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Robotizing the sterility testing process: scientific challenges for bringing agile robots into the laboratory

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Abstract. This article provides a detailed description of the membrane-based sterility testing process, the use case selected in the Horizon Europe project TraceBot for demonstrating the benefit of agile robotics in a laboratory setting and its interest for the pharmaceutical industry. Based on videos of human operators performing manually the sterility testing process, we detail its different steps, starting from a human perspective, with a more robotic approach in mind, and highlight the major atomic functionalities a robot should have for executing the process at hand. Together with the analysis of the process flow of actions, we also list all elements/objects involved, and analyse the technical and scientific challenges in this process and its application environment as well as in general pharmaceutical processes. Finally, with the objective to engage the community in collaborating and taking advantage of our use case study, the complete process flow description is made available on a website, together with associated data like the object's meshes and a generic robotic setting in ROS environment.

Keywords: laboratory automation, use cases, traceability, ROS

1 Introduction

Creating new medical, pharmaceutical, or healthcare products is always based on testing a huge number of samples. The need for microbial safety is inherent to life science suppliers (raw materials, consumables, media) and every pharmaceutical manufacturing process. It is of critical concern to the biopharmaceutical

industry, where a contamination event can arise from a contaminated cell line, raw materials, cell substrates, equipment, facilities or operators. Based on the estimated selling price and the market size [1] we can estimate the overall market in number of traditional sterility tests in the range of 18-29 million tests / year. Another way to make an estimation is via the number of facilities. Different market reports estimate the number of pharmaceutical facilities to be around 5,000-6,000 (> 25 employees) worldwide. Large pharmaceutical companies have multiple production lines, and there is a separate production unit for each production line. Based on known examples and using the assumption that each site is running between 2,000 and 5,000 sterility tests / year, we can estimate the overall market in number of traditional sterility tests in the range of 10-30 million / year. And with the increasing number of complex large molecule drugs, the need to perform sterility testing will continue to grow.

Today manual procedures dominate, since regulations require checking each step in the process and tick off an audit trail. Compared to the automotive or semi-conductor industry, drug manufacturing appears quite expensive, inefficient (40-50% labor cost is typical in biopharma facilities vs. 10-15% for other industries) and also non-innovative (M&M chocolate candies are made for example with a precision far beyond the capabilities of many drug manufacturers [6]).

Developing a technology able to change this status and that can apply to general laboratory applications, covering both the medical and pharma industries, is particularly relevant due to the following challenging constraints:

- the sterility of a medical product is critical to workers and to the supplier,
- testing needs to follow elaborated regulations,
- normally processes are still conducted by the human and there is little automation so far, and
- the contamination risk for the operators always exists and should be reduced.

Therefore, automation is highly desired to reduce cost and to improve the quality of production as well as working conditions in times when it is getting more difficult to recruit and retain staff.

Automation and robotization is already taking place in pharmaceutical processes, and several researches have been conducted since the pioneering work of Masahide Sasaki in the 90s, who proposed a highly specialized robot-centred laboratory [7]. A relevant overview of recent research and industrial developments can be found in [8]. Several companies are already proposing systems for the specific pipetting process. Examples of such liquid handlers are the BioSero platform⁸ or the Automata products⁹. Although these systems are well designed for this specific process, with specific grippers for handling microplates, they are not yet able to manipulate other types of objects, and cannot be therefore used for other types of laboratory processes. Recently, and probably boosted by the COVID-19 pandemia, the concept of Biofoundries appeared [5], as an attempt to augment testing sales thanks to automation and specific analytics

⁸ <https://biosero.com/>

⁹ <https://automata.tech/>

infrastructure. The association of a robotic manipulator with a mobile platform enables to extend the area controlled by the robotic system, and permits a more integral process automation. Recently, the University of Liverpool described an impressive experiment conducted with a KUKA mobile platform that operated autonomously during 8 days, and performed almost 700 different experiments in its laboratory environment [2]. The dedicated gripper was able to handle different laboratory items, but it remains specialized for the pre-selected objects. Also the traceability of the robotic operations is not detailed in the study. More generally, the robotic systems usually involved are very specific to their tasks, and cannot therefore adapt to processes too different. Also the traceability and verification of the robot actions are not sufficiently studied to enable the inclusion of such platform with other regulated processes.

The European project TraceBot¹⁰ investigates the (robotic) automation of the sterility testing process. This decision is driven by several factors. First, on a practical point of view, the focus on the sterility testing provides a bounded framework, with a semi-controlled environment. Indeed the process is usually handled within an isolator, in which only the needed material is present. Also the use of the pumping machine as illustrated later on, provides a central element around which all the operations are taking place. Still, the process is sufficiently generic that the developed techniques/skills could be expanded to a wide range of mission-critical regulated tasks. On an economical aspect, the automation of such manual process extensively used would contribute to the digitalization of the pharmaceutical industries, increase their competitiveness, while improving the human labour conditions (reduced contamination risk, less involvement in long operating cycles 24/7). Finally, from a scientific perspective, recent progress in AI and cognitive methods allow for breakthroughs in component technologies for robot manipulators operating in laboratory environment.

The purpose of this paper is to present the key robot capabilities required for laboratory automation. Furthermore, we highlight the major atomic functionalities a robot should have for executing the process at hand. Together with the analysis of the process flow of actions, we also list all elements/objects involved in the process, and analyse the technical and scientific challenges in this process and its application environment as well as in general pharmaceutical processes. Finally, we make the complete process flow description available on a website together with associated data like the objects meshes and a generic robotic setting in ROS environment.

2 Sterility use case

Overview The sterility testing procedure starts by setting up of materials, a central pump, and a sterility kit (as well known as the transfer kit) inside an isolator. Afterwards the sample is pumped from the sample containment (either directly, e.g., in a vial, or after its transfer to another bottle using the transfer kit

¹⁰ www.tracebot.eu

before the filtration begins) through a membrane (where the filtering takes place) into a canister. For the complete test, first a washing medium and afterwards the samples to be tested are pumped through the membranes on the bottom of two canisters and each canister is then closed and filled by one of two grow media. Afterwards, the canisters are visually inspected, and a cloudy appearance indicates contaminant growth (whereas the main goal is to check that there is no contamination). This finishes the process within the isolator and the canisters are transferred into incubators outside the isolator.

In the following of this section, we first describe the environment in terms of objects/items that are manipulated, then we focus on the workflow, defining the main process steps.

Elements of the environment Based on the video description we identified 16 main objects that are manipulated in this process which we clustered into the following categories (see Figure 1).






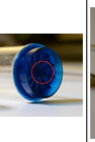


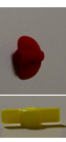










Sterility testing kit items								
								
Sterility kit	Sterility kit package	Tube	Canister	Canister air vent	Canister outlet port	Needle	Clamps	Plugs
Pump related items (Merck Millipore Sigma, 2021)								
								
Pump machine	Pump head	Bottle holder	Drain tray	Pump buttons	Pump screen			
Additional items								
								
Big bottle	Small green / red bottles	Septum	Petri dish	Vials				

Fig. 1. Illustration of the main items involved in the sterility testing process.

The *Pumping system* is the central element around which all operations take place. It is equipped with a *drain tray* where the *canisters* are placed for enabling the liquid transfer in and out. The head of the machine (*pump head*) is the mechanism enabling the liquid transfer in between the different containers. This linear hole is designed to host the tube connected to the liquid container. By a

pressure mechanism, it provokes a sucking mechanism which creates the liquid transfer from one container to the other. On the left side of the pump, the *bottle holder* is where *bottles* (containing liquids to be transferred to the canisters) are placed, once the transfer tube is placed in it. The pump is also equipped with a screen displaying information for the human operator (like for monitoring the pump pressure). It also provides a set of buttons used to activate/ deactivate the pumping mechanism and change pump parameters (time, speed, pressure).

The *sterility testing kit* (also named "steri test kit") is another key component of the process. It contains all non-liquid consumables, provided in a sterilized package (the "steri package") which is covered with a foil. The two canisters are themselves connected to a tube from their upper part. On the tube four clamps are placed - two clamps per tube (one red and one white). One end of the tube is connected to the canister. The other end goes to the *needle* used to pierce the *septum* of the different *media containers*. The clamps are open or closed to control the liquid transfer into the containers; each container flow can be stopped/intermitted independently. Another set of small plugs (red and yellow) is used at the end of the process to close the containers on top and bottom.

Additional items are finally required. First, the *bottle* (with a Volume of 300 ml and a mass of 561 g in our use case) that is afterwards placed in the bottle holder. This bottle is equipped with a septum which must be penetrated by the aforementioned needle. As an additional verification measure, a *petri dish* is placed in the isolator when starting the process and analyzed after completion of the process to see if any contamination spread inside the chamber. Finally, the sample container can vary: it can be provided within bottles, or *vials* that need to be transferred into a bottle prior to their use in the pump system.

Use case description The sterility testing can be described as a flow chart, as illustrated in figure 2. Segmented videos of each of the steps are available at the project showcase website¹¹. The main steps are the following ones:

1. Manual Preparation: The control petri dish is labelled and placed in the workbench.
2. Kit unpacking: The sterility kit is opened and unpacked.
3. Kit mounting: The canisters are placed into the canister tray, the tube is inserted into the pump, which is closed and set up.
4. Needle preparation: The needle cap is removed and inserted into the bottle through the membrane.
5. Wetting: The filter gets prepared for the sample filtering by running the pump with the needle attached to a new upside-down washing bottle, filling the canisters with washing medium. The bottle is brought back down and the red plugs get attached to the canister. The pump runs (creating overpressure in the canisters) until there is no washing medium left in the canisters.
6. Sample transferring: The sample is transferred from multiple vials into both canisters, one after the other.

¹¹ https://tracebot.gitlab.io/tracebot_showcase/

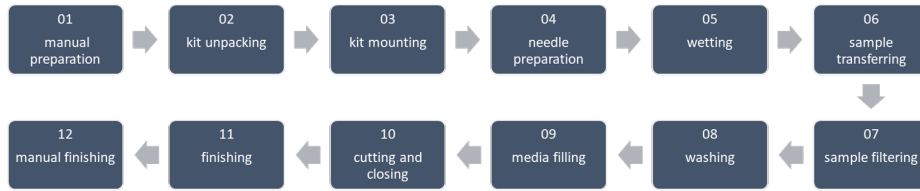


Fig. 2. Sterility process: main steps performed by the human operator.

7. Sample filtering: Samples are filtered (overpressure in the canisters pushes the sample through the membrane to the outlet port of the canisters and thus into the drain) and the canisters are labelled.
8. Washing: Put wash solution into holder and start pump, leaving the drain of the canisters open.
9. Media filling: The media (red and green small bottles) is pumped and fills the two canisters, each canister with only one media.
10. Cutting and closing: Close both clamps and cut the tubes.
11. Finishing: Unmount everything, tidy up, moving apart consumables.
12. Manual finishing: Clean up and move out Petri dish.

All these steps are related to high-level manipulations that a human operator could use to describe the successive operations of the process. The underlying perception operations, or object affordances are not present. We introduced on the website previously mentioned a finer analysis of the process, to get an exhaustive listing of the operations the robot should perform (the atomic process steps). Right now a 2 level depth was enough to reach atomic operations which can be related to concrete robotic operations.

Operation categorization So far, we identified 8 categories of operations that can be found in more than one of the process's sub-steps.

1. Labelling: Labelling consists in writing with a pen an identifier on an object.
2. Pick and Place: Several objects must be moved from one place to another in the environment. The initial picking requires first (visually) locating the object, and the final placing is either connected to a specific site onto the pump, or basically aiming at putting aside the object. The picking location may be deduced from the previous actions involving this object.
3. Insert/ Attach: The insert/ attach category gathers operations consisting in inserting an object into another or placing an object onto another.
4. Tube Manipulation: The management of the tube is critical in the process, and several steps require handling them precisely. Most of these operations require bi-manual manipulation.
5. Assemble/ disassemble (Pull Out/ Detach): These operations consist in disassembling connected elements, and require applying pulling forces on the objects.

6. **Containments Moving (insertion):** Several bottles and containers are used in the process. The manipulation is not only a simple pick and place but also involves some force-based insertions; it requires to coordinate well the grasping and release strategies.
7. **Complex manipulation:** This category gathers bi-manual manipulation not associated to the previous categories.
8. **Button management:** Some operations are performed interacting with the physical interface of the pump, through the buttons present on the pump.

This categorization is mainly a classification of the manual operations, as they are observed when the process is performed by the human operator. It does not necessarily reflect the complexity of the underlying operations, or the robotic challenge associated to it.

Process variability We analysed the very same process conducted by different laboratories, and several variations could be identified:

- The timeline is not always the same, in particular for some sub-operations.
- Operators do not always extract all consumables from the steri-kit at the beginning, and handle the item only when needed for the next action.
- The sample container is not always the same. It is sometimes provided through vials as in the process studied, but it can be also presented in larger bottle. Globally speaking, the liquid container can differ, in shape and size.
- Some steri-test kits may slightly differ. In some, the red caps used to close the container for pressure management are not provided in a plastic bag, but already connected to the canister through a small and flexible tube.
- It could also be noted different strategies for facilitating the liquid transfer from the bottle containers when connected through the tube to the canisters. In some cases, the needle is pulled-back a little to empty completely the bottle. Other operators even take out the bottle from the holder to ease the transfer when the bottle is almost empty.

A robotic system should thus be able to cope also with these variances, to comply with the laboratory practices, and / or with the client constraints. All together, this provides a set of challenges for the robotic system, which are now described.

3 Technical challenges

Vision Even though the environment is relatively controlled, vision processing is needed to confirm the location of items manipulated by the robot and to verify their pose once captured or released. The complexity of the visual process lies in the core characteristics of the manipulated items: (i) transparent objects are not well detected by depth cameras (ii) several pieces are quite small, like the caps or the needle, and (iii) various operations involve the flexible transparent tubes, for grasping them, or manipulating elements connected to them (like the canisters).

Visual challenges: small objects pose estimation; transparent object detection; flexible tube localization.

Dexterous objects handling More than 90 different grasping types have been detected in the process, and several ones are out of the well-known Cutkosky and Feix taxonomies [3, 4]. The design of a multi-purpose gripper is therefore per se a challenge. Objects manipulated vary from the 1 litre bottles to small objects (vials, caps) laying on a flat table. Furthermore, objects captured with one hand are frequently exchanged with the other hand to prepare the next operation. Indeed, the grasping configuration (hand mode, object-in-hand pose) is not always directly compatible with the release configuration. In-hand manipulation, to reposition correctly the object, or to compensate for a non perfect grasping, is frequently used. It requires good tactile sensing for analyzing the hand-object relationship. Finally, the videos show that the human hand is used as a multi-purpose system, involving some fingers for holding an item, while performing another task with the other fingers.

Hand manipulation challenges: multi-purpose gripper; small object capture; in-hand manipulation; tactile perception; multi-tasking; in-hand pose estimation.

Bi-manual manipulation Not all manipulations are bi-manual, but many operations cannot be achieved easily with a single arm. Thus, a proper framework to coordinate the arms is required, as frequently one arm is holding an object while the other arm conducts the assembly or insertion. The task load in between the two arms may not always be binary (an arm is stationary while the other actuates), and some operations like the needle insertion may be better achieved with a joint control. The manipulation of the two canisters, in particular before their insertion in the tray requires good coordination, as the canisters are connected through the flexible tube. Also, the insertion of this tube into the pump linear hole requires extending the cable in between the two grippers, while moving towards the target area.

A planning system is required to control the arms. Although the environment is quite controlled, the consumables are numerous, and navigation from one place to another requires avoiding obstacles. Also, the manipulation types (canister insertion, tube handling, bottle grasping and release, vials opening, ...) are numerous, and require several control mechanisms which should be loaded and unloaded seamlessly.

Bi-manual manipulation challenge: coordinated operations; joint manipulation; navigation in cluttered environment; multi-purpose manipulation; sensing-based manipulation.

Robot behaviours encapsulation and definition The robotic operations are numerous and require different types of controllers, which can be re-used multiple times in the complete process. The encapsulation of the robot capabilities, with *skills* or within a *behaviour tree framework*, should ease the process programming. The configuration of these skills/modules is critical to permit re-use in the process, and to simplify the plan definition. This directly brings the issue of the complexity of the configuration: the combination of behaviours should not

require the involvement of the robotic developers, and operators should be able to adjust the plan, in particular to cope with the variances previously defined. A trade-off must be found to enable non specialists to define an *action plan* and configure it, without entering into all the details of the underlying process.

As variances may occur, the system should permit the operator to define completely new behaviours or to adjust/specify the generic behaviours already defined. Learning capability is thus mandatory to avoid requiring complex re-programming every time an item of the environment is changed.

Robot behaviour challenges: reusable and configurable skill structure (embedded into a behavior tree framework, skill-set workflow definition in an action plan); human friendly interface; learning capability.

Reasoning and scene understanding The achievement of such use-case would definitely benefit from plan reasoning and scene understanding. As vision-based manipulation is required, failures may occur, and the system should be able to detect them and find mitigation means. Hard-coding through rule-based operations would be very tedious, so that the robot should have a semantic understanding of the action taking place, and of the environment state, to plan on-site adjustments of actions for recovering from failure situations, when possible. The association of semantic information (requirements to be launched, impact on the environment, ...) to the robot behaviours encapsulated into skill-like items permits such automatic reasoning.

Reasoning would also be beneficial for handling better the object manipulation. Items are frequently grasped and re-grasped, as the grasping options are not always compatible with the use or release mode. The management of the object affordance, combined with a proper grasp planner should permit avoiding encoding all sub-manipulations and limit the user configuration to high-level requests such as *take the sample container, and place it onto the bottle holder*, independently of the sub-manipulation the robot will have to perform to do so.

Reasoning should also permit handling the load distribution in between the two arms. If the arms and gripper are similar, the distribution should rely on an understanding of the following operations in the plan: *given the next required actions, is it better to grasp now the needle with the left or right arm?*

Reasoning challenges: situation and self-awareness; object affordances and relationship; action responsibility distribution

Regulation requirements (audit trail, verification capabilities) The sterility process is nowadays performed by a trained certified person, who can confirm at the end of the process that the operations were conducted following the procedure, certifying this way that the outcome of the testing is valid. The robotic system should provide a similar confidence. The importance of this task is even more critical for such reactive robotic system, as any operation (manipulation, grasping, motion, perception, ...) is prone to errors and deviations which can even bring to process failure if no mitigation plan is feasible.

The control of the (successful execution of) operations is thus necessary, and any action should be associated with verification processes. The verification can take place in the process itself, generating a confidence of the current action (i.e. no extra force generated during the canister insertion into the tray). The verification can also rely on additional check processes, involving other modalities (i.e. visually verifying the canister is well positioned wrt the tray after the insertion process). Specific robotic operations may also be required to confirm the previous operation success (i.e. pull the tube to verify correct insertion in the pump holder, pushing aside the canister to confirm good insertion in the drain tray).

The verification process should consider as well the process itself: is the liquid being transferred from the container to the canister?, is the container empty and should it be replaced by another? Multi-modal perception and reasoning is thus also required to confirm the good execution.

Finally, the verification process should provide an audit trail, gathering all verification means and conclusions, demonstrating the good execution of the process. A tracing framework must be implemented, as many different actions are to be controlled. Also the audit trail should be rendered for human reading, providing information of the overall process advancement, as well as, if necessary, more detailed proofs of success for any of the lower-level actions that took place.

Regulation challenges: audit-trail generation; action tracing; systematic multi-modal verification; systematic error monitoring.

Software interfacing The pumping system is a central component of the process, and the human is frequently monitoring its digital screen, and launching some operations through its physical interface. Robotic system could be programmed to handle the pump as the human does, but a more relevant interaction would be to directly connect digitally with it. Interoperability is thus necessary, in particular to get compatibility with different versions of the pump, as the API may change, and to cope with different manufacturers, which may have different interfaces. The usage of a standard interoperability framework is necessary to enable such interaction, in a standard and controlled way, following all security rules that are inherent to the pharmaceutical environment.

Interfacing challenges: system interoperability.

Robot-compliant process and equipment A non trivial decision is to define up to which point the robot has to perform the process as the human does it, using similar consumables packaged as they are nowadays. The generation of a versatile system permits the adjustment to possible variances, and to get a core system able to cope with slightly different processes. Nevertheless, from an efficiency and marketing point of view, it is necessary to study further the process with manufacturers to suggest adjustments of the process and consumables to get a good compromise in between the versatility of the system, and its efficiency and robustness to perform the actions.

Industrial challenge: robot compliant setting.

4 Data available

Several items are made available to any interested people. We consider it as common ground that could be used to launch related projects, focusing on any of the challenging but interesting topics previously mentioned.

The complete sterility testing use case is being documented on the showcase website¹². Screenshots are presented in Figure 3. All the main steps mentioned earlier are described, including illustrative videos. These steps are further on detailed to reach robotic operations. All items involved in the process, consumable, sterility kits are listed, and actions involving them are cross-referenced. When possible 3D models of these elements are also provided.

We also give access to a ROS environment¹³ containing the manipulated items and a bi-manual robotic system, composed of two UR arms and equipped with a Depth camera (see Figure 4). The ROS framework relies on Gazebo to provide a simulation of the robotic arms, and permit an emulation of the environment including physical interaction. We created this *playground* to define our software architecture, and it can be useful to launch any related development, and we hope this material will be useful to foster related development by our robotic colleagues.

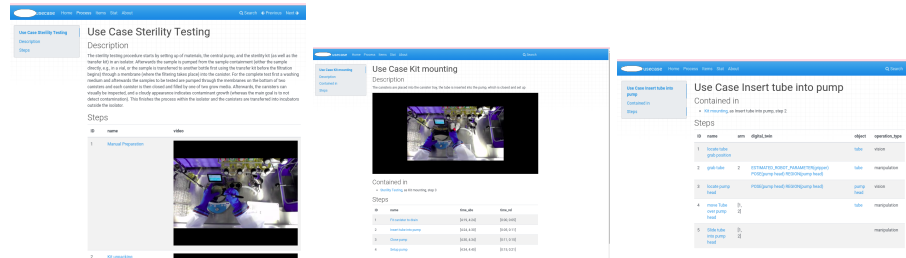


Fig. 3. Screenshot of the TraceBot showcase website providing segmented videos of the use case, which is detailed up to atomic operations.

5 Conclusion

With this document, the European project TraceBot aims at sharing with the robotic community the first analysis of a use case which illustrates the operations required in a pharmaceutical application. The sterility testing process is documented and detailed to go from a human segmentation towards the more atomic capabilities a robot should have to conduct the operations. We also detailed the different scientific challenges that such use case raises. The complete

¹² https://tracebot.gitlab.io/tracebot_showcase/

¹³ <https://gitlab.com/tracebot>

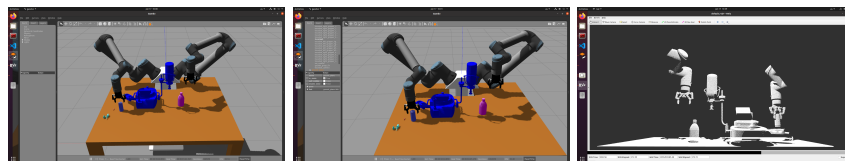


Fig. 4. Illustration of the ROS environment provided with the use case. The two first images are views of the Gazebo environment. Third screenshot illustrates the depth information perceived by the 3D camera.

resolution of the process definitely requires cutting edge technologies and can be the root of many researches. We also give access to several digital models, scene objects, and ROS settings to permit any researcher to launch quicker their work under this specific but typical application, with the objective to foster the application and development of agile robotics for pharmaceutical and laboratory applications. We envision to update and complement all that material during the lifetime of our project.

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