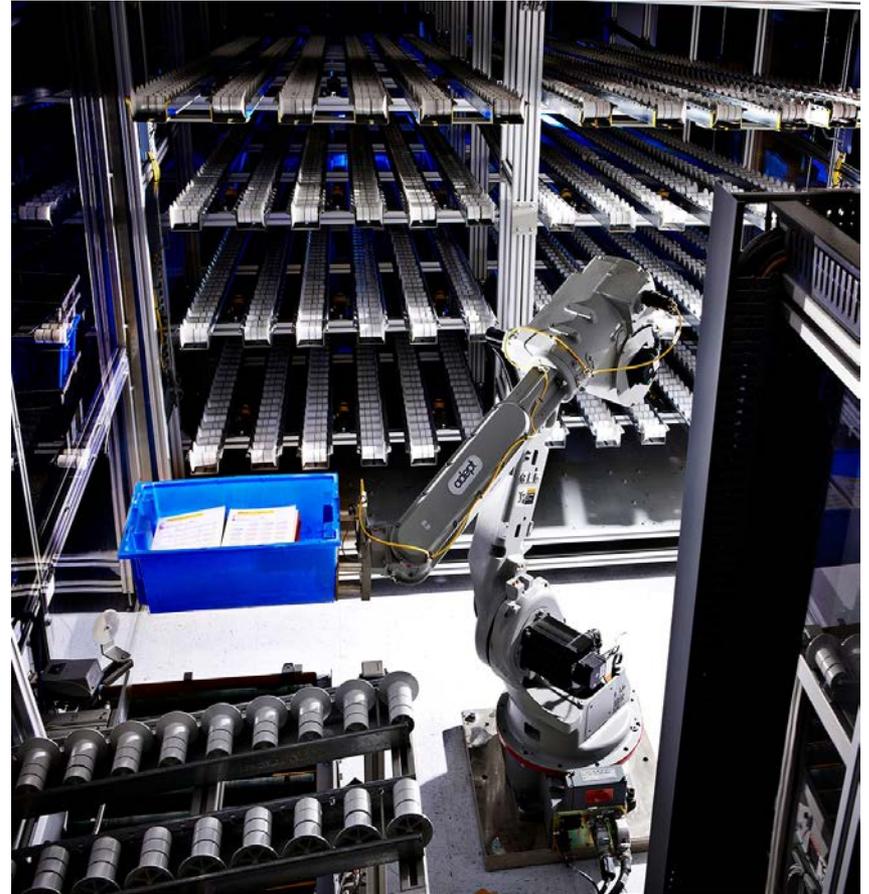
Patient Centric Innovative Technology with Superior Quality and Service

- Highest Accuracy and Quality with a Validate-able Process
- Streamline Processes to Improve Patient Care
- Enhance Pharmacist capability to focus on the Patient



Develop and implement new Pharmacy and Facility technology that provides unprecedented quality and service benefits to the patient

Omnicare Hub & Spoke Video Overview



Auto Label Verify (ALV) Automation

- Omnicare has Developed an Automated Technology for Dispensing of Medications called Auto Label Verify - ALV
- A Commitment to Quality and Enhanced Patient Care
 - **Utilized the Highest Industry Standard for Validation: ISPE – GAMP**
ISPE – International Society of Pharmaceutical Engineering
GAMP - Good Automated Manufacturing Practices
 - **Absolute Quality: the Right Patient Label & the Right Product, Every Time**
- Multi-year Development and Implementation Cycle
 - Concept Development 2005
 - 1st Generation Design, Build & Test – The Pilot 2006-07
 - 2nd Generation Design, Build & Test 2007-08
 - First ALV machine in operation at a Pharmacy in Ohio July 2008

Current ALV System Status

- The ALV Automation System is providing industry leading quality results in several states with a total of 22 ALV systems in operation:
 - Ohio
 - Wisconsin
 - Indiana
 - Tennessee
 - Illinois
 - Texas
 - Pennsylvania
 - Maryland
 - Virginia
 - New Jersey
 - California
 - Connecticut
 - Massachusetts
 - Missouri
 - Florida
 - New York
 - South Carolina
 - Georgia

Nationally, the ALV systems have dispensed over 94 Million prescription picks without an error

ALV - Quality Based Validated Design

What is Validation?

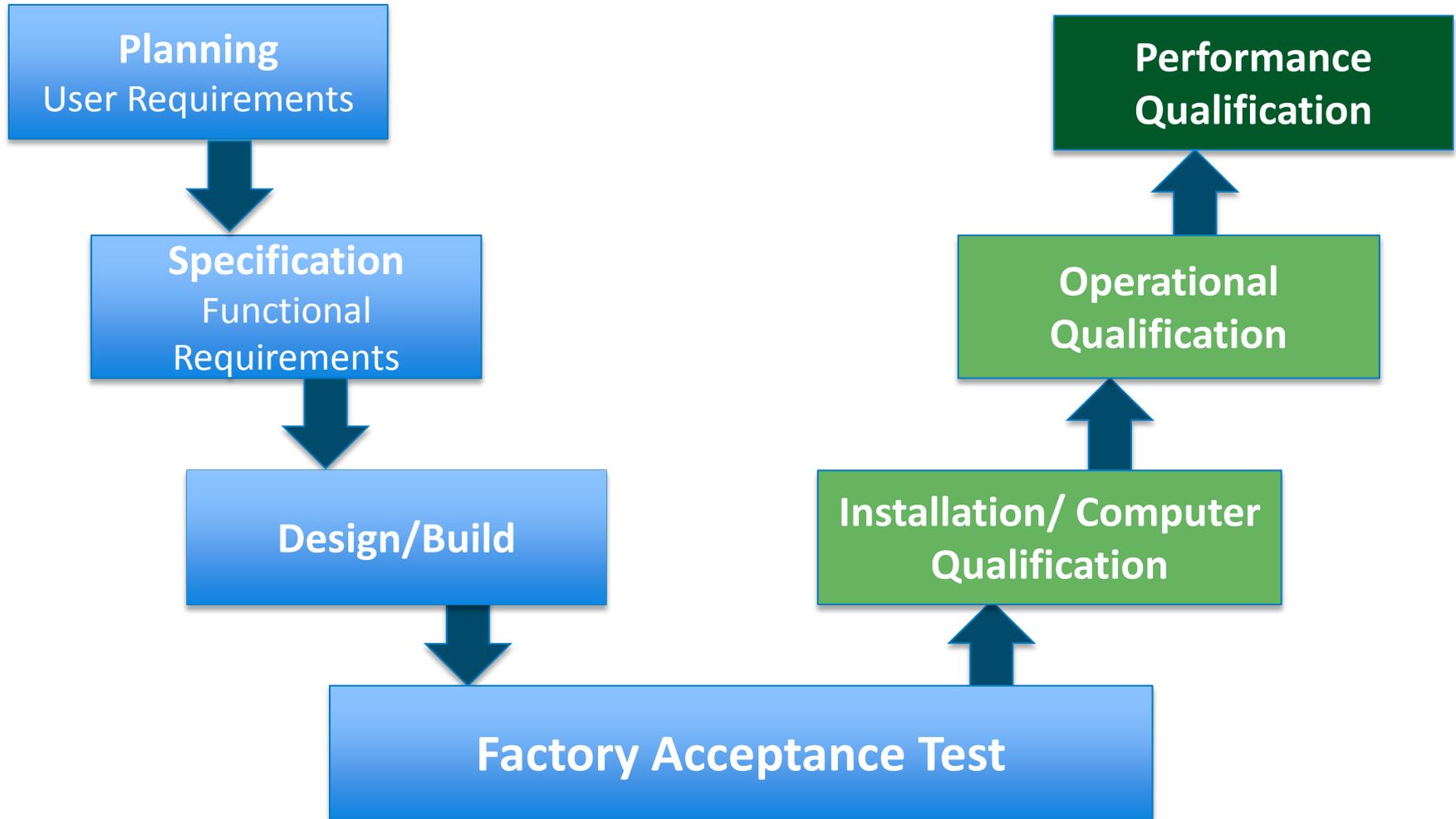
- *Series of qualification testing procedures designed to challenge a system to ensure it behaves as intended and designed*
- *Procedures follow guidelines established by the International Society of Pharmaceutical Engineering (ISPE) - Good Automated Manufacturing Practices (GAMP 4)*
- *Highly documented, physical execution of “progressing” protocols and test procedures*



Quality Risk Management Approach & History

- Science based Risk Management Methods for validation of computerized systems (automated systems)
- GAMP – Good Automated Manufacturing Practice guidelines enhance:
 - Patient safety
 - Product quality
 - Data integrity
- GAMP History
 - GAMP is a global organization with communities of practice in the America's, Europe and Japan.
 - Started in 1991 by a group of Pharmaceutical experts to meet changing FDA expectations for GMP compliance of manufacturing and related systems.
 - The ISPE – International Society of Pharmaceutical Engineers joined GAMP in 1995
 - GAMP guidelines are accepted by regulators world wide (FDA and PIC/S)

Quality Risk Management – GAMP “V-Model”



Auto Label Verify (ALV) Automation

- Auto Label Verify - ALV

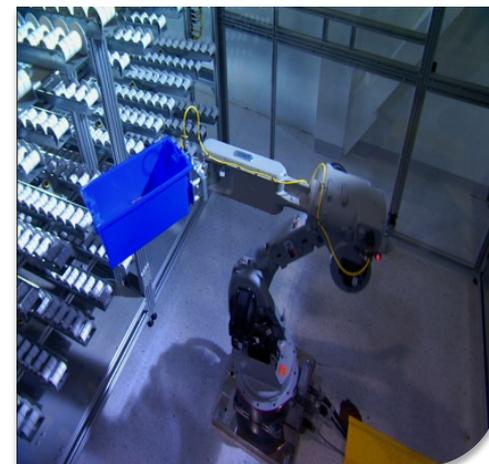
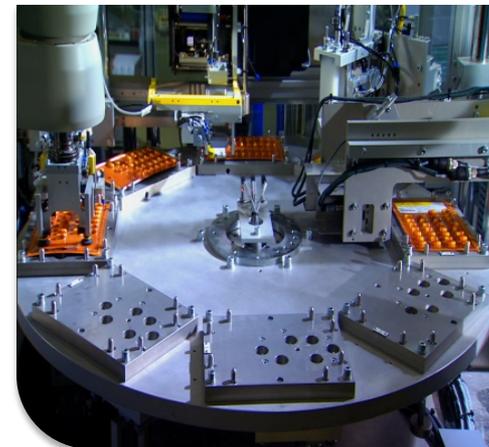
- 22 ALV systems are currently in operation Nationally

- Benefits include:

- Highest Accuracy and Quality with a Validate-able process
 - Improved service (from 9 touches to 3)
 - Improved pharmacy efficiency

- Results with Automation

- The Lodi & Canoga Park CA ALV processes have processed more than 4 Million prescription picks in total, with zero medication errors to date
 - Overall, external non conformances have been significantly reduced



Auto Label Verify (ALV) Automation Video Overview



Pharmacist Accountability

- Auto Label Verify (ALV) Automated Dispensing system is under the supervision of a Pharmacist
- Pharmacist responsible for the clinical order processing and verification of all orders (PVI)
- Pharmacist check in-house pharmacy produced packages of blister cards
- Pharmacist securely logs into the ALV system and enables it to process prescriptions
- Pharmacist securely logs into the ALV system to process QA and reconciliation orders
- Pharmacist supervise the registered technicians in restocking the automated system



Automation Rule Elements

- Detailed Policy and Procedures
- Pharmacist Supervision and Accountability
- Operator Training & Certification
- Computer Validation Guidelines - GAMP
- Six Sigma Process Design
- Preventive Maintenance by an Electrical Mechanical Technician
- Computerized Maintenance Management System
- Change Control Process
- Start-up Testing
- Ongoing Quality Assurance Program & Reporting
- Robust Recordkeeping, Documentation & Compliance Programs



Auto Label Verify (ALV) Summary

Auto Label Verify Automation...

System to enhance Patient care

System to reduce opportunity for errors

System to improve delivery

System to ensure:

Right Product

Right Patient

... Every time



Questions & Answers

