TRACEBOT

Use Case Specification 2

Deliverable 1.4

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Abstract	This document explains, on the one hand, which steps from the complete description of the use case provided in deliverable D1.6. are used in the project for research and shown in the final demonstrator. On the other hand, it describes the evaluation of the usefulness of TraceBot developments from the perspective of another use case.

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Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01	27.08.2024	C. Coulon (INV)	Initial start
v.02	26.9.2024	C. Coulon (INV)	First full draft for TMC Meeting
v. 02	16.10.2024	C. Coulon (INV)	Integrated results from site visit
v. 03	17.10.2024	C. Coulon (INV)	Integrated parts from UOB, TEC, CEA
v. 04	18.10.2024	C. Coulon (INV)	Integrated part from TUW
v.1.0	30.10.2024	C. Coulon (INV)	Ready for internal revision
v.2.0	15.11.2024	C. Coulon (INV)	Revised version ready for submission

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1 Executive Summary

The use case of “sterility testing” is intensively described in D1.6 and was published at https://tracebot.gitlab.io/tracebot_showcase/. Within the TraceBot demonstrator several steps were selected to feed, enable and demonstrate the research targeted within TraceBot. This document summarizes how these steps are used for research in TraceBot and which are demonstrated in the final demonstrator.

In addition, the transferability of the TraceBot technologies (compare exploitation plan D7.13) was evaluated with regard to built-in verification and audit trail generation using the bioburden process as an example. In the discussion with users which paid a system-integrator to create an automated solution for bioburden-testing the value assumption of TraceBot has been confirmed: If verification and audit trail generation would be already included in the state of the art of robotic systems, the effort for development and qualification of such solutions would decrease. However, this would require TraceBot's developments to find their way into the development environments of system integrators and robotics manufacturers.

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2 Introduction

The TraceBot demonstrator has been developed and is being tested against the requirements in the current phase. Within the third chapter we first summarize the selected steps and advances made. Secondly the value and suitability of the TraceBot developments will be described from the perspective of a pharmaceutical application.

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3 Description of work & main achievements

3.1 Summary of the Demonstrator Process for Sterility Testing

In this section we go back to the initial use case and revise the steps that have been studied during the project. The complete description of the process is available on a dedicated website, https://tracebot.gitlab.io/tracebot_showcase. We identify the (sub)steps that are demonstrated in TraceBot and describe why some steps were not covered.

3.1.1 Process Overview

Globally speaking, the process has been divided into 12 steps:

Step ID	name	Brief description
1	Manual preparation	The control petri dish is labeled 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 gets turned back down and the red plugs get attached. 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.
7	Sample filtering	Samples are filtered (which means that overpressure in the canisters pushed 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
11	Finishing	Unmount everything and tidy up the workbench, moving apart consumables.
12	Manual finishing	Clean up and move out petri dish.

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3.1.1 Step 2: kit unpacking

List of Sub-Steps:

1. Open kit [covered]
2. Unpack kit

A solution is proposed to open the kit, based on force learning. We have treated this as a standalone action, and further development would be required to start the process and end it in a comfortable state. Indeed, the unpacking of the kit has not yet been handled as it is done by the human. If the kit is free on the table, the kit can be located. If a model of the kit is known in the digital twin, this can also be used to determine its orientation. Extracting the canister by holding the cables then requires the objects to be placed on the table in order to re-grip the canisters from such a static position. Further engineering work on object grasping from unknown positions is required to achieve a robust implementation. We anticipate that initial experiments will provide an indication of the complexity of such an operation. Also, the unpacking of small caps, which will be performed later by the human operator, could be addressed at this stage. The plastic bag is easy to locate on the table, but difficult to see inside the plastic kit. The management of the small plastic cap is still an issue given the small size of the elements it contains. We believe that a better design of the sterility kit would allow for a more reliable and less complex management of the kit (more details in deliverable D1.2 Design-Guidebook (Coulon, D1.2 Robot-friendly Design Guidebook, 2024)).

Steps covered: 1/2

- ➔ Additional development:
  - Robot friendly design of the sterility kit

3.1.2 Step 3: kit mounting

List of Sub-Steps:

1. Fit canister to drain
2. Insert tube into pump
3. Close pump
4. Setup pump

Canister insertion is the first isolated use case we considered. Automatic canister detection was validated. A specific control was designed for the insertion of the canister into the tray. We have demonstrated the management of the two canisters but starting from a convenient position of the item (unknown position, but assuming a vertical configuration of the canisters). Management from a "random" initial position would require extending the selection of the gripping mode to the current position of the canister.

We also addressed the tube insertion into the pump, using a dual arm control with compliance and force control.

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The interaction with the pump could not be done digitally as the API of the pump device is not accessible. Despite several attempts, we have not been able to get a commitment from the manufacturer to give us access to their API. As of today, we propose to handle the pump through a tending process, where the robot physically interacts with the physical interface. Further discussions with the manufacturer (or even the competition) should be pursued to digitally handle these operations.

Handling the canister was a challenging but realistic use case for our digital twin technology. The canister is a rigid object that can be 'simulated' in the game engine environment that powers the digital twin. Flexible objects still pose challenges for real-time and photorealistic simulations, which we are mainly interested in exploring. This is particularly important in order to successfully replicate the manipulation actions performed by the TraceBot demonstrator, and to perform the targeted experiments over the course of the project after extensive development. This will allow us to develop components for inference and verification techniques, for example to verify the successful grasping of an object or the attachment of consumables to the sterility testing kit. We also demonstrated the control of the pump in the digital twin environment. By creating a detailed model with a specific simulation controller, we were able to show that such devices can also be represented in our technology. This is important not only to replicate the manipulation actions on rigid objects, but also to simulate actuated devices (the pump actually moves its head to lock in the inserted tubes) necessary for the overall process.

The development of digital twin components led to the URoboSim framework. A software component for simulating robots and complex environments in a game engine environment. It has been published in (Michael Neumann, 2021).

- ➔ Steps covered 4/4
- ➔ Additional developments:
  - Implement canister grasping from any configuration.
  - Pursue digital connection to pumping system

3.1.3 Step 4 : needle preparation

List of Sub-Steps:

1. Remove needle cap
2. Insert needle

In the human manipulation process, the transition from tube insertion and pump activation to needle cap management is almost direct, but in the robotic system, needle grasping is an additional step. We have demonstrated needle management (grasping, cap removal, insertion into bottle) as an isolated use case. We aim to combine this operation with the previous step in the final demonstration, including perceptual means to estimate the needle pose in the environment (Ausserlechner, 2024). Nevertheless, more attention should be paid to needle detection. It would be convenient to implement some regrasping procedures (grasp object, bring closer to camera, refine pose estimation, use second gripper for intermediate grasp, grasp needle correctly for further use). In fact, grasping options from

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the table may not provide suitable options for further use. Also, the grasp may not be precise enough to perform the next action correctly. Therefore, this re-gripping process would be a relevant addition.

On the Digital Twin side, needle management provides an interesting use case for handling object compositions. From the start of the process, the cap of the needle is attached to the needle to avoid injury to the person handling it. Therefore, we needed to extend our object models to reason about the changes in this object composition during task execution. The insertion of the needle into the bottle was also an interesting research challenge for the modelling of the attachment, as the septum of the model is made of rubber and requires a certain force to attach or remove the needle. The needle cap was also a step towards handling smaller items of the sterility testing kit compared to the canister we investigated in our first demonstrators. The study of object composition and related attachment operations had a strong influence on our research into imagistic reasoning. We investigated an attentional mechanism to visually compare the real world sensor data with the expected 'mind's eye' imagery of the digital twin. This work has resulted in two publications:

1. (Mania P. S., 2024)
2. (Mania P. N., 2025)(submitted)

Finally, needle manipulation provided a relevant context for implementing a tactile-based verification means to check whether the needle insertion task has been successfully performed or not, relying on feedback from the embedded tactile sensors together with supervised learning techniques.

➔ Steps covered: 2 / 2
➔ Additional developments:
  - Regrasping procedure
  - Automatic grasping mode estimation from perception

3.1.4 Step 5: Wetting

List of Sub-Steps:

1. Start pump [covered]
2. Hold bottle upside down [covered]
3. Wait
4. Take bottle down [covered]
5. Stop pump [covered]
6. Open plug and cap bag
7. Attach red plug [covered]
8. Start pump [covered]
9. Wait
10. Stop pump [covered]
11. Detach red plug

The complete step has not been implemented, but we can look at each of the steps involved. As already mentioned, the pump interaction (start, stop pump) would be performed manually by the robot. We have demonstrated the ability to grasp the bottle and turn it upside down in a stand-alone demonstration, so we can assume that the second sub-step is achievable. The Wait sub-step implicitly assumes that the system is able to detect that enough liquid has been transferred to the canister in the

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first case, and that the pumping system has stopped in the second case. The management of the cap bag is still to be achieved and would require specific controllers or had-hoc engineering to enable the robot to open the bag. The transparent plastic bag is small, but it can be detected. The caps are even smaller and we are working on an attention pipeline to locate the caps, move the camera closer to get a higher resolution image, then identify the object and estimate its pose. The first concept was presented at ICRA@40 2024 in Rotterdam (Ausserlechner Philipp, 2024). If the CEA gripper is able to grasp the cap, automatic grasping is still a challenge. In our isolated demonstration, we used a special holder for the red cap. However, due to the small size of the cap and its rubber-like structure, insertion onto the canister pin is very complex. Again, additional work on regrasping processing would allow refinement of in-hand pose estimation, possibly combined with tactile information. In any case, the initial perception of such a small object may require specific holders. Finally, a redesign of the cap itself may be appropriate to ease its insertion and removal.

On the digital twin side, the manipulation of the bottle is similar to that of the canister, as it is another rigid object. Representing the stopper bag is not easy in our simulation environment. Starting the pump is possible but not yet integrated as we do not have an automated process for this on the real demonstrator. Attaching the red plug should be possible with the methods we have developed, but is highly dependent on the initial pose estimation and also the in-hand pose estimation. (Ausserlechner Philipp, 2024).

- ➔ Steps covered: 7/11
- ➔ Additional development:
  - Visual monitoring of liquid transfer
  - Sealed bag management
  - In-hand red cap perception
  - Red cap holders or red cap itself robot friendly design

3.1.5 Step 6: Sample transferring

List of Sub-Steps:

1. Pull out needle
2. Take sample [covered]
3. Break vial
4. Insert needle [covered]
5. Pump sample (wait)
6. Pull out needle
7. Put down sample [covered]
8. Reiterate step 2 until end.

This step was not covered in our experiments, but we assume that the insert needle strategy could be adapted to this case: The choice of the sample liquid container, a vial, required handling to break it. If the operator uses a tool to do this, it may be useful to choose a container that is easier for the robot to handle, such as a bottle with a septum, for which we demonstrated needle insertion. Again, the ability to visually monitor the liquid transfer is a capability that can be implemented. We can assume that sample release is achievable, although, depending on the container used, special care may be required to reposition the empty item on its rack.

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In the digital representation of the scene, the insertion and the pulling out of the needle should be easy to reproduce because it is mainly a free movement in space of the robot arm and its gripper. The breaking of the vials could be represented in the digital twin environment if we get some parameters from the real vials. If they reliably break at a certain position, investigating this sub-step could be interesting in future work, as it could show the potential and/or limitations of handling such objects in the game engine environment. Liquid simulation would be a major challenge, as we would need to accurately model the containment of the liquid in the vial, as well as the actual pumping/sucking action, in order to represent the phenomena involved and use them robustly for imagistic reasoning.

- ➔ Steps covered: 3 / 7
- ➔ Additional developments:
  - Vial management and breaking (vs robot friendly container)
  - Visual monitoring of liquid transfer

3.1.6 Step 7: Sample filtering

List of Sub-Steps:

1. Attach red plugs [covered]
2. Start pump [covered]
3. Label canister
4. Wait
5. Detach red plugs

The sub-step "Attach red plugs" is similar to the operation commented in step 5 and has the same limitations. We did not process the removal of the cap. Canister labelling would be more appropriately handled by scanning a unique identifier on the canister. It is interesting to note that the Sartorius canisters have such a tag.

Step covered: 2/5

- ➔ Additional developments:
  - Visual monitoring of liquid transfer
  - In-hand red cap perception
  - Red cap holders or red cap itself robot friendly design
  - Vision-based canister scanning and logging.

3.1.7 Step 8: washing

List of Sub-Steps:

1. Move bottle into holder [covered]
2. Attach red plugs [covered]
3. Stop pump (waiting for washing)
4. Detach red plugs

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The first sub-step has been handled through learning by demonstration in an isolated use case. The other actions have been already mentioned in previous steps.

- ➔ Steps covered: 2/4
- ➔ Additional developments:
  - Visual monitoring of liquid transfer
  - In-hand red cap perception
  - Red cap holders or red cap itself robot friendly design

3.1.8 Step 9: media filling

List of Sub-Steps:

4,5,7,11,12,14.15 6 could be considered?

1. Cover canister outlet port (no)
2. Take bottle down (no major problem)
3. Pull out needle (not handled / not tried)
4. Insert needle [covered]
5. Close tube [covered]
6. Start pump [covered]
7. Move bottle into bottle holder [covered]
8. Stop pump (required monitoring)
9. Take bottle down (already mentioned)
10. Pull out needle (already mentioned)
11. Insert needle [covered]
12. Close tube [covered]
13. Open tube (isolated mode)
14. Start pump [covered]
15. Move bottle into holder [covered]
16. Stop pump (already mentioned)

If, as before, the use of the pump (start/stop) can be handled by touching the device with the robot's fingers, the stop requires monitoring of the liquid transfer. Closing the canister outlet port is an operation that still needs to be addressed. It requires very precise positioning of the two objects, and the design of specific fixtures to handle it could relax the relative positioning accuracy required. The opening and closing of the clamps (open/close tube) has been demonstrated in a stand-alone case, but it is very complex to achieve directly on the tube, in a "random" configuration, as the finger positioning must be very precise to be successful. A redesign of the tube opening and closure would be required to achieve a robust design. Placing the bottle in the holder and inserting the needle could be achieved using the strategy presented in the individual demonstrations.

Focusing on the Digital Twin aspect, all sub-steps except 1 and 5/16 are already mentioned in the previous steps. Similar reasoning applies. Sub-step 1 should be possible as it is similar to the other attachment operations in the DT framework. Substep 5/16 (close tube => clamp operation) would require precise manipulation of a semi-flexible object and precise modelling of the latch. In addition, the pose estimation of the tube would also need to be accurate and include a good position of the clamp on it to properly replicate its manipulation. This presents an interesting challenge for future

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research in creating an accurate simulation of flexible objects and coupling them with attached semi-flexible objects.

- ➔ Steps covered (reducing to single media management) : 8/16
- ➔ Additional developments:
  - Visual monitoring of liquid transfer
  - In-hand yellow cap perception
  - Yellow cap holders or yellow cap robot friendly design
  - Clamp friendly design

3.1.9 Step 10: cutting and closing

List of Sub-Steps:

1. Close tube at 1st canister [covered]
2. Close tube at 2nd canister (already mentioned)
3. Cut tubes (not addressed)
4. Attach cut tube to canister air vent (not addressed)

The clamp closure was mentioned in the previous step. A specific attachment could be used in the field to handle the cutting of the tube, and a dedicated force-based process should be developed to perform the operation (unless the cutting pressure is automatically provided by the physical attachment). Covering the canister vent with the cut tube is a challenge that can be addressed by inserting a dedicated cap.

- ➔ Steps covered (reducing to single canister) : 1/4
- ➔ Additional developments:
  - robot friendly tube cutting mechanism
  - robot friendly canister air vent cap

3.1.10 Step 11 – finishing

List of Sub-Steps:

1. open pump [covered]
2. remove tube from pump [covered]
3. take bottle down
4. clean up
5. store canister

We have not addressed this step, but we can assume that opening the pump (pump management) is feasible, as is tube extraction, using a similar strategy to insertion. Similarly, we can assume that removing the bottle from the holder should be feasible given current movement capabilities. Cleaning requires recognition and grasping of the different objects in the scene.

- ➔ Steps covered (reducing to single canister) : 2/5

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➔ Additional developments:
- Implement tube extraction (no major concern)
- Complete object detection to grasp and store them aside.

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3.2 Evaluation of transferability TraceBot Components to Bioburden Testing

The transferability of the TraceBot technologies (exploitation assets explained within Deliverable D7.13 (T. Cichon, 2022)) was evaluated by visiting a pharmaceutical production site of LONZA in Visp (Switzerland). At this site LONZA uses an automated system for bioburden testing in quality control (Figure 1). During this visit the following experts from LONZA were present to evaluate the applicability of the results of TraceBot:

1. Associate Director, QA, Robotics and Automation
2. Robotics and Automation Lead
3. Scientific lead who is responsible for operating the system

Part of the evaluation have been the following steps:

1. Presentation of technologies developed within TraceBot clustered in:
    a. Pose detection by vision
    b. Dexterous handling of objects
    c. Learning new skills and the adoption of skills
    d. Tracing and Verification
    e. Built-in generation of audit-trail

    Reference: Presentation form TraceBot Symposium in Konstanz 27.09.2024.
2. Evaluation of the question by expert opinion:
    "What would have been simplified during development and qualification of the automated system (Figure 2)

    - if -

    a development environment would have been available providing the functionality developed in TraceBot"

Figure 1: This figure shows the steps performed by the automated system in comparison to the manual process. From left to right you see: sample reception – preparation – filtration –

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washing and transfer – incubation – visual evaluation - documentation - data transfer to the LIMS (Lab Information Management System)

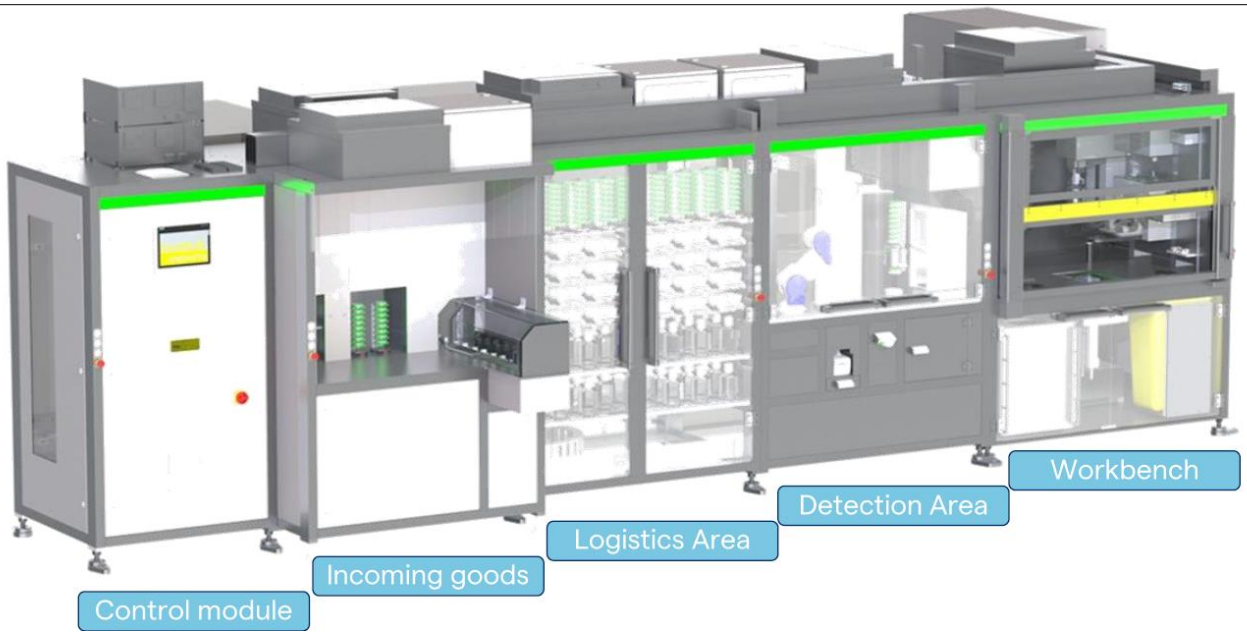

Figure 2: Front-view to system for automated bioburden testing installed at LONZA. A video of the system can be watched at Automated Bioburden Testing - YouTube

3.2.1 Evaluation of the benefit of developments within TraceBot for automated bioburden testing

The experts of LONZA present in the visit stated the following advantages with respect to the evaluation named above:

1. Due to the challenges in the exact position detection of transparent objects by vision, the existing automation does not use vision-based position detection.
    a. To enable precise and reliable gripping of objects,
        i. the probability of inaccurate positioning of objects was reduced several times by means of format parts and mechanical auxiliary constructions
        ii. and the repeatability of the robot movements was optimized.

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b. When feeding different objects, manufacturing tolerances, for example in the consumables, lead to slight inaccuracies. This occasionally causes unplanned stops due to unexpected collisions.

Combining

a. TraceBot position detection and
b. TraceBot gripper finger force sensing with automatic gripper position correction

would have had the following advantages:

a. time savings by avoiding optimization cycles for accuracy at the time of commissioning
b. avoiding unplanned stops during operation

2. Due to the lack of built-in traceability of the automated system the qualification of the overall system is based on functional testing of every single step.
   a. As a consequence, there had to be a manual set-up of the overall system to create the pre-condition for each function

Combining

a. TraceBot built in traceability based on
b. TraceBot vision
c. TraceBot gripper finger force sensing
d. TraceBot digital twin
e. TraceBot audit-trail generation

would have had the following advantage:

a. Executing trial runs for qualification of multi-steps utilizing the generated audit-trail for documentation avoiding much of the manual documentation of single steps

In total the expectation of the experts can be summarized, that:

"*If there would have been a product like development environment providing the named functions developed within TraceBot there would have been a huge gain in time saving during installation and testing especially with respect to qualification. They also expect that TraceBot perception would avoid unplanned stops. To verify this assumption, it would be necessary to test if TraceBot perception is able to handle the inaccuracies brought in by the manufacturing tolerance of the consumables.*"

4 Deviations from the workplan

none

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5 Conclusion

The sterility testing use case has proven to be a good way of enabling the research objectives in TraceBot. All steps relevant to the research objectives serve as requirements for the research of the individual partners. In the demonstrator, these steps are used to show the research results to a broad audience.

The evaluation of the bioburden use case confirmed the value assumption of TraceBot: If verification and audit trail generation become part of the state of the art for robotic systems, the effort for development and qualification of such solutions will decrease significantly. However, this would require TraceBot's developments to find their way into the development environments of system integrators and robot manufacturers.

To evaluate the applicability and usefulness of TraceBot technologies in detail, requirements from a pharmaceutical point of view were described in the Verification and Validation Plan (Coulon, D1.5 Verification and Validation Plan, 2024). These will be used in the next phase to test the TraceBot demonstrator.

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