Model-Based Systems Engineering for High Volume Central Fill Pharmacies

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Forward

Model-Based Systems Engineering (MBSE) is a relatively new phenomenon that is transforming the way complex technical systems are designed. NASA JPL has been a leader in advancing MBSE through its application to the design of deep space missions, and today MBSE is becoming standard practice within DoD, as well as many major corporations, such as Boeing and Lockheed. The deployment of MBSE reduces the ambiguity that plagues document-based systems engineering, enables the integration and automation of a broad range of system analyses, and makes possible much more frequent critical review of system design and development decisions. It is making systems design and development faster, better and cheaper.

With the advent of Industrie 4.0, "the smart factory", and "the internet of things", production systems are becoming much more technical and complex. There is every reason to believe that the benefits of applying MBSE to space missions and aircraft programs also can be realized in applying it to the design and development of production systems.

This case study is one of a series intended to illustrate and promote the application of MBSE to production systems. The presentation of the case uses the semantics of discrete event logistics systems (DELS) developed over the course of several sponsored research projects performed in the W. M. Keck Virtual Factory Lab, beginning in 2007 and continuing today.

The work reflected in this case owes a large debt of gratitude to MBSE thought leaders, particularly Sandy Friedenthal, formerly of Lockheed, and the author of a leading textbook on the OMG Systems Modeling Language™ or SysML, and Dr. Chris Paredis, currently BMW Chair in Systems Integration at Clemson University. Any errors and/or omissions in this document are completely the responsibility of the author. Comments or questions may be directed to leon.mcginnis@gmail.com.

High-Volume Central-Fill Pharmacy Case Study

Introduction

A central fill pharmacy (CFP) is "a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user" (21 CFR 1300.01 (44) [Title 21 Food and Drugs; Chapter II Drug Enforcement Administration, Department of Justice; Part 1300 Definitions]). The main advantages of a CFP include cost reduction, through inventory consolidation and improved resource utilization, and giving pharmacists in local pharmacies the flexibility to focus on customers. The disadvantage is the delay associated with sending a prescription to the CFP, and the transport cost and delay associated with the physical delivery to the local pharmacy or direct to the patient. This delay is not critical for "routine" refills.

A high-volume CFP (HVCFP) is a CFP using automation to speed the filling of prescriptions, further improving labor productivity and substantially reducing the cycle time and cost for fulfillment. Fundamental challenges in designing and operating an HVCFP include: (1) selecting the right portfolio of automation technologies; (2) designing the material handling automation to integrate the drug dispensing technologies; (3) assigning drugs to dispensing technologies, and perhaps configuring the technologies for operation; and (4) operational control to achieve goals regarding accuracy, cost, throughput and response time.

This case study identifies the "product" produced by an HVCFP, the processes required to produce that product, the resources used to execute the required processes, and the organization of resources into a facility. It also identifies the control functions of the HVCFP, using the ISA-95 standard architecture as a framework. The system description is based on a particular HVCFP architecture and the case study is for a specific instantiation of that architecture. However, the system model and simulation model contain elements that are reusable for other HVCFP architectures, although new model elements might have to be developed for those architectures.

Concept of Operation

An HVCFP will be capable of filling prescriptions, or "scripts," for many drugs, perhaps several thousand, and the demand rates for these drugs will differ significantly. Drugs are identified by their National Drug Code, or NDC. The NDC Pareto curve may be extremely skewed, with the top 2 or 3 percent of the NDCs accounting for 70% of the scripts filled. Generally, the most often dispensed drugs will be for controlling blood pressure or cholesterol level, or for diabetes.

The HVCFP receives orders via the internet from local pharmacies. In one operational protocol, these orders may be transmitted at any time; orders received when the HVCFP is not operating are accumulated for the following day and available orders not completed in one day are carried over to the next day. All orders from a particular customer (pharmacy) completed during the HVCFP daily operation will be accumulated for delivery overnight. Other protocols are possible, such as guaranteeing that orders received before a designated cutoff time will be filled on the day received and delivered

overnight. In another scenario orders may arrive with due dates, and can be filled and delivered earlier. There are many possible variations.

A given HVCFP will serve a large number of local pharmacies, perhaps several hundred. The populations served by these local pharmacies may differ demographically, and if so, their ordering patterns may be quite different. The HVCFP will see significant day-to-day variability in the volume of scripts and mix of drugs ordered. The average volume and the mix of drugs ordered also may change depending on the season, and even the time of the month. The total number of scripts to be fulfilled, as well as the mix of drugs will change over time, driven by both demographic changes and advances in medicine.

HVCFP Product

An HVCFP produces batches of patient-specific orders ready for delivery to the originating local pharmacy. At regular intervals, e.g., the end of each working day, these batches will be loaded into a delivery vehicle for transport to the local pharmacies. In a particular pharmacy's batch, each individual patient's order will consist of one or more NDCs in appropriate packaging—vials for pills, bottles for liquids, and various unit-of-use packages. These NDCs must be packaged together, along with necessary paperwork, for delivery to the individual at the originating pharmacy.

Each NDC can be characterized as "dispensable" or "manual". Scripts for dispensable drugs—typically in pill form—can be filled using automation, whereas scripts for manual drugs must be filled by a human operator. The latter might correspond to liquids to be measured, items that come prepackaged in a form not suitable for automation ("unit of use"), drugs requiring refrigeration, etc. An order for a particular patient may include both dispensable and manual drugs.

HVCFP Processes

There are three phases of operation in a HVCFP. The first phase is the dispensing of individual drugs. The second phase is assembling individual patients' orders, which may consist of multiple scripts. The third phase is assembling all the orders for a specific pharmacy and delivering them. Note that dispensing drugs to fill a script and accumulating scripts to complete an order are referred to as the "fulfillment" function of the HSCFP. Accumulating the orders by pharmacy is referred to as the "delivery function". There are four fundamental processes for dispensing a drug, four fundamental processes for completing an individual's order, and three fundamental processes for completing a pharmacy's delivery.

To dispense a drug (dispense phase):

1. Prepare an appropriate container into which the drug will be dispensed. If the drug is prepackaged as a "unit of use" this process is not required.
2. Dispense the drug. This involves counting pills, measuring liquids, or retrieving a unit of use.
3. Verify the drug and quantity. In HVCFP facilities, this process is a regulatory requirement to insure patient safety.
4. Seal the container. Once a drug has been dispensed and verified, the container must be sealed. For prepacked unit-of-use drugs, this process is not required.

To complete an individual's order (order accumulation phase):

1. Accumulate all scripts for the individual order. Individual scrips in the order may be filled using different technologies, but all scripts must be brought together to complete the order.
2. Add each script's container to customer-specific packaging, typically a plastic bag.
3. Add drug-specific instructions, required notifications and other documentation.
4. Seal individual order.

To complete a pharmacy's delivery (pharmacy accumulation phase):

1. Accumulate all the individual orders for the specific pharmacy.
2. Seal the pharmacy order
3. Deliver the pharmacy order to a shipping dock, load into a delivery vehicle and transport to the pharmacy.

Of course, there are other related processes in an HVCFP. For example, inventory processes for storing drugs prior to use in filling orders, refrigeration processes, replenishing automation, etc. However, this case focuses specifically on the operational processes in supplying individual orders to pharmacies.

HVCFP Resources

Over the past twenty years, a number of drug dispensing automation technologies have been developed, and HVCFP solutions are offered by several suppliers (see, e.g., http://www.computertalk.com/feature-stories/cover-story-september-october-2014-the-evolution-of-central-fill or http://www.mckesson.com/about-mckesson/our-company/businesses/mckesson-high-volume-solutions/) .

Dispense Phase Resources

For dispense phase processes, there are essentially four kinds of automation resources. The first is automation resources for dispensing, labeling, weighing and capping vials, which [will] contain pills. For example, dispensing, labelling and weighing empty vials may be combined into a single automated process, where the weighing determines a tare weight, used later to verify the dispensed pill count. There also may be stand-alone resources for weighing or capping vials.

Second, there are resources that can automatically dispense a specific number of pills from a drug-specific canister into a vial. The automation technologies for dispensing drugs in pill form essentially use gravity to remove pills from an inverted canister, along with a mechanism that counts the number of pills dispensed and stops the flow when the required number of pills have been dispensed. There are two variations of this technology, which might be termed "high speed" and "high flexibility". A high speed resource will receive empty, but labeled and tared vials transported in a "puck" on a conveyor, see Figure 1. The puck will be moved under a dispenser, the vial filled with pills, and then moved in the puck to stations for verification, weighing, and

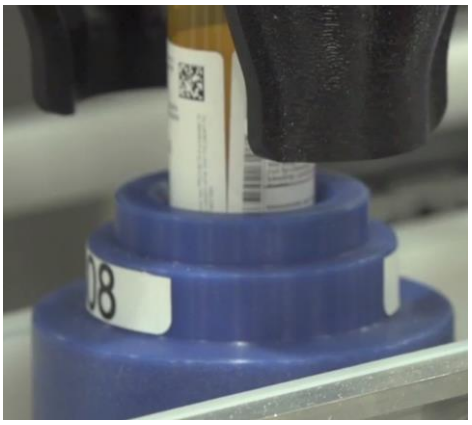

Figure 1 Vial in Puck

http://www.mckesson.com/pharmacies/mail-order/central-fill/

capping. The vial never leaves the puck. A single dispensing machine might have, say, six dispensers, and machines can be "ganged" together to provide a multiple of six dispensers, all served by the same puck conveyor. Clearly, high speed dispensing technologies require considerable integration of all the individual resources and the puck conveyor, but can be very effective for dispensing drugs for which there is a high demand rate.

A high flexibility resource operates quite differently. It is essentially a robotic workstation, which may have as many as 200 or more canisters, or pill types. Labeled and tare weighed vials may be delivered to the workstation via pucks and the vials removed from the pucks by the robot. Alternatively, the workstation may have its own capability to dispense, label and tare weigh vials. Figure 2 shows a robot holding a vial under a dispensing canister. For high flexibility workstations with vial dispensing capability, the filled vials are dropped into totes moved on a tote conveyor. There can be multiple high-flexibility workstations, as well as manual fill stations integrated via the tote conveyor. This technology can be effective for drugs that are ordered often enough to keep the robot reasonably busy. Extremely rarely ordered drugs are probably most economically handled manually.

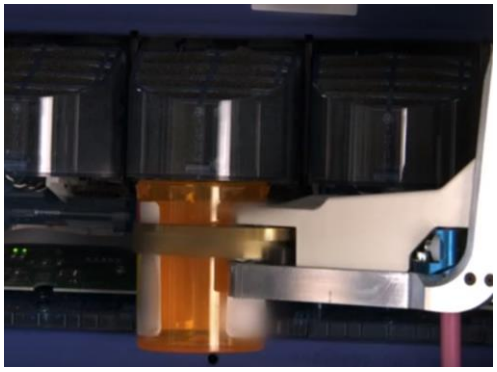

Figure 2 Robotic Workstation

https://www.youtube.com/watch?v=cBUig

As a comparison, a high speed technology might be capable of fulfilling 18 different drugs, each at a rate of 3 scripts/minute (for a total of 54 scripts/minute) and a capital cost of $175,000, while a high flexibility technology might be capable of fulfilling any one of 200 different drugs at a total rate 2 scripts/minute and a capital cost of $200,000. These are illustrations only, and do not define the complete range of automated solution capabilities and costs.

The third kind of technology for the dispense phase is visual verification, which involve imaging the dispensed pills in the vial, and having the image verified by a pharmacist.

Finally, there is transport technology for moving vials between dispensing processes. For high speed dispensing or high flexibility dispensing with separate vial dispense, label and tare weigh, the pucks must be transported between the various stations or technologies that are performing the necessary dispensing, labeling, and other processes. For high flexibility dispensing with built-in capability for vial dispense, label and tare weigh, the robot provides all the needed transport of the vials between operations.

Order Accumulation Phase Resources

In the order accumulation phase, there are four basic technologies. There is the technology of accumulating the scripts in a customer order, which is accomplished by delivering the scrips to a bagging station that can, itself, be completely manual, partly automated or completely automated. The scripts can be delivered to the bagging station via a puck conveyor, if all the scripts in the order are filled from the high-speed technology. When some scripts are filled from manual workstations, or from the high-flexibility technology workstations with built-in vial dispense, label and tare weigh, then they are

delivered to bagging in a tote via a tote conveyor, and they are accumulated in the tote as the tote travels to each dispense workstation along the tote conveyor. There is a special case of orders, called "combo orders" that have at least one script filled from the high-speed technology, and one script filled manually or from tote-based high-flexibility technology. In this case, one or more scripts filled from the high-speed technology, and contained in a puck must be transferred to the tote containing the rest of the scripts for the combo order. This can be accomplished by a vial transfer station (VTS), a robotic cell that removes vials from pucks, places them in temporary storage, then when the target tote is available, retrieves the pucks and deposits them into a tote, where the other items in the order are already accumulated.

Pharmacy Accumulation Phase Resources

Multiple orders from a given local pharmacy may be filled throughout the day and appear somewhat at random in the stream of orders coming from the fulfillment system. These orders must be accumulated into a pharmacy-specific container for delivery. At any time during the day, the stream of orders being delivered to the order consolidation process might contain orders for any of the customer pharmacies. Thus, the order consolidation process requires some form of sortation and accumulation by pharmacy. In an HVCFP processing tens of thousands of orders per day, automation is likely to be required, and there are a number of technological alternatives. All of them, however, have a similar functional form, i.e., the bagged orders are oriented on a conveyor, scanned to determine the destination pharmacy, conveyed past accumulation "lanes" and individual bags are diverted to the lane corresponding to their destination pharmacy. Figure 3 illustrates a portion of such a system, where there are accumulation lanes on either side of the sortation conveyor. An accumulation lane is assigned to a particular pharmacy and orders for that pharmacy are discharged from the sort conveyor and fall into the bin. When the bin is full, it is sealed and moved to a staging are prior to loading into a delivery vehicle.

Figure 3 Order Sortation System

https://www.youtube.com/watch?v=VdHcq0_zq_M

When the number of pharmacy customers is large, in the hundreds, it may not be possible to dedicate an accumulation lane to each pharmacy; rather some operational policy may be necessary to permit accumulation lanes to be shared by multiple pharmacies. This policy may address both the way that orders are released for fulfillment and the way the sortation/accumulation system is managed. A fundamental challenge with shared accumulation lanes is that bagged orders for a pharmacy may arrive to a lane that is shared, but not currently assigned to that pharmacy. This possibility dictates the need for a "sort error" lane, where such sort failures can be accumulated for later disposition. This disposition may involve running these orders through the sorter again, if there are many, or perhaps manually sorting them, if there are not so many.

Facility

The order fulfillment resources in the HVCFP are organized logically into seven subsystems:

- High speed dispense system that employs a range of fast dispense resources, as well as resources for dispensing and tare weighing vials, verifying dispense quantity and NDC, capping and bagging
- Puck conveyor system that provides all product movement through the high speed dispense system
- High flexibility dispense system that consists of a range of automated and manual workstations to dispense drugs that either cannot be automatically dispensed, or are ordered often enough to justify automated dispensing, but not often enough for high speed dispensing
- Tote conveyor system that provides all product movement through the high flexibility dispense system
- Vial transfer system that moves vials from the high speed system to the high flexibility system
- Take-away conveyor system that removes bagged orders from both high speed and high flexibility systems
- Order sortation/accumulation system that sorts orders by ordering pharmacy

Operational Control

The control processes can be distinguished according to the ISA 95 standard, which is illustrated in Figure 4. In level 3, manufacturing operations management, decisions will be made such as the release of orders to the fulfillment process, or management of the sorting capabilities. Level 2 is where operations management decisions are translated into execution by production resources, e.g., controlling the movement of a package on a conveyor, based on level 3 routing decisions. Deciding when a manual station should be staffed and by whom would be an operational decision. Lower level control decisions focus on data acquisition, and managing the execution of predefined behaviors in automation. In this case study, the focus is on operational control, i.e., level 3.

For the HVCFP, the level 3 control decisions will include:

- Whether to accept an offered order
- When to release each of the scripts in an accepted order for fulfillment
- If multiple resources are available to execute a given fulfillment process, the assignment of process step to resource
- If a resource must be re-configured to execute a process, when to change the resource configuration

It is important to be able to judge whether or not a control system is performing well. In the case of the HVCFP, criteria might include:

- Maximum achievable rate of order fulfillment, measured in scripts per hour
- Distribution of fulfillment cycle time, from order release to bagging
- Resource utilization distributions

Other criteria might be defined. In general, what a system owner will care about is system cost (investment and operating), system service level (fraction of accepted orders filled on time), and capacity margin (room for demand growth).

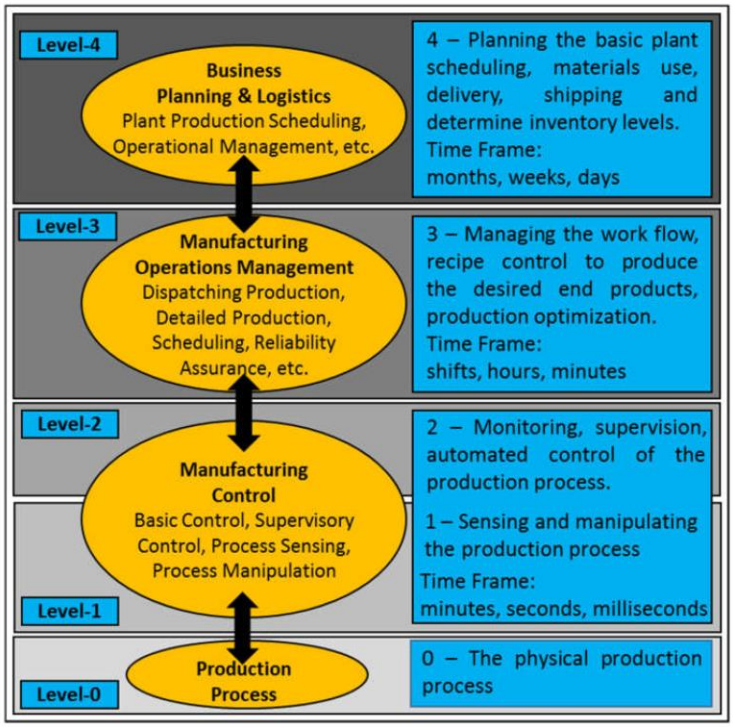

Figure 4 ISA-95 Control Hierarchy

http://www.mdpi.com/1999-5903/9/3/35/htm

System Summary

A HVCFP represents a significant investment, and promises significant operational cost savings over stand-alone local pharmacy operations. Realizing these potential savings depends on making good decisions about the selection of technologies, planning, and executing operations for a system that has many individual components, and large amounts of data related to capabilities, capacities and daily demand. This is an ideal setting in which to apply the principles and methods of Model-Based Systems Engineering (MBSE).