



CONNECTED SYSTEMS
INSTITUTE

Rockwell
Automation



Functional Requirements Document

FOR

Vial Filling Cell

Functional Requirement Specification

Document Authorizations

	Name	Date	Signature
Author:	Alan Diehl	05/23/2018	
Reviewer #1:	Joseph Zaccaria	05/23/2018	
Reviewer #2:			
Approver #1:			
Approver #2:			

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Note: Referenced documents herein will be hyperlinked back to this table.

Functional Requirement Specification

Acronyms Definitions

Acronym	Definition
FRS	Functional Requirement Specification
PAC	Programmable Automation Controller
HMI	Human Machine Interface
MES	Manufacturing Execution System
ERP	Enterprise Resource Planning
Ra	Roughness Average
GMP	Good Manufacturing Practice
cGMP	Current Good Manufacturing Practice
CFR	Code of Federal Regulation
ASME	American Society of Mechanical Engineers
GAMP	Good Automated Manufacturing Practices
FAT	Factory Acceptance Test
VFC	Vial Filling Cell
dtVFC	Digital Twin Vial Filling Cell

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1 Introduction

This document defines the requirements for both a physical Vial Filling Cell (VFC) and a digital twin Vial Filling Cell (dtVFC) that university faculty and students will use for both education and research to further the advancement of the Connected Enterprise. This Functional Requirement Specification (FRS) defines the important standards, components, variables, and options necessary for the Supplier to provide a functional VFC and its digital twin that meet the needs of the Connected System Institute. In addition, the VFC shall exclusively use products from Rockwell Automation Encompass Partners, Rockwell Automation, and Rockwell Software. All the physical system components shall integrate, seamlessly within a fully integrated architecture and connected enterprise using cutting-edge smart-data devices at all layers. The Supplier has the freedom to propose, design, develop, deliver, and quote either or both the physical and digital twin cell to meet the requirements discussed herein.

This FRS is an integral part of the procurement agreement with the Supplier. The Supplier will abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions provided within the [Reference Document Table](#).

Note: while the remainder of this document specifically discusses the physical VFC in depth, its digital twin must be capable of mimicking movements in a realistic representation and interface. The digital twin shall give the faculty and staff the same impressions as its physical counterpart from similar perspectives. Additionally, both the physical and digital twin must share their data tables in a bidirectional manner to enable educational and research needs to advance the capabilities of a connected enterprise.

2 Overview

The VFC shall process vials through a series of modular stations where faculty and students can deploy various studies and research within a realistic, fully automated connected enterprise. The concept is to allow the faculty and students the flexibility to make automation changes, analyze data associated with the change, and devise better connected enterprise solutions. The VFC's educational goal is to prepare students and create talent needed to transform their future employer's enterprise into a secure and fully capable digital manufacturing enterprise.

Generally, the VFC is going to use available potable water and commercially available containers of concentrated food coloring to produce serialized, filled vials of specific, recipe-driven volume and color. The desire is to allow the faculty and students as much flexibility as possible in the configuration of the VFC to easily enable studies and research not yet imagined.

Conceptually, the VFC will feature four (4) filling stations. Three (3) filling stations will wet fill the vials with water and red, yellow, and blue food coloring matched to a recipe. One (1) filling station serviced by a Delta robot will dry fill vials per a recipe. The recipe for each vial will be tied to that specific vial via serialization and the unique barcode on the vial. Filling stations of this design will provide the faculty and students the ability to configure the system in a broad number of ways and deepen their understanding of how to improve the efficiencies of a particular filler, or the entire VFC.

Additionally, as illustrated in [Figure 1](#), each filling station area on the transporter incorporates a straight segment of conveyor that allows vehicles to bypass a station if desired.

The VFC will also feature a capping station that will seal the vials with a stopper to simulate a ready-to-sell product. Each vial does not need to be capped, and the station shall only cap a certain percentage of vials as configured from the VFC HMI. The capping station will utilize a SCARA robot for functionality.

An inspection station downstream of vial capping will be utilized to further studies and research into machine vision and object inspection. The inspection station shall be capable of inspecting fill-level, color, weight of a filled vial. Following inspection, vials shall be qualified as good, salvageable, or trash product and removed from the line using one of the robotic applications that will be detailed below.

The VFC shall include the following functions:

3 Transporter

The flexible and configurable conveyance system will include independently controlled moving vehicles using Rockwell Automation's MagneMotion MagneMover Lite for fast, precise movement, positioning and tracking of small, light loads. The MagneMotion system will be set to run in 'Taxi Mode' which allows the Magnemotion system to respond to instructions on puck destination and determine the optimal traffic path internally. Programming of each vehicle and the entire transporter shall use Rockwell Automation's software that has programming languages discussed within the IEC 61131 standard referenced within the [Reference Document Table](#).

The goal is to install Seven (7) modular stations into the transportation system that will demonstrate a real-world application of a formulation VFC within a connected enterprise environment. See [Figure 1](#). Note: this is a conceptual system, the VFC's final layout and the number of vehicles needed will be defined as the design finalizes.

Required motors:

- Curve: Qty 19
- Right Switch: Qty 7
- Left Switch: Qty 8
- 1 Meter Straight Section: Qty 16
- 250 mm Straight Section: Qty 5

3.1 Transporter Vehicles

The minimum and maximum/allowable carrier repeatability: ± 0.5 mm

The minimum allowable fixture dimensions: 90 mm

The maximum allowable fixture weight: 2.2 lbs

Center of mass should always be in the center of the vehicle, commonly called a puck.

Fixtures can be 3D printed to meet the VFC's vial requirements.

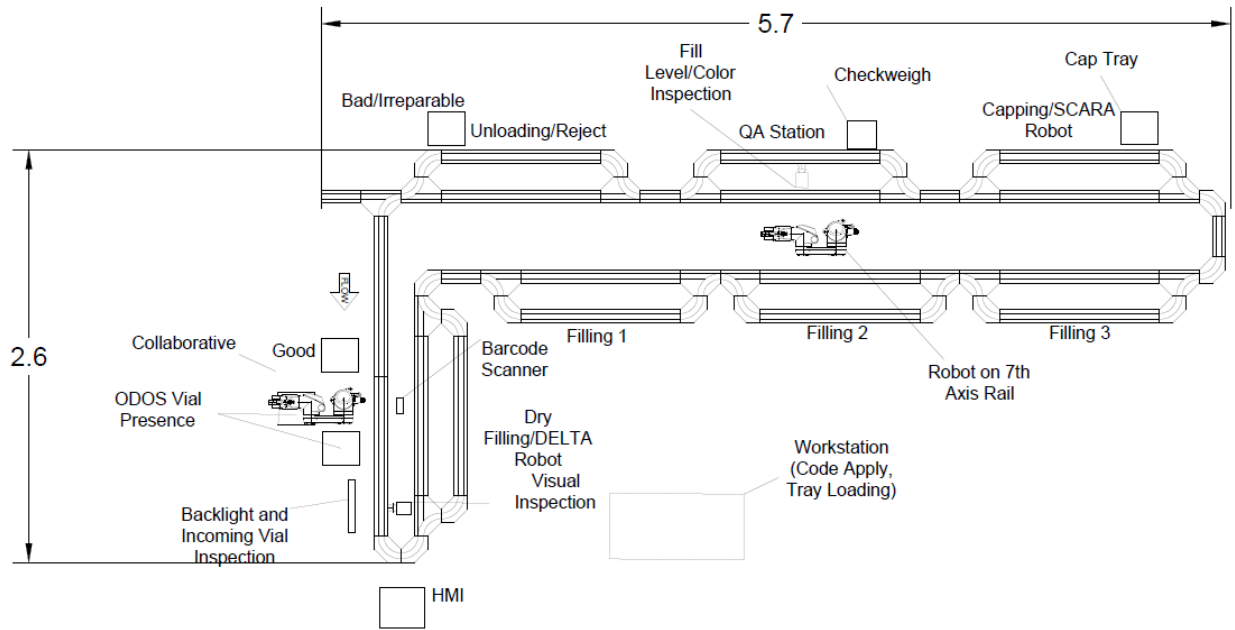


Figure 1: Conveyance System

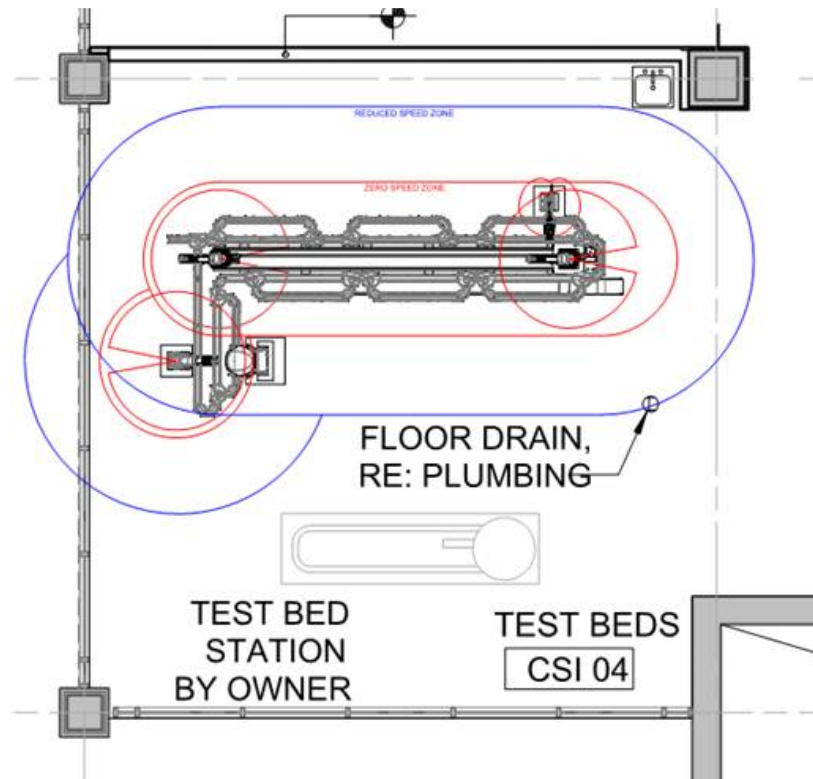


Figure 2: CSI Layout with Safety Zones

4 Robotics

The VFC will feature a suite of FANUC robots that will perform material handling/filling/capping tasks. The design constraints (acceleration, deceleration, max speed, etc.) of each robot shall be configurable to allow simulation of different manufacturing scenarios. The VFC will feature two (2) 6-axis robots, a Delta robot, and a SCARA robot. One of the 6-axis robots will be built with a 7th axis rail system to expand its working envelope. Robotic systems that directly interact with vials on the conveyance system will only be required to interact with stationary pucks upon receiving a signal from line control that the puck has arrived. Robotics systems are as follows:

4.1 Rail Robot

The VFC will feature a collaborative robot installed with a 7th axis rail to allow it to service stations 2 through 7. The rail will be servo-driven and capable of single-axis motion. The rail-robot's primary functions will be unloading quality-rejected product and assisting the QA station. Flexibility and configurability of the rail's functionality is important as faculty and students should be able to test various pick-and-place algorithms and determine the robot's efficiency. The rail shall be sourced from Gudel to manipulate the position of the robot to allow access to 6 of the 7 stations. The rail robot will feature an end effector capable of handling the vials. A vision system shall be integrated with the robot to allow it to select open slots in a vial tray. An integrated safety solution shall be devised such that the rail and robot operate in accordance with the safety documents referenced in this FRS. The robot will likely be a FANUC CRiA7/L Collaborative Robot or similar.

4.1.1 Rail Robot Specifics:

The minimum and maximum/allowable repeatability: ± 0.5 mm

Maximum Payload: < 2 lbs

4.2 Loading/Unloading Robot

The VFC will feature a six axis robot that will load/unload vials to/from the conveyance system. The robot shall sit on a fixed platform and will interact closely with faculty and students. Flexibility and configurability of the robot's functionality is important as faculty and student should be able to test various pick-and-place algorithms and evaluate their effects on the robot and system. The loading/unloading robot will feature an end effector capable of handling the vials. The robot will be required to pick vials from various tray docking stations and place them onto the transporter pucks and vice-versa. A vision system shall be integrated with the robot to allow it to determine vial placement within a vial tray. The robot will likely be a FANUC LR Mate 200iD/7L.

4.2.1 Loading/Unloading Robot Specifics:

The minimum and maximum/allowable repeatability: ± 0.5 mm

Maximum Payload: < 2 lbs

4.3 Filling Robot

The VFC will feature a Delta robot at Station 1 that will exhibit dry-fill and sortation methods. The filling robot will feature an end effector as necessary to complete the filling process. The robot will be a FANUC M-1iA enclosed by a transparent safety-cage to facilitate viewing while functioning as an example of a physical safety barrier for robotic applications.

4.3.1 Filling Robot Specifics:

The minimum and maximum/allowable repeatability: ± 0.5 mm

Maximum Payload: < 2 lbs

4.4 Capping Robot

The VFC will feature a SCARA robot at Station 5 that will be capable of capping vials. The robot would be required to pick-and-place caps from a filled tray onto a vial. The capping robot will feature an end effector as necessary to complete the capping process. The robot will likely be a FANUC SR-3iA.

4.4.1 Capping Robot Specifics:

The minimum and maximum/allowable repeatability: ± 0.5 mm

Maximum Payload: < 1 lbs

The vendor is required to follow all aspects of ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard, referenced within the [Reference Document Table](#). Further, all robotic safety requirements/compliance will be verified by authorized integrator.

5 Vial Loading Station

The vial loading station will have at least three (3) tray docking areas that can be configured for empty vials, completed/good vials, and rejected vials as needed. The loading/unloading robot will be responsible for manipulating the vials between the trays and conveyance system. ODOS imaging systems will be implemented at each docking station to identify vial presence/absence for pick-and-place. Configurability of the tray docking stations needs to allow both the Faculty and Students to use their imagination to configure the docking stations in any sequence they desire to realize efficiencies on the entire VFC as explained within the Vials, Trays, and Tray Docking Areas below.

5.1 Vials

Core to the nature of this project are the vials used in the VFC. The vial will drive the type of tray, vehicle holder, and stopper selection. The intention is to use an inexpensive, commodity-available, clear, plastic vial repeatedly until it is physically unusable. Additional considerations revolve around Vial Identification/Order Labeling, details to follow. The vials to be used for the VFC are detailed in the Operational Requirements.

Note: Glass vials are not allowed on the VFC due to the risk of breakage and the additional safety/PPE requirements glass products would incur.

5.2 Vial Trays

These trays shall have an array of pockets that hold both empty and filled vials. The faculty and students shall manually load trays with empty vials and empty full vials from these trays. The intention is to use an inexpensive, commodity-available, plastic tray that will hold each vial. The preference is for trays to be designed such that the vials require a small force to be extracted. The intention is that a tray containing vials be turned upside-down without vials falling out of the tray for ease of rinsing, but be loose-fitting enough to be easily removable by the robots.

As an option, every tray could be identifiable by using a printed bar code label and scanner or an RFID tag, encoder, and reader such that the VFC can track and trace vials as they progress through the VFC.

5.3 Tray Docking Areas

The tray docking areas shall allow for trays to easily be inserted/removed from the docking area. Each docking area shall have a certain number of tray stations that allow for the tray to be locked down while it is in service. The tray locking mechanism is required to avoid shifting of the tray during robotic interaction.

The tray docking area shall be manageable and configurable from the VFC HMI. As trays are loaded, the user shall be able to inform the system where a tray has been added and the purpose of that tray, be it loading/unloading or for good/bad vials.

Each tray dock shall also measure the total weight of the tray and monitor that weight as vials are removed to accurately determine the weight of each vial to accurately tare the checkweigher at the inspection station.

6 Vial Identification/Order Labeling

Each vial shall be traceable throughout the VFC through some identification method. The selected identification method is barcode/QR labels applied to each vial prior to use with the VFC. Print-and-apply labels were chosen to limit the number of items that must be sourced/inventoried by the university and provide students and faculty the ability to test different coding methods through the system. A label printer shall be supplied with the VFC. Labeling vials ensures full track-and-trace and serialization capability throughout the system as each vial will be tied to a specific MagneMotion puck. Robotic manipulation during vial loading in the presence of the barcode scanner is required to compensate for inconsistent placement of labels on the vial and varying vial orientation within each tray. A Teledyne Dalsa Imaging system will be used for this application.

7 Incoming Vial Inspection Station

A fully-capable vial inspection station will be located immediately downstream of the loading station. The vial inspection station will incorporate a vision system as required to inspect each incoming vial for physical defects/damage. The inspection system will also verify the clarity of the vial to prevent the use of vials which have yellowed with age, causing quality inspection issues. If a vial is found to be out-of-spec, that vial will bypass all filling stations and proceed to the reject station for removal by the rail robot. A Teledyne Dalsa Vision System will be used for this application. A second handling option for rejected vials is the loading robot will place the rejected vials in a tray identified as “for disposal” vials.

7.1 Vial Filling Stations

The modular, configurable vial filling station’s purpose is to fill a vial with an accurate amount of potable water and food coloring according to the current recipe. There will be four (4) filling stations total (1 dry and 3 wet). It is desired for the recipe to also control which filling station will fill a particular vial. Each wet station must also be capable of blending the resulting solution together to achieve a uniform color throughout. Blending could be performed by filling with water as the last step in the process. Each wet station will share common water, red, yellow, and blue feeds, so only one station may use a particular feed at any time. In the case where the liquid handling / filling system is enabled through use of multiple designated flow meters, the filling stations can be used independently and simultaneously.

7.1.1 Filling Heads

The filling head at each station shall be 316 stainless steel and the filling station will be designed to be corrosion resistant. The four (4) filling heads at each station will be independent from one another to avoid cross-contamination.

7.1.2 Filler Headers

The filler headers in each station will make use of a variety of metering types to expose students to a range of technologies. All equipment should be easily accessible and swappable to allow students and faculty additional flexibility in the station configuration. Two flow meter types are to be implemented (Coriolis and Electromagnetic) to allow students to compare the two flow meter's performance. Because the flow rates and total volumes will be typically small, the fill system will consequently have to maintain a constant pressure. Also, the fill system will integrate high precision valving to minimize variability in the fill dosing.

The Endress + Hauser flow meters for this application will be:

Promass A (GI C) 300 Flowmeter, Part # 8A3C02-*****SAAASAA1

Promag H 300 Flowmeter, Part # 5H3B04-*****A1P*AA1

Note: the following variables were determined based on a 20 mL vial, if the vials are larger, then the flow rates should be scaled appropriately; however, the dosing cycles should remain at 2ms.

Potable Water Valve:

Minimum Flow Rate: 12.5 ml/s

Maximum Flow Rate: 50 ml/s

Dosing Cycle: ≥ 2 ms

RYB Concentrate Valves:

Minimum Flow Rate: 1 ml/s

Maximum Flow Rate: 4 ml/s

Dosing Cycle: ≥ 2 ms

7.1.3 RYB Concentrated Food Coloring Containers

Three (3) commodity available buckets of concentrated Red, Yellow, and Blue (RYB) food coloring containers will be located within a process area of the VFC. Two pumps will be dedicated to each color. Designing in this manner means the VFC can dose RYB color at only two stations simultaneously. A pressure controlled header system can also be employed to allow for fully independent use of each station.

Regardless of method, a means of transporting the concentrate from the containers to the filler header, detecting the level of concentrate that remains in each container, warning, and alarming on the container level, and a means to track and trace new containers introduced into the system is necessary to simulate a realistic process area.

7.1.4 Process Tank Checkweigh

Each process tank shall measure the total weight of the tank and fluid and monitor that weight as vials are filled to accurately determine the weight of the fluid consumed through the course of a run. Final functionality for this option will be determined during detailed engineering.

7.2 Vial Stoppering

The modular, configurable capping station's purpose is to seal a filled vial by some means. The desired method is a rubber stopper that is recyclable and commodity-available. A certain number of tray docking stations, identical to the ones used in the loading station, will be required in this area. The stoppers could also be fed via a dispersion system of a reliable and repeatable design.

Functionality of the docking stations shall be the same. The stoppering mechanism shall have a means of either counting down the number of stoppers remaining in each tray to produce a warning and empty tray operator message or a visual solution to directly evaluate the stoppers remaining and their orientation. A SCARA robot may be used in this station to pick-and-place vial stoppers.

7.2.1 Stoppers

The intention is to use an inexpensive, commodity-available, rubber stopper repeatedly until it is physically unusable. The stopper must appropriately seal the vial and prevent the vial's contents from leaking out. If the SCARA robot is implemented, the stoppers must be manipulated directly by the robotic end effector. The stoppers to be used are detailed in the Operational Requirements.

7.2.2 Stopper Trays

These trays shall have a number of pockets that hold stoppers. The faculty and students shall manually load trays with stoppers. The intention is to use an inexpensive, commodity-available, plastic tray that will hold each stopper.

As a future option, every tray could be identifiable by using a printed bar code label and scanner or an RFID tag, encoder, and reader such that the VFC can track and trace stoppers as they progress through the VFC.

7.2.3 Tray Docking Areas

The tray docking areas shall allow for trays to easily be inserted/removed from the docking area. Each docking area shall have a certain number of tray stations that allow for the tray to be locked down while it is in service. The tray locking mechanism is required to avoid shifting of the tray during robotic interaction.

The tray docking area shall be manageable and configurable from the VFC HMI. As trays are loaded, the user shall be able to inform the system where a tray has been added and the purpose of that tray, be it loading/unloading or for good/bad vials.

Each tray dock shall also measure the total weight of the tray and monitor that weight as stoppers are removed to accurately determine the weight of each stopper to accurately tare the checkweigher at the inspection station.

7.3 Vial Inspection Station

The modular, configurable vial inspection station's purpose is to inspect the vial for fill level, color accuracy, and weight by some means. Fill level and color accuracy could be determined through visual inspection means, while a checkweigher will be implemented just off the line to measure weight. The weighing process would require assistance from the rail robot to pick-and-place full vials onto the weigh station. The weigh station will require information on each vial and stopper's weight to accurately calculate the weight of only the fluid inside the vial. A Cognex In-Sight 7802 vision system will be used for this application.

7.4 Vial Unloading & Reject Station

The final station is reserved for vials to stage when they are to be unloaded from the system or recirculated for color/level correction. Any pucks with vials will stage in this area until assisted by the rail robot. The rail robot will unload the appropriate vials into a "bad product" tray outside the line. When appropriate, vials to be recirculated will automatically leave the staging area and proceed to a filling station to attempt quality correction.

7.4.1 Trays

These trays have the identical requirement as discussed within the Vial Tray section.

7.4.2 Tray Docking Areas

These tray-docking areas have the identical requirement as discussed within the Vial Tray Docking Areas section.

8 Operational Requirements

8.1 Commodities

Vials

Vial Size (Dram) Type	Material	Neck Finish (mm)	Height (mm)	Diameter (mm)	Part Number/ID	Supplier
9	Styrene	N/A	71	27	0710-04	SKS
12	Styrene	N/A	71	31	0710-05	SKS
15	Styrene	N/A	87	31	0710-06	SKS

Vial Stoppers

Material	Color	Size	Supplier	Comments
Cork	Natural	13	Various	For use with 27mm vials
Cork	Natural	16	Various	For use with 31mm vials
Plastic	White	27mm	SKS	Snap cap included w/ vials
Plastic	White	31mm	SKS	Snap cap included w/ vials

Vial Trays

Material	Length (in)	Width (in)	Height (in)	Pockets (#)	Part Number/ID	Supplier	Comments
Plastic	16	8	3	45	63599	InterDesign	For vials

Vial Trays

Material	Length (in)	Width (in)	Height (in)	Pockets (#)	Part Number/ID	Supplier	Comments
Foam Insert	16	8	1	45			Fabricated

8.2 Performance

This flexible, configurable VFC shall process the vials through the system in as timely of a manner as possible. While a requirement is not a quantifiable value of vials/min, the intention is to make this VFC as realistic as possible for the faculty and students for both research and study on techniques where they could improve, optimize, and increase the throughput of the VFC through analysis, research, and studies.

8.3 Functions

Within this section of the functional requirements specification, we will discuss the various ways in which the VFC, specific areas, stations, and equipment will operate in a proper or particular way. Generally, the VFC shall operate within setup/teach, manual, semi-automatic, sequential stepping, dry cycling, and automatic modes.

Additionally, system operators shall be capable of either including or excluding any area or station from a particular mode. If excluded, transporter vehicles will pass thru those areas or stations without performing any work. The safety of everyone who interacts with this cell is of an upmost importance.

8.3.1 Vial Filling Cell Safety Functions

As a realistic VFC within a university setting, it is of an upmost importance that no injury shall occur. The VFC design, development, and delivery ultimately shall follow all best practices and requirements to prevent injuries, but more so this vial filling cell shall maintain a program where the design and development follow a safety lifecycle program as is described within ISO 12100:2010 standard, referenced within the [Reference Document Table](#).

While physical fencing around cells occur within real manufacturing cell settings, this cell shall use a more modern approach such as using laser scanners to zone out areas where university faculty and students may wish to interact with the cell and allowing physical devices to maneuver at a safe limited speed. As such, the solution shall deploy configurable techniques, but ultimately the safety of anyone who interacts with the cell in a manner is of the upmost and paramount concern.

The VFC shall use safety-zoning techniques where the system or anyone who is interacting with a particular area or station can safely continue performing service or work within that area or station. The transporter conveyance system is purposely illustrated to allow vehicles to bypass at seven (7) of its stations (see [Figure 1](#)). If a fault occurs on one or more specific stations, or a system operator is working on a station, then transporter vehicles bypass that station so the vial-filling cell can continue to process vials.

The supplier shall follow all aspects of ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard, referenced within the [Reference Document Table](#).

8.3.2 Functional Modes

Due to the nature of the VFC, we encourage the Supplier to use Rockwell Automation's Integrated Line Control and Line Performance Solution, RAPID. Each station shall be designed, developed, and delivered as a fully compliant Organization for Machine Automation and Control (OMAC) PackML machine.

Note: tools, techniques, and consultancy are available from Rockwell Automation so please discuss this with your local Distributor and/or Rockwell Automation account manager.

For more information, please refer to the PackML Unit/Machine Implementation Guide, referenced within the [Reference Document Table](#).

8.3.2.1 Setup/Teach Mode

While the VFC is within the setup/teach mode, the entire cell's kinetic energy is maintained in a zero state, thus, anyone can interact with any station to prepare it for other modes of operation. For example:

1. The transporter's vehicles could receive new fixtures to hold different vial sizes.
2. Tray docking areas shall allow adjustments for trays needed to support a variety of vial sizes.
3. Therail robot shall allow system operators to remove and replace different grippers for different vial sizes, along with teaching the rail robot in a systematic and proper way.
 - a. The need for a regimented procedure to teach the rail robot is required for each area or station it serves.
 - b. The goal for teaching the rail robot is to inform the automation system its working envelope and not to teach it move patterns as the automation system can do this more effectively in a dynamic pick and place system.
4. The vial identification and labeling station shall allow system operators to validate placement and readability of the labeling process and that the automation system correctly reads the same into its data stream.
5. The vial stoppering station shall allow system operators to remove and replace fixtures to stopper different vial sizes.

8.3.2.2 Manual Mode

While the VFC is in manual mode, kinetic energy is present and system operators shall be capable of safely bumping all physical devices in a systematic and proper way. The transporter/vehicles, rail, all robots, vial-filling stations, and vial stoppering station will require regimented procedures to assure they operate manually in a safe and predictable way.

8.3.2.2.1 Transporter / Vehicles Manual Mode

Movement of vehicles can occur for vehicles that are presently within a particular area or station. Vehicle to vehicle automatic collision avoidance within the area or stations is necessary. No vehicle shall move within its area or station until all the devices within the area or station are in the safe docked positions.

8.3.2.2.2 Rail Robot Manual Mode

System operators shall be able to maneuver the rail robot through its entire range of movements in a specific and proper way. We recommend that the robot shall take all automatic measures necessary to

protect itself from moving into objects, i.e. crashing, while the university faculty and students are maneuvering the rail robot while in this mode.

8.3.2.2.3 Vial Filling Manual Mode

Bumping and moving of devices within the vial filling areas are possible. However, system operators must follow regimented procedure to avoid damage and spills occurrences. We recommend that the vial filling station shall take all automatic measures necessary to protect itself from moving into objects, i.e. crashing, while the university faculty and students are bumping devices while in this mode. This shall include, not releasing blended food coloring from the blend tube until all its limits are satisfied.

8.3.2.2.4 Vial Stoppering Manual Mode

Similarly, to the Vial Filling Manual Mode above, moving of devices within the vial stoppering is possible thru following a regimented procedure to avoid damages to its devices and other equipment. We are recommending again that the vial stoppering station shall take all automatic measures necessary to protect itself from moving into objects, i.e. crashing, while the university faculty and students are bumping devices while in this mode. This shall include, not attempting to stopper a vial already stoppered within the stoppering station and assuring all its limits are satisfied before releasing a stopper.

8.3.2.3 Semi-Automatic Mode

While the VFC is within the semi-automatic mode, kinetic energy is present and a series of system operators shall perform the task that the rail robot performs in a safe and secure manner. Operators stationed throughout the system to physically pick and place vials from trays to vehicles and vice-versa throughout the system without using the rail robot. Thus, system operators will signal the automation solution to advance the vehicles, as vials are loaded, unloaded, or rejected in the cell through some means. Semi-automatic mode will require pushbutton or HMI stations in specific areas.

8.3.2.4 Sequential Step Mode

While the VFC is within the sequential step mode, kinetic energy is present and system operators shall be capable of taking a single vial from its source tray through the entire cell's processing in a safe and secure manner. This mode allows operators to visualize each decision made by the automation solution to process a vial.

8.3.2.5 Dry Cycling Mode

While the VFC is within the dry cycle mode, kinetic energy is present and vial processing is similar to automatic mode with the exception that vials are not filled, stopped, or inspected in any way. This mode puts the vials thru the paces but performs no work and functions in a safe and secure manner.

Note: Alternatively could be called Demo Mode.

8.3.2.6 Automatic Mode

While the VFC is in automatic mode, kinetic energy is present and the automation system is processing vials through the entire process as selected on the HMI, just as a production ready vial filling system would. System operators are required to interact with the VFC cell at the vial loading, labeling workstation, filling station process areas, reject area, inspection area, and unloading area to keep the system operating.

Note: with additional machinery and automation techniques this entire vial filling cell could operate in a 24/7 lights out manner with system operators supplying it with only raw materials.

8.4 Recovery

Generally, during any type of recovery situation the system shall not lose any piece of transactional or positional data. Furthermore, the system shall avoid collisions, breaking devices or fixtures, and injuring any operators. In addition, the system shall only reboot or continue to process vials upon going thru a procedural visual inspection and resetting process which will bring the system online with minimal interruptions and little to no quality issues.

Under no circumstances shall the system's operators need to interact with the VFC by clearing or removing its current vials from the system, nor place vials into the system during the recovery process, except for a few exceptions such as power failure, emergency stop, and processor failures or faults, discussed below.

8.4.1 Power Failure

An interrupted power source either to the facility, the facilities room, VFC, or a specific trip of a fuse or circuit protection device on a series of drives or controllers, and possible physically disconnecting the power to a particular station will cause the system to go thru a recovery process. Process disruptions are likely to occur in vial filling, stoppering and inspection that will cause quality detection problems. The system must be capable of continuing processing, but the disrupted vials shall end up within the reject tray. For example:

If the order was to fill one hundred (100) vials with a green hue blend and power was interrupted to the campus facility immediately after vial seventy five (75) was placed into the upload tray, and eight (8) of the ten (10) vehicles have been assigned, but six (6) of them were disrupted during identification/order filling and stoppering, when power returns, the system operator would issue a clear command to enter into a stopped state, then issue a reset and start command to begin executing the batch that will then send those six (6) disrupted vials to the reject tray and continue to produce one hundred (100) vials with a green hue.

8.4.2 Emergency Stop

An emergency stop can only occur through human intervention by cable pull switches or button stations located strategically around the transport conveyance system and within the laboratory where the machine is located on walls or beam areas. Generally, as the name implies, an emergency is occurring. As such, and discussed previously, our top priority is the safety of anyone in or around the VFC. Ideally, the goal is to continue processing after the event, but as this is an emergency condition, additional procedural considerations prior to clearing, resetting, and starting of the system could mean removal of all vials from the system and starting from a "zero" state may be required.

8.4.3 Processor Failures or Faults

Processor failures could mean a number of things, but for this sake, it is a hardware malfunction. Furthermore, processor faults fall into two categories, recoverable and unrecoverable. The following subsections discuss exceptions for these conditions.

8.4.3.1 *Processor Failures*

The likelihood of continuing to process from a processor failure is unlikely, as the processing hardware module has failed. Therefore, should this occur, the cell operators would need to clear all the vials from the system and restart their batch from a known useable data point or from a “zero” state.

8.4.3.2 *Processor Recoverable Faults*

The VFC likely can continue with the following exceptions. Process disruptions are likely to occur in vial filling and stoppering that will cause quality problem during inspection. The system must be capable of continuing processing, but the disrupted vials shall end up in the reject tray.

Note: this is similar to how the system should respond during a power failure as described above.

8.4.3.3 *Processor Unrecoverable Faults*

The likelihood of continuing to process from an unrecoverable fault is unlikely. Therefore, should this occur, the cell operators would need to clear all the vials from the system and restart their batch from a known useable data point or from a “zero” state.

8.4.4 *Crashing*

Crashing by here means the collision of two bodies.

While the automation solution will take every consideration to avoiding crashing, there are always risks of a crash. For example, an inexperienced programmer could make a change that causes a crash by the automation solution, or something mechanically may physically break do to fatigue, stress, and wear and the automation solution thinks it is not on a collision path but the object is really within the collision path while under its direct control.

Therefore, should this occur, the cell operators would likely issue an emergency stop. Nonetheless, damage has occurred; therefore, the cell operators would need to clear all the vials from the system and restart their batch from a known useable data point or from a “zero” state.

8.5 *Alarms and Warnings*

The primary function of the alarm and warning system is to notify operators of abnormal process conditions or equipment malfunctions and support the response. The alarm system also includes a mechanism for communicating the alarm information to the operator via an HMI, usually a graphical computer screen or an annunciator panel. Additional functions of the alarm system are an alarm and event log, an alarm historian, and the generation of performance metrics for the alarm system. There are external systems that can use the data from the alarm system.

Alarms and warnings shall be rationalized against what should alarm and when, to whom it should alarm and how are they notified, how is the operator to respond, and how should the alarm be triggered. The user’s goal is to follow a design and development Alarm Management Lifecycle program as described within ANSI/ISA-18.2-2016 standard referenced within the [Reference Document Table](#). While this document specifically references processes, it forms an Alarm Management Lifecycle approach for this university setting. Furthermore, the ISA-TR18.2. (1-7) discusses valuable techniques to create a great alarm system for this project. Particularly of interest would be ISA-TR18.2.6-2012 Alarm Systems for Batch and Discrete Processes standard referenced within the [Reference Document Table](#).

8.5.1 Immediate Alarm Stops

Immediate alarm stops can occur within a specific safety zone or through human intervention to stop the VFC as discussed within the emergency stop section above. This section will discuss some of the causes of immediate alarm stopping along with detailing whether they are cell-wide or zoned types. Zone triggered immediate alarm stops will only remove the kinetic energy within specific mechanisms in the zone.

When zone-triggered immediate alarm stops remove the kinetic energy from its zone, the VFC's transporter conveyance vehicles shall be bypassed through the straight areas to allow the VFC to continue processing, just as systems would within a real manufacturing setting. Procedural processes will begin and the cause for the immediate alarm stop recovery processes will begin following the general recovery processes.

8.5.1.1 Immediate Alarm Stops List

Note: the following list is not complete; however, these shall give the Supplier a general idea of some causes of an immediate alarm stop. Generally, these are failures or faults from utilities, drives, servos, sensors, timing errors, etc. It is the Supplier's responsibility to program this class of alarm stops such that the faculty and students can diagnose and recover with an appropriate decision tree approach.

Immediate Alarm Stops	
Trigger	Immediate Type Cell Wide or Zoned
All Laboratory Wall or Beam Area Emergency Stops	Cell Wide
Power Failures – By any means	Cell Wide
Transporter Conveyance Failures or Faults	Cell Wide
Air Pressure	Cell Wide
Potable Water Pressure	Cell Wide
Vacuum Pressure	Cell Wide
Rail Robot Faults or Failures	Cell Wide
Cable Pulls or Emergency Stops	Cell Wide
Faults generated at the Loading Area	Zoned
Faults generated at the Identification / Order Labeling Area	Zoned
Faults generated at any of the filling stations	Zoned
Faults generated at the stoppering station	Zoned
Faults generated at the inspection area	Zoned
Faults generated at the reject / upload stations	Zoned

8.5.2 Cycle Alarm Stops

Similar to the thought process implied by the immediate alarm stops type above, cycle alarm stops can occur within a specific station, or thru human intervention to stop the VFC. This section will discuss some of the causes that generate cycle alarm stopping along with detailing whether they are cell-wide or zoned types.

Cycle alarm stops is a process where a cycle stop signal commanded either by the automation solution or via a system operator. When the command is activated for the entire cell to cycle alarm stop, no more new vials will be picked at the loading area, however all vials within the cell are processed through

to completion. When the last vial is either uploaded or rejected, the rail robot will move to its stopped position and all devices will be within a stopped state. Note: kinetic energy is present within the cell as well as each station.

Zone-triggered cycle alarm stops will only place the station that issued the cycle alarm stop command into a stopped state. Stations that can issue these are vial loading, filling stations, and stoppering station. Raw material run outs are the general causes for the cycle alarm stop.

8.5.2.1 Cycle Alarm Stop List

Note: the following list is not complete; however, these shall give the Supplier a general idea of the types of things that can cause cycle alarm stop. Generally, raw material shortages cause these type of alarm stoppages. It is the Supplier's responsibility to program this class of alarm stops such that the faculty and students can diagnose and recover with an appropriate decision tree approach.

Cycle Alarm Stops	
Trigger	Immediate Type Cell Wide or Zoned
Operator initiated cycle stops	Cell Wide
Vial shortages at Vial Loading	Cell Wide
Raw material shortages at Vial Identification/Order Labeling	Cell Wide
Raw material shortages feeding all Vial Filling Stations	Cell Wide
Raw material shortages at Vial Stoppering	Cell Wide
Maintenance concern at a specific Vial Filling Station	Zoned

8.5.3 Operator Alerts

When an operator alert occurs, the VFC must continue to operate. The operators must review the message, acknowledge the alarm, and begin to resolve the cause of the alarm while the machine continues to operate. Under this condition, the operators must correct the condition before the condition reaches its next level, a cycle alarm stop. Generally, these are raw material shortages that need an operator's intervention to correct or if left alone to long will cause a cycle alarm stop condition.

8.5.3.1 Operator Alert Warnings List

Note: the following list is not complete; however, these shall give the Supplier a general idea of the types of alerts the user is expecting from the automation solution. Generally, raw material pending shortages cause these types of alerts. It is the Supplier's responsibility to program this class of alert warning such that the faculty and students can diagnose and recover with an appropriate decision tree approach.

Operator Alert Warnings	
Trigger	
Operator initiated a system reset, system start is pending	
Shortages of Vials is pending at Vial Loading	
Shortage of raw material is pending at Vial Identification/Order Labeling	
Shortage of raw material is pending at all Vial Filling Stations	
Shortage of raw material is pending at Vial Stoppering	
Low air pressure	

Operator Alert Warnings

Trigger

Low water pressure

8.6 Data & Security

The VFC intention is to provide the Operational Technology (OT) data source for a comprehensive Connected Physical System (CPS). As such, the data produced by the operation and individual asset's performance will be available for analyses and research. Rockwell Automation will provide the needed computing modules, chassis mounted, controller integrated, and self-contained industrial computers, to provide the platform for data collection and transfer to the MS Azure environments.

8.7 Interfaces

The VFC has a countless number of interface possibilities. The reason for creating this laboratory for faculty and students is to perform studies and research into the countless and unimaginable areas and fields made possible for a truly connected world on Ethernet. Thus, Ethernet will be our primary communication interface medium using both physical and wireless technologies. The user's preference is to use wireless technologies as much as possible. The VFC communication link to the OT level will be wireless 5G.

8.7.1 Interface with Operators

To enable the faculty and students into the IT/OT and application space the VFC, ThinManager is our primary medium. This will provide or allow both the faculty and students to choose how they wish to interface with the VFC, the data center, PAC, and HMI applications within this laboratory setting. This will make the interface agnostic to the operating platforms of the tablets, laptops, and desktop personal computers the university's faculty and staff wish to use.

8.7.2 Supervisory Interface

The VFC will be an elemental part of a complete, enterprise connected physical system. As such demand for production will be driven to the VFC via the Rockwell Automation FactoryTalk Production Center and Pharma Suite applications. In manual mode the recipe, lot size, lot number and serial number range will be manually inputted into the machine mounted user interface. A Rockwell Automation Industrial Data Center (IDC) will be the platform on which the FactoryTalk suite, Visualization and other MES/MOM applications will reside. The IDC will also be the platform on which ThinManager visualization and supervisory system will reside as well as the firewall to facilitate the IT/OT convergence. The test bed supplier will be required to create the system supervisory / operating interfaces to effectively operate the VFC. FactoryTalk MES/MOM applications will be developed by Rockwell Automation or others. The test bed supplier will be required to make the necessary data available within their programming and design methods.

8.7.3 Data Collection

The VFC will utilize a redundant means to capture data by using both local to the PAC via FactoryTalk Historian ME and on the IDC using FactoryTalk Historian SE. By virtue of the storing and forwarding capabilities of Historian ME, the solution will significantly reduce the risk of losing data due to network

or other system interruptions. FactoryTalk Transaction Manager will also be utilized to disseminate data to multiple clients. Data collection is to be developed and implemented by others.

9 Environment

9.1 Layout

9.1.1 Floor Space

Please note: these are approximated measurements.

Length: 26 feet

Width: 16 feet

Ceiling Height: 11 feet to Suspended Ceiling

9.1.2 Floor Loading/Anchoring

The VFC shall in no way violate the maximum floor load rating of the UWM library in that area. UWM shall verify floor rating. In the event the VFC cannot be designed within this constraint, a steel platform may be built to accommodate the VFC.

It is the preference that the VFC be anchored directly to the concrete floor. In the event this is impossible, a steel structure on which the VFC shall be mounted must be built.

9.1.3 Installation Obstacles

It is highly recommended that the supplier, rigger, user, and the university review all means of entrance and egress into the laboratory area for the VFC.

Comment: the VFC shall have no piece larger than would fit through a nominal 6 feet wide by 7 feet high doorway.

9.2 Physical Conditions

9.2.1 Location

University of Wisconsin – Milwaukee Connected System Institute
Golda Meir Library – 1st Level, East Wing
2311 East Hartford Avenue
Milwaukee, WI 53211

9.2.2 Vial Filling Room Classification

Laboratory - Wet

9.2.3 Ambient Conditions

9.2.3.1 Temperature Ranges

Minimum: 20° C / 68° F

Maximum: 26° C / 79° F

Control Point: 23° C / 73° F

9.2.3.2 Relative Humidity Ranges

Minimum: 30%

Maximum: 60%

Ideal Control Point: 45%

9.2.3.3 Vibration and Shock

Vibration: < 2 g @ 10---500 Hz

Shock: < 30 g

9.2.4 Noise

< 80 dB (Conversational Speech Level)

9.2.5 Emissions

Emissions may be verified by a 3rd party if required.

1. Electrostatic Discharge (ESD) Immunity
 - a. Contacted Discharge: < 6 kV
 - b. Air Discharge: < 8 kV
2. Radiated Electromagnet Field Immunity
 - a. < 10 V/m with 1 kHz sine-wave 80% AM from 80---2000 MHz
 - b. < 10 V/m with 200 Hz 50% Pulse 100% AM @ 900 MHz
 - c. < 10 V/m with 200 Hz 50% Pulse 100% AM @ 1890 MHz
 - d. < 3 V/m with 1 kHz sine-wave 80% AM from 2000---2700 MHz
3. Electrical Fast Transient Immunity
 - a. No more than ± 2 kV at 5 kHz on Ethernet ports
4. Surge Transient Immunity
 - a. No more than ± 2 kV line-earth (CM) on Ethernet ports
5. Conducted Radiated Electromagnet Field Immunity
 - a. < 10 V rms with 1 kHz sine-wave 80% AM from 150 kHz --- 80 MHz

10 Assumptions

1. The requirements within this document are not complete; collaboration between the user and Suppliers is required prior to quoting this solution and coming to a final agreement.
2. There are likely numerous unknown and unconsidered factors associated with this project; collaboration between the user and supplier is required prior to quoting this solution as the supplier has more experience supplying equipment than us.
3. Required regulatory and standards are not complete; collaboration between the user and supplier is required prior to quoting this solution as the supplier has more experience supplying equipment than us.

11 Constraints

11.1 Milestones and Timelines

Spring 2019 - Core campus facility opens in the east wing of UWM Library. Delivery of the system is to occur at this time. Start-up/commissioning shall occur with intent to have the system operation for Fall 2019.

11.2 Technical Standards

The following is by no mean inclusive of all the technical standards required for the VFC; the supplier experience is required. See the [Reference Document Table](#) provided herein for a means to access the documents listed below.

1. OSHA 29 CFR 1910.212 – General Requirements for all machines
2. NFPA 79 - The Electrical Standard for Industrial Machinery
3. ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard
4. PackML Unit/Machine Implementation Guide

12 Compatibility

12.1 Controls

To automate and control the VFC, use only Rockwell Automation Encompass Partners, Rockwell Automation, and Rockwell Software products, with no exceptions.

12.1.1 Enclosures

Enclosures utilized throughout the entire vial-filling cell shall include windows without affecting the enclosures NEMA or IP ratings.

Rating: NEMA 4 or IP 66

12.2 Product Contact Parts

No special requirements are required. Nonetheless, good engineering practices are required, as the VFC will be within a university setting for both research and studies by faculty and students.

All system equipment may be cleaned/wiped down with rags and alcohol. Please specify any concerns w/ this process.

12.3 Utilities

12.3.1 Voltage

12.3.1.1 Branch Feeder

It is the user's goal to source the VFC with a nominal 480VAC 60 Hz 30A circuit through a single, local disconnect.

Connector drops, circuit capacity, and location shall be discussed with the user x weeks prior to the installation within the university's laboratory.

12.3.1.2 Secondary Service

Critical to the VFC is that no transactional or positional data is lost. If uninterruptable power supplies are required please identify this within your proposal along with why you feel they are required.

12.3.2 Water, Waste Water

12.3.2.1 Main Water Supply

A nominal source of potable water at a nominal pressure will be available within the universities laboratory at one or more locations.

12.3.2.2 Waste Water Drains

The university will have typical floor drains within the general area to allow hosing down concentrated RYB food coloring spills or mishaps in and around the filling stations and process area in one or more locations.

12.3.3 Compressed Air Supply

12.3.3.1 Main Air Supply

The VFC shall provide its own on-board, ultra-quiet, oil-less, air compressor with the following nominal requirements:

Capacity: 4 Gallons

Maximum Pressure: 125 psi

Flow Rate: 3 CFM @ 90 psi

12.3.4 Vacuum Supply

The VFC shall provide its own on-board, ultra-quiet, vacuum pump that meets your requirements for the intended purpose and intention. Please provide those details within your proposal.

13 Procedural Constraints

13.1 Regulatory Compliance

The supplier shall follow local, city, county, state, and government regulations, no exceptions.

The following is by no means inclusive of all the regulatory or standards required for the VFC; the supplier experience is required. See the [Reference Document Table](#) provided herein for a means to access the documents listed below.

13.1.1 Industrial Regulatory and Standards Requirements

1. OSHA 29 CFR 1910.212 – General Requirements for all machines
2. ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard
3. PackML Unit/Machine Implementation Guide

13.1.2 Automation Regulatory and Standards Requirements

1. ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard
2. ANSI/ISA-18.2-2016 – Management of Alarm Systems for the Process Industries
3. ISA-TR18.2.6-2012 – Alarm Systems for Batch and Discrete Processes
4. ANSI/ISA-101.01-2015 – Human Machine Interfaces for Process Automation Systems
5. PackML Unit/Machine Implementation Guide

13.1.3 Control Regulatory and Standard Requirements

1. OSHA 29 CFR 1910.212 – General Requirements for all machines
2. ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard
3. ANSI/ISA-101.01-2015 – Human Machine Interfaces for Process Automation Systems
4. PackML Unit/Machine Implementation Guide

13.1.4 Electrical Regulatory and Standards Requirements

1. OSHA 29 CFR 1910.212 – General Requirements for all machines
2. NFPA 70 – National Electrical Code
3. NFPA 79 - The Electrical Standard for Industrial Machinery

13.1.5 Safety Regulatory and Standards Requirements

1. OSHA 29 CFR 1910.212 – General Requirements for all machines

2. ISO 12100:2010 Standard Safety of machinery - General principles for design - Risk assessment and risk reduction.
3. ANSI/RIA R15.06-2012 – Industrial Robot Safety Standard

13.1.6 Product Contact Regulatory and Standards Requirements

None required, nonetheless, the User is expecting the supplier to use good engineering and design practices, as the VFC will be within a university setting.

13.1.7 Change Parts

Document all changeable or commodity parts with:

1. Manufacture
2. Manufacture's part number
3. Size
4. Description

14 Maintenance

The system shall run production for 5 years before significant maintenance is expected. The user requires an exception list that includes identified spare/wear components. See spare parts below.

14.1 Instructions

1. A schedule will be provided that identifies maintenance items and their duration intervals
2. Adjustment points shall be identified, and instructions provided on best practices on making those adjustments
3. Lubrication points shall be identified, and instructions provided on type and quantity of lubricant required.

14.2 Tools

1. All equipment shall use standard and readily available tools for maintenance and repairs.
2. Identify all special tools required for equipment maintenance, with both a part number and source for the tool.

14.3 Spare Parts

A suggested spare parts listing of the following items below, plus shall include the manufacture, make, model, catalog number, and description such that these items can be purchased from a commodity vendor.

1. Normal wear parts
2. Parts that easily break
3. Parts that wear out
4. Long lead time parts, i.e. greater than 2 days
5. Electronic components that are not readily available, i.e. greater than 2 days

Please review the Lifecycle section below to provide this within the correct format. Ideally, this document should include the following columns:

1. Supplier's Item Number
2. Manufacture
3. Make
4. Model
5. Catalog No.

6. Lead Time (days)
7. Wearable Part (Y/N)
8. Key Spare Part (Y/N)
9. Quantity
10. Part Description

15 Lifecycle

15.1 Development

1. The Supplier shall provide a Quality and Project Plan as part of the proposal.
2. The Supplier shall have a Quality system in place.
3. Internal quality procedures shall be available for the User's review.
4. The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
5. The project shall utilize GAMP methodologies when developing the system and documentation.

15.2 Testing

1. In order to verify machine performance, the Supplier shall provide an approved Factory Acceptance Test (FAT) protocol to the User for review and approval 8 weeks prior to FAT.
2. The Supplier shall notify the User 4 weeks in advance of the start of the FAT

15.3 Delivery

The supplier shall deliver the VFC, with all options, equipment, and documentation and one Bill of Landing (BOL) via Free on Board (FOB) shipping. After accounting for all the items in the BOL, the User will acknowledge the shipment complete.

15.4 Documentation

1. The Supplier shall use the formats described in the current version of the GAMP Supplier Guide to produce the documentation.
2. The Supplier shall provide the documentation for preliminary review upon request from the User.
3. The Supplier shall provide documentation reflecting "as-built" condition with the final delivery. We will not accept marked up documents.
4. Documents supplied electronically via email or cloud based sites for download must be identify them as contractually required documents.
5. The Supplier shall provide documentation in the language of the destination country.
6. All documents shall be unlocked and editable.

15.5 Support and Training

15.5.1 Support

15.5.1.1 Installation Support

The supplier is fully responsible to rig, erect, level, and assembles their contractual scope of supply

15.5.1.2 Start-up and Commissioning Support

The supplier is fully responsible to start-up and commissions their contractual scope of supply.

15.5.1.3 Product Qualification Support

The supplier shall support the User's Product Qualification runs for **x** weeks of full time assistance.





15.5.1.4 *Post Product Qualification Support*

The supplier shall support post product qualification support via remote phone, email, text, or instant messaging support request question and answers for a period of **x** years.

15.5.2 *Training*

1. The training instructors must be certified instructors or highly proficient technicians that are completely familiar with all aspects of operating the machine.
2. Operator, Supervisory, and Maintenance levels of specific user training are required.
3. Each user's training shall consist of 8 hour of classroom training and 16 hours of equipment training.
4. Testing of each trainee is required to assess their suitability to perform their role. The training instructor may determine how to assess the trainees' suitability; however, the results of user's test go directly to the Human Resources Department. The trainer shall not discuss the results with any personnel.
5. Each user completing a training program will receive a certificate of training, no matter their training evaluation score.
6. Provide electronic forms of the formal training materials, as detailed within the document table above.

Appendix A
Use Case Table

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CSI - USE CASES						
Item	Use Case Name	General Description	Methodology	Detailed Description	Communication Pathways	Resources
0	Line Control Variables	The line control variables define the general functionality of the test bed. Examples of line control variables are line speed, fill rate, dwell times, puck accel/decel, etc.	Line Control PLC Program	The line control variables are to be manageable via the HMI. The variables are to be locked behind a login screen to prevent unauthorized access. Users may make changes to the overall behavior of the line using the line control variables. Any changes that are made will be effective upon entry.	Bidirectional via HMI - PLC	Haskell
1	Recipe Parameters	Each vial processed by the test bed will be defined by a specific set of recipe values. The recipe values are received by the PLC from SAP. Recipe defines vial fill level, color of fill, and filling station to perform the filling operation.	Line Control PLC Program	Recipe parameters are received from SAP. These recipe parameters fully define a specific completed vial. Recipe parameters are to be used for only one vial at a time. Batch production of vials will require repetition of a specific recipe and must come from SAP. Upon receiving and validating a recipe, a vial is loaded onto the test bed and tracked by the PLC throughout the process.	Unidirectional SAP - PLC	Haskell
2	ODOS – Unified 3D Time of Flight Application	ODOS imagers will be used to identify vial presence, location, and orientation on both the incoming and outgoing trays.	ODOS Imager	ODOS imagers mounted on/near the loading/unloading stations are to be utilized to define specific pick-and-place instructions for a particular robot. For loading, upon instruction to load a vial, the ODOS imager will identify vial locations in a tray for the robot to pick. For unloading, upon instruction to unload a vial, the ODOS imager will identify empty slots within a tray for the robot to place.	Bidirectional via ODOS - PLC	ODOS Application Engineer/Haskell
3	Barcode/QR-Code Scanning	Vials will be labeled with QR codes as part of the track and trace functionality of the line. QR codes will be printed and applied manually.	Dataman 262	Vials will be labeled with unique QR codes that are printed in the lab and applied manually. These codes will be scanned as vials are loaded into the system by the loading robot. To properly scan codes, the robot will be required to manipulate the vial in the presence of the scanner. Robotic manipulation will compensate for varying code location and initial vial orientation. Once a code is scanned, the vial code will be loaded into the tracking array for that vial and the robot cleared to load the vial onto the next available puck.	Bidirectional PLC - Scanner	ACS/Haskell
4	Track and Trace - Advanced	Full system traceability is required. Vial processing points are to be fully traceable before, during, and after processing.	Line Control PLC Program	Trays will be labeled with a unique numeric value that must be input into the HMI by the operator upon loading a tray into a tray docking station. Vials from a loaded tray will not be allowed into the system until the tray number has been input into the HMI. Vials will be labeled with unique barcodes that are to be scanned as they are loaded into the system robotically. Each conveyance puck is constantly tracked by the conveyance system. The puck on which a particular vial is loaded will be tracked. When a vial is fully processed and unloaded from the system, the tracking data will be transmitted to the historian software.	Unidirectional PLC - Historian	Haskell
5	Incoming Vial Scans	Incoming vials will be fully inspected for proper usability within the system. Failing the incoming inspection will result in the vial bypassing all stations and being removed from the line.	Cognex vision	After empty vials are loaded onto the conveyance system by the loading robot, pucks will advance the vials into the incoming vial inspection station. A vision system at this area will inspect the vials for large physical defects (cracks, dents, etc.), and verify the vial is of the correct type/size. Vials that fail inspection will bypass all stations and proceed directly to the unloading area. Vials that pass will be processed normally. The recipe associated with failed vials will be run on the next vial loaded into the system.	Bidirectional Cognex - PLC	ACS/Haskell
6	Scrap Rate Limits	Scrap rate limits define the window of product efficiency within which the line should consistently be producing. Specific line control variables will be modifiable to adjust the running scrap rate.	Line Control PLC Program	The current acceptable scrap rate will be a configurable value on the HMI. This scrap rate (a certain percentage of vials within a time period), will determine the acceptable quality defects produced by the line. There will be two modes associated with line behavior in reference to the scrap rate, manual and automatic. In manual mode, the line will run at the set line control variables and alarm if the scrap rate limit is exceeded. In automatic mode, the line will attempt to optimize the line control variables to run at the fastest rate possible within the defined scrap rate limits.	Bidirectional HMI - PLC	Haskell

7	Rework Station / Product Rework	Ability to rework vials (without discarding product) based on vision referenced quality measurement. Vials that are found out of spec could recycle through the system in an effort to correct fill/color issues.	Cognex vision/Line Control PLC Program	On the HMI, users may select if the line will attempt to rework faulty product. If enabled, the system will determine if product may be salvageable based on feedback from the quality inspection station. Rework may include correcting fill level (only low level can be corrected) or color (only absence of color can be corrected). Following a rework attempt, the reworked product will be fully inspected and either unloaded into the good or bad/unsalvageable product trays. Any failures will result in that recipe being rerun on the next available vial. If a product is reworked, the information passed to SAP will include a rework flag.	Bidirectional Cognex - PLC	ACS/Haskell
8	Change Over Optimization	Change overs from one order/recipe to the next will be fully automatic. Transition to a new order should appear seamless.	Line Control PLC Program	As a new order (batch of recipes) is passed to the PLC from SAP, that new order will automatically begin production. There will be little to no gapping between orders as separate orders could reside on adjacent pucks on the conveyance system. This feature is inherent in the line programming.	Unidirectional SAP - PLC	Haskell
9	Independent Cart Traffic Optimization	Ability to set up congestion and traffic conflicts for students to resolve. Cart traffic may also be optimized based on value/margin from SAP.	Line Control PLC Program	On the HMI, users may enable/disable automatic traffic optimization. As part of SAP, each puck will have a profit margin associated with the recipe it is currently running. If enabled, the system will optimize cart traffic such that the higher margin items are prioritized over the lower margin items. This could be done by moving low priority carts to the slower filling stations, moving them to side paths to allow higher margins to pass, etc. In addition, congestion must be programmable into the system as a troubleshooting exercise for students. As an example, setting some fill stations to run slower than others would be good practice for students to optimize the line under those constraints.	Unidirectional SAP - PLC	Haskell Note: Rockwell resource required for training.
10	Tak Time Optimization	Allows users to optimize the line around definable constraints. Tak Time Optimization reduces the WIP time of each product.	Line Control PLC Program	Based on the line control variables, certain production constraints will be present on the line. Tak Time Optimization allows the user to define line behavior around those constraints to minimize WIP and maximize production. For instance, the dwell time at two of the filling stations could be significantly longer than the other two. The user could tell the system to queue a set number of pucks at that station and run the rest through a faster station. Requires the line to have a manual and automatic mode for its own internal optimizations. Production control will have two modes: dedicated station as defined by the recipe and first-available mode.	Internal - PLC	Haskell
11	Vibration Monitoring	Vibration of critical system components will be monitored through strategically located sensors for predictive maintenance purposes.	Dynamix 1443 Series, ANSYS	Sensors will be mounted at specific points on the test bed to monitor vibration as a means of predictive maintenance. Areas that may be monitored are the robotic gantry, robotic mounts, pumps, and conveyor supports. Within the PLC, the system will present a warning if vibration exceeds a certain threshold that will be determined during initial testing. The vibration information will be passed to the ANSYS model for simulations.	Unidirectional PLC - ANSYS	ANSYS/Haskell
12	Acoustic Monitoring	The ultrasonic frequencies of the test bed will be monitored through strategically located sensors for predictive maintenance purposes.	ANSYS	Ultrasonic sensors will be mounted at specific points around the test bed to monitor ultrasonic frequencies produced by the system's components. Within the PLC, the system will present a warning if frequency or amplitude exceeds thresholds determined during initial testing. The acoustic information will be passed to the ANSYS model for simulations.	Unidirectional PLC - ANSYS	ANSYS/Haskell
13	Thermal Monitoring	Thermal sensors mounted at specific areas on the test bed will be used as a form of predictive maintenance.	873T Series Sensors, ANSYS	Thermal sensors mounted on the conveyance system, control panels, and robotic applications will be used to monitor the thermal state of the test bed. Any deviations from the baseline determined during testing would result in a warning presenting on the HMI to alert maintenance of a behavior change. The thermal data will be passed to ANSYS for simulation.	Unidirectional PLC - ANSYS	ANSYS/Haskell Note: Rockwell resource required for training.
14	LITE Operating / Programming Mode	Areas of the programming or modes of operation will be implemented to allow students to program/operate specific areas of the test bed without risk of damage/permanently altering the test bed.	Line Control PLC Program	The PLC will be programmed as modular as possible to allow for safe silos where students may alter and test program changes. These silos will only affect a predefined area of the line and will be fully restorable from AssetCentre.	Unidirectional AssetCentre - PLC	Haskell
15	Diagnostic / Maintenance Mode	The system will allow users to diagnose issues through manual operations from the HMI and feature ease of access maintenance modes.	Line Control PLC Program	From the HMI, a user with specific permissions will be able to operate the test bed in a manual mode to diagnose any failures. In addition, any recurring maintenance tasks that require the system to be in a certain configuration will be directly accessible from buttons on the HMI. Pressing a maintenance button on the HMI will send the system directly to the correct state for ease of access.	Bidirectional HMI - PLC	Haskell

16	Process FMEA	Users will be able to force process failures to allow students to visualize the effects of certain failures on downstream processes.	Line Control PLC Program	From the HMI, a user with specific permissions will be able to force process failures such as track and trace failure, fill failure, color dosing failure, pick-and-place failure, and simulate equipment malfunctions to allow students to see process failure modes and their effects on the test bed process. Any induced failures will only occur once before normal operation resumes.	Bidirectional HMI - PLC	Haskell
17	Force Product Failure	The system will have the ability to force a particular product failure for learning purposes.	Line Control PLC Program	From the HMI, a user with specific permissions will be able to force product failures such as a puck/vial mismatch or simulate a sensor failure to allow students to visualize and debug those failures. These failures will be recurring to provide students time to debug the problem.	Bidirectional HMI - PLC	Haskell
18	Energy Monitoring	The energy consumption of the test bed will be monitored to create a per unit cost basis. Power monitoring will be as granular as possible.	Power Monitor Series	Energy consumption of the test bed will be monitored at key locations to allow test bed users to monitor how changes to the process may affect the cost of producing a unit. Energy consumption at specific points will need to be individually monitored to provide helpful data. The overall energy, individual station consumption, electrical hardware, and individual robotic consumption will be monitored.	Internal - PLC	Haskell
19	Transport system power signature	Electrical current of all motors will be monitored as part of the per unit energy cost.	Line Control PLC Program	The PLC will receive live motor current feedback from each component on the test bed. The power signatures from the equipment will be used to calculate the live per unit cost basis while the test bed it running. This data will be passed to the cloud for data computation.	Unidirectional PLC - SAP	Haskell
20	Safety / Safe Operation	The test bed will utilize a redundant supervisory safety system that is inaccessible to students and unauthorized users. This system will ensure safe operation and comply with all safety regulations.	Safety Series PLC	A safety PLC will work in tandem with the line control PLC to ensure safe operation of the test bed. It is critical that no physical barriers be necessary on the test bed. Laser scanners will be heavily utilized to detect presence of foreign objects that will limit any moving components to a safe-operation speed or cycle stop equipment as necessary. Once the foreign object leaves the safety restricted area, normal operation will resume. Estops will also be mounted along the line in case of emergency.	Internal - PLC	APT/Haskell
21	Safety Modes	There will be two safety reactions on the test bed, collaborate/interact mode, and safe zone mode. These modes are toggable from the HMI.	Safety Series PLC	From the HMI, a user with specific permissions may set the safety mode of the test bed while it is running. The two safety modes, collaborate and safe zone, define the behavior of the test bed. Collaborate mode puts the entire test bed into a permanent safe mode where users may closely interact with all areas of the system. Safety zone mode automatically switches isolated areas of the test bed into collaborate mode when someone enters that zones safety area as identified by laser scanners/light curtains.	Unidirectional HMI - PLC	APT/Haskell
22	Weigh Station	A checkweighing station will be included next to the quality inspection station. Checkweighing requires assitant from the gantry robot. Checkweighing will check proper full weight of a vial against a known good window.	Hardy Solution Hardware	The checkweighing station will receive vials transported from the conveyance system to the checkweigher by the overhead robot. The tare weight of each tested vial will be known from the information received from the tray docking stations as vials and stoppers are removed. The full weight of the vial will be tested against a known good value window. If the vial is underweight, it may be reworked. If the vial is overweight, it will be removed from the system by the gantry robot and placed in the unsalvageable tray. Historical data will be passed to the historian.	Bidirectional Checkweigh - PLC Unidirectional PLC - Historian	Haskell
23	Digital Twin – Maintenance and Ops (Emulate 3D)	The Digital Twin will allow maintenance and operations personnel to debug system issues and alter equipment states.	Demo 3D		N/A	Haskell - Sheldon Smith
24	Augmented / Cognitive	An augmented reality system will be implemented with Vuforia to allow users to visualize line performance in AR. Thingworx will be implemented to display line performance data in a web browser.	Thingworx/Vuforia	AR markers will be placed at key areas on the line that will be set up in Vuforia with a specific augmented reality object. Vuforia may also be used to display sequence steps for maintenance or troubleshooting on the line. AR objects may present line data, area specific warnings, explanations, etc. Thingworx will be used to display station/robot specific line performance data in a web browser or mobile platform.	Unidirectional PLC - MES	Haskell/Rockwell/PTC Note: PTC resources will be required for design, training, and implementation.
25	Product Realization	The capability for students/businesses to create/devise real-world style products and test those on the system.	Inherent	The test bed will be designed for spare/isolated IO points to allow students and businesses to easily integrate newly designed products into the test bed for testing. The spare IO will exist in an isolated control panel, and the code for that IO modular, to ease integration.	Internal - PLC	Haskell
26	Color Sortation	In this mode, the system will preload the line with various color-filled vials. The system will then sort these colors based upon user-input algorithms.	Line Control PLC Program	Areas of the PLC program will allow students/researchers to input sortation algorithms that they may test on the test bed against an assortment of vial colors. The test bed will fill vials with a certain color as set by an array on the HMI. The sortation algorithm will attempt to sort the vials toward a goal array also set on the HMI.	Bidirectional HMI - PLC	Haskell

Appendix B

Typical Control Panel BOM

CP101
Control Panel BOM
10/22/2018



Item	Part #	Manufacturer	Quantity	Description	
1	140G-G2C3-D10		AB	1	140G - Molded Case Circuit Breaker, G frame, 25 kA, T/M - Thermal Magnetic, Rated Current 100 A
2	140G-G-FMX04		AB	1	140G/1494V Product Handle Accessories/Operating Mechanisms, 140G Flex-Cable , Painted Metal Flange Handle , 4 ft ,
3	140G-G-TLC13		AB	1	Frame-G, Terminal Lug, Qty 3, FCCu 1x14-1/0(2.5-50)
4	1492-PD31123		AB	1	1492 Power Block, Power Distribution Block, 3-Pole, Aluminum, 1 Opening Line Side, 12 Openings Load Side, 380 Amps
5	1492-PBC3		AB	1	Power Block Cover
6	194E-A32-1753-6N		AB	1	IEC Load Switch, Open - Base / DIN Rail, OFF-ON 90°, 32A 3 Poles, Supplied with a Type N Red Yellow Actuator
7	599-GR2		AB	1	Ground Lug Kit, 200A
8	1497B-A10-M14-O-N		AB	1	Transformer, 750VA,240x480V 60HZ PRIMARY-120V/240V Secondary
10	1492-SPM2C020		AB	2	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC 2 Pole Configuration, Trip Curve C, 2A
11	1492-SPM1C020		AB	5	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 2 A
12	1492-SPM1C040		AB	2	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 4 A
13	1492-SPM1C080		AB	5	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 8A
14	1492-SPM3C050		AB	1	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 3 Pole Configuration, Trip Curve C, 5A
15	1492-SPM1C050		AB	1	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 5A
16	1492-SPM1C200		AB	2	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 20 A
17	1492-SPM1C010		AB	1	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 1 A
18	1492-SPM3C020		AB	2	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 3 Pole Configuration, Trip Curve C, 2A
19	1492-SPM1C060		AB	1	Bulletin 1492 Miniature Circuit Breaker, Standard configuration, AC, 1 Pole Configuration, Trip Curve C, 6 A
20	1756-A13/B		AB	1	ControlLogix Standard Chassis Series B, 13 slot
21	1756-PB75/B		AB	1	Power Supply (15 Amp @ 5V)
22	1756-L84ES		AB	1	Logix5500 Integrated Safety Controller With 20Mbyte Memory
23	1756-L8SP		AB	1	Logix5500 Safety Partner
24	1756-EN2T		AB	2	Ethernet 10-100M Interface Module (supports both TCP/IP connections)
25	1756-IB16		AB	3	10-31 VDC Input 16 Pts (20 Pin)
26	1756-OB16E		AB	5	10-31 VDC Electronically Fused Output 16 Pts (20 Pin)
27	1756-N2		AB	4	Slot Filler module for standard ControlLogix chassis
28	855T-B24SA1		AB	1	Control Tower Stack Light, Black Housing, 24V AC/DC Full Voltage Transducer Style Single Tone
29	855T-B24TL3		AB	1	Control Tower Stack Light, Black Housing, 24V AC/DC Full Voltage, Green Steady LED (socket mount)
30	855T-B24TL4		AB	1	Control Tower Stack Light, Black Housing, 24V AC/DC Full Voltage, Red Steady LED (socket mount)
31	855T-B24TL5		AB	1	Control Tower Stack Light, Black Housing, 24V AC/DC Full Voltage, Amber Steady LED (socket mount)
32	855T-BPM10		AB	1	Control Tower Stack Light Mounting Base, 10cm Pole Mount, Black Housing, No Cap
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34					
35	1783-BMS10CGL		AB	1	Stratix 5700 Switch, Managed, 8 Ethernet 2 Combo Ports
36	199-DR1		AB	6	DIN Rail
37	1492-J3		AB	200	Gray Terminal Block
38	1492-CJ15-10		AB	50	Center jumper - 10 pole
39	1492-EBJ16		AB	20	Partition plate for 1492-J3
40	1492-EBJ3		AB	20	1492-J3 End Barrier
41	1492-EAJ35		AB	40	End Anchor
42	1492-WFB424		AB	32	Fuse Terminal Block

43	GMC-2A	AB	32	2A Fuse	
44					
45	1492-CABLE050TBNH	AB	6	Digital I/O Module Ready Cable, 20 conductors, #18 AWG, w/1756-TBNH connector, length 5.0 meter (16.4 feet)	
46	1585J-M8UBJM-*	AB	***	Male RJ45 to Male RJ45 Patchcord, Braided and Foil Twisted Pair, Teal PUR Cable, *m (LENGTH DETERMINED BY PANEL BUILDER)	
47	1734-AENT	AB	1	Pont IO Power Supply and Ethernet Adapter	
48	1734-IB8	AB	2	Point IO Input 8 Pts	
49	1734-OB8	AB	1	Point IO Output 8 Pts	
50	1734-TOP	AB	3	Point IO Terminal Base 8 Screw Clamp Connections	
51	700S-CF620EJBC	AB	0	Safety Control Relay, 8 Pole, 3 N.O. / 1 N.C. Base, 3 N.O. / 1 N.C. Auxiliary, 24V DC (w/Elec. Coil)	
52	700-HLT1Z24	AB	8	700-HL Electromechanical Relay Output, , w/ Screw Clamp Connections 24V DC Touch-Safe Terminal Construction	
53	6200P-19WS3C1	AB	1	Industrial Computer, 18.5-inch Widescreen Display, Projected Capacitive Multi-Touch Screen, 128GB SSD, Dual Port Ethernet , Windows 10 IoT Enterprise (64-bit), Single Display Out	
54	1606-XLS480E	AB	2	1606-XLS480E: Performance Power Supply 24-48V DC, 480W, 120/240V AC / 10-300V DC Input Voltage	
58	1756-CMS1B1	AB	1	1756 Compute Module-Windows 10	
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Operator Station
BOM
10/23/2018



Item	Part #	Manufacturer	Quantity	Description
1	800TCQRBH2G	AB	1	30.5MM PB MOM. CONTACT PB-ILLUM., GREEN, 1. N.O.- 1 N.C.
2	800HC-FRXJTQH2RA5	AB	1	30.5MM, PB ILLUM. PUSH-PULL/TWIST, RED, 2 N.C.
3	800TC-XD4S	AB	1	CONTACT BLOCK, SELF MONTORING, 1 N.C.
4	800F-15YE112	AB	1	LEGEND PLATE, 60MM ROUND, EMERGENCY STOP, YELLOW
5	800HC-AR6B	AB	1	30.5MM, PB, RED, 2 N.O.- 2 N.C
6	800TCQRBH2A	AB	1	30.5MM PB MOM. CONTACT PB-ILLUM., AMBER, 2. N.O.- 2 N.C.
7	800H-W371	AB	1	LEGEND PLATE "STOP"
8	800H-W521	AB	1	LEGEND PLATE "RESET"
9	800H-4HZ4C	AB	1	800H (30.5 mm) Definite-Purpose Enclosure, 250 mm x 80 mm x 85 mm (9.84 in. x 3.15 in. x 3.35 in.) , Gray
10	800H-W510	AB	1	LEGEND PLATE "START"
11	800T-XA1	AB	1	CONTACT BLOCK, 1 N.O/ 1 N.C. FOR E-STOP PB

This is a typical Control Panel BOM. It is for discussion purposes and should not be considered complete or accurate until detailed engineering is complete.

Appendix C

Endress + Hauser Flowmeters

Misc
BOM
10/23/2018



Item	Part #	Manufacturer	Quantity	Description	
1	8A3C02-*****SAAASAA1	Endress + Hauser	(4 or 8)	Promass A (GI C) 300 Flowmeter	
2	5H3B04-*****A1P*AA1	Endress + Hauser	(4 or 8)	Promag H 300 Flowmeter	

Appendix D
Transportation Narrative

1. Document Purpose

The purpose of this document is to detail the restrictions/methodology associated with the transport and assembly of the test bed from the Haskell office located at 2800 Century Parkway NE Suite 400, Atlanta, GA 30345 to the UWM Campus Library East Wing.

2. Disassembly/Transportation

The following are load size restrictions for a single piece of the test bed as it is to be transported.

- 2.1. No single piece of the test bed may be shipped that is larger than a standard pallet.
- 2.2. All single pieces of the test bed must fit within a cube with dimensions 4' wide X 6' long X 8' tall.
- 2.3. All single pieces of the test bed must be maneuverable through a door space with dimensions 4' wide X 8' tall.

The following is a general description of the disassembly/transportation of the test bed from Haskell offices.

- 2.4. Following successful testing at Haskell offices, the test bed will be disassembled into the necessary component parts to meet the size descriptions listed above.
- 2.5. Legs and support structures will be designed in such a way that will facilitate disassembly into sections as described in 2.2.
- 2.6. Disassembly steps will be carefully noted to ease reassembly.
 - 2.6.1. Mechanical/Electrical shipping splits will be photographed and labeled.
 - 2.6.2. Mating components will be identified by stickers (A:A, 1:1, etc.)
- 2.7. Each part or set of parts will be skidded onto regular pallets or boxed as necessary for safe transportation.
- 2.8. The test bed will be shipped via dedicated truck (DT) to the UWM Campus Library East Wing.

3. Delivery/Assembly

The load size restrictions in section 2 meet or exceed the load size restrictions necessary for acceptable delivery.

The following is a general description of the delivery/assembly of the test bed at the UWM Campus Library East Wing.

- 3.1. The test bed's component parts will arrive via DT at the UWM Campus Library East Wing and APT.
- 3.2. The parts will be unloaded and stored safely within the library until Haskell personnel arrive on-site to reassemble the test bed.
- 3.3. Following the notes made during disassembly, Haskell personnel will reassemble the test bed on site.
- 3.4. Mechanical/Electrical contractor support will be required on-site to assist in the permanent installation.
- 3.5. Once assembled and connected, the test bed will be debugged and tested on-site.

Appendix E
Capital Cost Estimate

